

## Legal Aspects of Medical Action without Informed Consent in ER Jember Lung Hospital in 2020

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### Abstract

Before working on a medical action, the doctor must provide information and get approval from a competent patient or next of kin, in the form of informed consent documents. The formulations of these research problems are a) How is the implementation of informed consent for emergency patients at Jember Lung Hospital Emergency Room (ER)? and b) What are the legal aspects of working on a medical action without informed consent in handling the emergency patients? The research method that is used is juridically normative with the method of legal approach. The data sources are from primary and secondary legal sources, and interview results. The research site is at Emergency Room of Jember Lung Hospital. During January to March 2020 there were 956 emergency patients who received medical action at the Emergency Room of Jember Lung Hospital. Four of the 956 emergency patients were taken without informed consent.

**Keywords:** emergency; informed consent; medical action.

### Abstrak

Sebelum melakukan tindakan kedokteran, dokter harus memberikan informasi dan mendapat persetujuan dari pasien yang kompeten atau keluarga terdekat, dalam bentuk dokumen informed consent. Rumusan masalah penelitian ini adalah a) Bagaimanakah pelaksanaan informed consent bagi pasien gawat darurat di IGD RS Paru Jember? dan b) Apakah aspek hukum tindakan kedokteran tanpa informed consent dalam penanganan pasien gawat darurat? Metode penelitian yang digunakan yuridis normatif dengan metode pendekatan perundang-undangan. Sumber data dari bahan hukum primer, hukum sekunder dan hasil wawancara. Lokasi penelitian di IGD RS Paru Jember. Selama Januari sampai Maret 2020 terdapat 956 pasien gawat darurat yang mendapatkan tindakan kedokteran di IGD RS Paru Jember. Dari 956 terdapat 4 pasien gawat darurat yang dilakukan tindakan kedokteran tanpa informed consent.

**Kata kunci:** gawat darurat; informed consent; tindakan kedokteran.

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## Introduction

According to the Law of the Republic of Indonesia Number 36 of 2009 on Health, health services are part of human right and one of the elements of welfare that must be realized in accordance with the ideals of the Indonesian. Health care is essentially a fundamental right for every citizen guaranteed by the constitution. As stated in Article 28H paragraph (1) of the Constitution of the Republic of Indonesia of 1945 which mandates the state to ensure the right of citizens to live prosperously through the provision of health services (Syafrudin, 2015).

Health service creates a legal relationship between doctors and patients. The legal

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relationship between doctor and patient is manifested in the form of informed consent documents. One of the purposes in setting up informed consent documents is to provide legal assurance to the public and doctors. The characteristic of medical action is the permissible of doctors to perform medical actions on the human body as an action to maintain and improve the health's condition. Therefore, Article 45 paragraph (1) of the Law of the Republic of Indonesia Number 29 of 2004 on The Medical Practice provides a limit that every medical action that will be carried out by doctors over patients must get approval through informed consent.

The legal position between doctors and patients in informed consent is equal according to their respective responsibilities. The patient's position is responsible for their health and for the medical action towards them. While the doctor's position as a professional in medical field is responsible in trying to improve their skill (Rokhim, 2012). The decision to accept or refuse medical action becomes the full right of the patient embodied in the form of informed consent documents (Samino, 2014). Informed consent is a statement of approval of medical actions from patients that is given freely, consciously and rationally after obtaining complete, valid, and accurate information's from a doctor. Informed consent can prevent fraud or coercion from doctors towards patients. Elements of informed consent consist of competence, information delivery, information understanding and freedom of consent. Consent must arise from the patient's free will. It should be the answer to information from the doctor that is in accordance with the actual circumstances. This agreement must arise from the free decision of a competent person (Felenditi, 2009).

According to Article 8 of the Law of the Republic of Indonesia Number 36 of 2009 on Health, Article 45 of the Law of the Republic of Indonesia Number 29 of 2004 on The Medical Practice and Article 13 of the Regulation of the Health Minister of the Republic of Indonesia Number 290/MENKES/PER/III/2008 on approval of medical action, informed consent is an absolute requirement before medical action. This means that without informed consent, no medical action should be taken to the patient by the doctor.

Approval of medical action (informed consent) is often filled incomplete. One example is the implementation of informed consent at Bangkinang Regional General Hospital; it's already available but filled by doctors and nurses incompletely (Trisna, 2016). In one of the hospitals in Surabaya, 4% of all medical actions are not equipped with informed consent (Winarti, 2013). Another example is lack of applying medical action approval (informed consent) in childbirth process that is carried out by midwives (Pratiwi, 2014). Every medical action absolutely requires informed consent. Failure in implementing informed consent can causes legal responsibilities. Form of legal liability can be administrative legal responsibility, civil law responsibility, and criminal law responsibility (Mudana, 2014).

This study specifically examined the legal aspects of doctors and patients in informed consent at the Emergency Room of Jember Lung Hospital. Jember Lung Hospital has various types of health services. One of health service at Jember Lung Hospital is health

services for emergency patients in Emergency Room that is contained in Article 45 of East Java Provincial Governor Regulation No. 45 of 2017 on Hospital by Laws of Jember Lung Hospital.

Problems arise when dealing with emergency patients who require immediate medical action but are incompetent and not accompanied by competent next of kin so there is no one can provide informed consent. The reality is that not all patients can be asked for approval of medical action or informed consent. One example of patients who are not competent in providing informed consent is patients with mental disabilities (Jayajendra, 2020).

This study is an independent research conducted at the Emergency Room of Jember Lung Hospital. Medical records data of Jember Lung Hospital showed the Emergency Room services of the hospital in the period of January – March 2020 have served 956 emergency patients. Of the 956 patients, there were 4 (four) cases of emergency patients who performed medical actions without informed consent. These four cases are cases of emergency patients in the Emergency Room of Jember Lung Hospital with high risk of life-threatening patients if no medical action is taken immediately but not accompanied by informed consent.

Patient safety is something that is always preferred by doctors. According to legal norms, informed consent is a mandatory thing to be held before medical action. This will be difficult to do in life-threatening emergency patients but not accompanied by anyone competent to provide informed consent. Based on the description above, the author is interested in conducting research on Legal Aspects of Medical Action without Informed Consent in the Emergency Room of Jember Lung Hospital in 2020.

## **Research Problems**

Based on the background above, this research is organized into two main problems. *First*, how is the implementation of informed consent for emergency patients in the Emergency Room of Jember Lung Hospital? *Second*, what is the legal aspect of medical action without informed consent in handling the emergency patients? The main purpose of this study is to find and examine the implementation of informed consent in the Emergency Room of Jember Lung Hospital and determine the appropriate legal aspects in handling the emergency patients.

There are several benefits that can be obtained from this study. First, with the acquisition of the right legal aspects of doctors' practices in hospitals, this study tries to answer and offer an idea in order to guarantee and protect the rights of patients, especially emergency patients. Second, through this research, it is expected to give some contribution of ideas to the development of law studies, especially in the legal relation between doctors and patients.

## **Research Method**

The type of this research is juridical normative (legal research) with a statutory approach, a case approach and a conceptual approach. Sources and ways of retrieving data from primary and secondary legal sources, interviews with key informants of health workers of Jember Lung Hospital Emergency Department, observation of the implementation of informed consent in the Emergency Department of Jember Lung Hospital, as well as the search of documents about informed consent at Jember Lung Hospital.

The statute approach is intended to review and analyze every law and other related regulation related to legal issues concerning informed consent. Through this approach, the author focuses on hierarchical order of the laws and regulations. In addition, the author also adjusts the existence of norms, in the sense of whether the norm is in a special or general law, or whether the norm is within the old or new laws and regulations. Thus, the main focus in this approach lies in the author's understanding of the principles and theories of the hierarchy of laws and regulations as taught by Han Kelsen and Hans Nawiasky (Marzuki, 2014).

The case approach is intended to examine cases related to the problem at hand. In this case, Marzuki stated that in using the case approach, at least what must be understood by the author is related to the *decidendi ratio*. Considering the approach of the case does not refer to the *dictum* of the court's decision only, but must also refer to the judge's *decidendi ratio* (Marzuki, 2014). By understanding the concept, the author can rest his guidelines on doctrines aimed at building legal arguments in solving the studied problems (Shamsudin, 2007). Conceptual approach, Marzuki asserts that this approach can be done if the author does not move away from the existing rule of law. In a sense, this approach can be done because it has not been or there is no rule of law for the problems at hand (Marzuki, 2014).

The sources of primary legal source that is used are: The Constitution of the Republic of Indonesia of 1945, the Civil Code, the Criminal Law Code, the Law of the Republic of Indonesia Number 29 of 2004 on The Medical Practice (State Gazette of the Republic of Indonesia Number 116 of 2004 and Supplement of State Gazette Number 4431), Law of the Republic of Indonesia Number 36 of 2009 on Health (State Gazette of the Republic of Indonesia Number 1441 of 2009 and Supplement of State Gazette Number 5063), Regulation of the Minister of Health of the Republic of Indonesia Number 290/MENKES/PER/III/2008 on Approval of Medical Action, Regional Regulation of East Java Province Number 37 of 2007 concerning East Java Health Office and Governor Regulation of East Java Province Number 45 of 2017 on Hospital by Laws of Jember Lung Hospital. The source of secondary legal source that is used is legal source that is obtained from all publications relating to the law of informed consent.

The process of analyzing legal source is carried out by these steps (Marzuki, 2016): identifying legal facts and eliminate irrelevant matters to establish legal issues to solve (informed consent in the Emergency Room of Jember Lung Hospital), collecting legal sources related to informed consent, conducting a review based on the sources that have been collected, make conclusions in the form of arguments that answer the legal issues,

namely the implementation of informed consent to emergency patients and provide prescriptions based on arguments that have been created into the conclusions. The research site is at the Emergency Room of Jember Lung Hospital.

## Discussion

### Literature Review

**Legal Aspect.** In life, there are various norms that govern in how to behave and dealing with other individuals, one of which is legal norm. The legal norm is directed towards the attitudes and deeds of humanity. The legal norm actually contains normative facts about what should be done, because in law what matters is not what happens, but what should happen. Legal norms contain orders and prohibitions that are imperative or contain facultative approvals (Mertokusumo, 2003). This legal norm is referred to as the positive law, which applies in a country and in a certain time (*ius constitutum*).

In fact, the terms of law in various legal literatures are quite diverse. The term of law in English is called law, in French it is called *droit*, in Dutch it is called *recht*, in German it is called *recht*, while in Arabic it is called *shari'ah* (Shahrani, 2008). In relation to the definition of law, jurists are quite difficult in defining law by default, so that every expert is very diverse in providing a legal definition, as expressed by Lemaire (Rosmalie, 1985).

Utrecht, in his introductory book of Indonesian law states that the law is a set of life instructions (orders and prohibitions) that govern the order in a society, and therefore should be obeyed by people. Furthermore, Wirjono Prodjodikoro in his book sense of justice as the basis of all laws states that the law is a series of rules regarding the behavior of people as members of society. Meanwhile, Soerjo Wignjodipoero in his book the science of law states that the law is a set of rules of life that are coercive, containing an order, prohibition or permission to do or not do something with the intention to regulating the order in society (Rosmalie, 1985).

**Medical Action.** The term medical action as stated in the Law of the Republic of Indonesia Number 29 of 2004 on The Medical Practice is a series of activities carried out by doctors on patients in carrying out health efforts. Doctors are doctors, specialists, dentists, and dentists who graduate from medical or dentistry education both at home and abroad who are recognized by the Government of the Republic of Indonesia in accordance with the laws and regulations.

According to the Law of the Republic of Indonesia No. 29 of 2004 on The Practice of Medicine, in Chapter II, regarding the regulation of medical action aimed at several things, including providing protection to patients, maintaining and improving the quality of medical services provided by doctors, providing legal certainty to the public, doctors, and medical action implemented based on agreements between doctors and patients, in efforts to maintain health, disease prevention, improve health, disease treatment, and health recovery. Article 1 paragraph (3) of the Regulation of the Minister of Health of the Republic of Indonesia Number 290/MENKES/PER/III/2008 10 concerning the Approval of Medical

Action, medical action is a medical action in the form of preventive, diagnostic, therapeutic or rehabilitative carried out by doctors on patients. Doctors who cannot do medical action should make notice or appoint a replacement doctor. The substitute doctor must be the doctor who has a license to practice. Doctors who already have a license to practice and perform medical actions must install medical signage (Law of the Republic of Indonesia Number 29 of 2004 on The Medical Practice).

**Informed Consent.** Informed consent contains the understanding of an agreement or rejection of medical actions given by patients or competent closest family after being informed of medical actions to be carried out and any risks that may occur. Informed means that it has been notified, has been submitted, or has been informed. Consent means the consent that has been given to someone to do something.

Essentially informed consent is a process of communication, not a form. The form is only a documentation that proves there is an interaction between the patient and his doctor. The law imposes on health practitioners, the obligation to disclose and inform fundamental aspects of treatment (Tan, 2006). Medical action approval is a unilateral statement from the patient and not an agreement between the patient and the doctor, so it can be retracted at any time. Approval of medical action is the process as well as the result of effective communication between the patient and the doctor and not just the signing of the consent form (Utja, 2006). Informed consent or translated as approval of medical action is the consent given by the patient or the competent family after being fully explained about the medical action to be carried out on the patient.

**Medical Action towards Emergency Patients.** Emergency patients are in a high risk of life-threatening and/or disability if medical action is not taken immediately. In an emergency situation, to save the patient's life and/or prevent disability for the patient if no one competently gives consent then medical action can be done without informed consent. In accordance with Article 4 paragraph (1) and (2) of the Regulation of the Minister of Health of the Republic of Indonesia Number 290/MENKES/PER/III/2008 concerning the Approval of Medical Action, medical actions in emergency situations are decided by doctors without the approval of competent patients or closest family.

This is in line with Article 13 paragraph (1) and (2) of the Regulation of the Minister of Health of the Republic of Indonesia Number 290/MENKES/PER/III/2008 concerning the Approval of Medical Action, informed consent can be excluded for emergency patients. Law of the Republic of Indonesia No. 29 of 2004 on The Medical Practice explains in emergency situations, to save the life of patients no need for approval of medical action. But after the patient is aware immediately given an explanation and made approval. All this is done on the basis of healing and the safety of the patient itself. Handling emergency patients is the implementation of the principle of patient protection and safety stipulated in the Law of the Republic of Indonesia Number 36 of 2009 on Health.

According to Article 45 of the Law of the Republic of Indonesia Number 29 of 2004 on The Medical Practice and Article 4 paragraph (1) of the Regulation of the Minister of Health of the Republic of Indonesia Number 290/MENKES/PER/III/2008 on Approval of

Medical Action, for emergency patients informed consent can be excluded. In emergency situations, medical action is focused to provide assistance on humanity. Medical action on the basis of patient protection and safety in accordance with Article 2 of the Law of the Republic of Indonesia Number 29 of 2004 concerning the Medical Practice.

When a doctor gets approval of a medical action through informed consent, it should be understood that the approval is limited to the things that have been approved. Medical action shall not exceed the scope of such consent, except in emergencies. The purpose is to save lives or preventing the patient's disability (Utja, 2006).

### **The Implementation of Informed Consent for Emergency Patients at Emergency Room of Jember Lung Hospital**

Understanding the approval of medical action or informed consent according to the Indonesian Medical Council is (Utja, 2006):

1. The patient's consent or who is validly representing him or her on the medical action plan submitted by the doctor, after receiving sufficient information to be able to make consent;
2. Approval of medical action is a unilateral statement from the patient and not an agreement between the patient and the doctor, so that it can be withdrawn at any time; and
3. Approval of medical action is the process as well as the result of an effective communication between the patient and the doctor, and not just the signing of the consent form.

Informed consent includes various aspects of the relation between doctors and patients, including (Utja, 2006):

1. Confidentiality and disclosure of medical secrets requires patient consent. For example, to open patient information to doctor colleagues, employers or insurance companies, the patient must know in advance what information and to whom it will be provided;
2. Screening examination for a healthy individual, for example to detect early signs of a potentially life-threatening condition;
3. Informed consent is required if the patient is involved in the teaching-learning process. If a doctor engages a student (co-ass) while receiving a patient consultation, then the patient needs to be asked for his or her approval. Similarly, if the doctor wants to record, make photos or make films for educational purposes; and
4. Involving patients in research is a process that requires informed consent. Before starting a research, the doctor must get approval from the research ethics committee.

In this case the Ministry of Health has published guidance on research ethics.

When informed consent is viewed from the type of action and its purpose, then it is divided into three, namely (Thohari, 2013):

1. Aiming for research (patients are required to be the subject of research);
2. Aiming to seek a diagnosis; and
3. Aiming for therapy.

Informed consent forms are very important and very helpful (and sometimes legally necessary). Sometimes people emphasize the importance of signing medical action consent forms. However, what needs to be understood is the signing of a medical action consent form (informed consent) without effective communication between patients and doctors is insufficient (Utja, 2006). The main thing is to hold detailed discussions with competent patients/closest families, patients/closest families who are competent to understand the information provided by the doctor, and competent closest patients/families are given the freedom to give approval or rejection of medical actions, and documented in the patient's medical record.

Informed means that it has been notified, has been submitted, or has been informed. Consent means the approval that has been given to someone to do something. Essentially, informed consent is a process of communication, not just filling out forms. Approval of medical action is the process as well as the result of effective communication between the patient and the doctor and not just the signing of the consent form (Utja, 2006). Form is only a documentation that proves there is an interaction or communication between the patient and the doctor. The law imposes on health practitioners, the obligation to disclose and inform fundamental aspects of treatment or care carried out on patients (Tan, 2006). Thus, the process of medical action approval is a manifestation of maintaining a respectful and communicative relation between doctors and patients, who together determine the best choice of action for patients to achieve agreed health care goals (Utja, 2006).

When a doctor gets approval of a medical action through informed consent, it should be understood that the approval is limited to the things that have been approved. Medical action shall not exceed the scope of such consent, except in emergencies. With the aim of saving lives or preventing the patient's disability, approval of medical action (informed consent) is also sought to contain of what to do in the moment of an unexpected incident (Utja, 2006).

Based on Article 1 paragraph (1) of the Regulation of the Minister of Health of the Republic of Indonesia Number 290/MENKES/PER/III/2008 concerning the Approval of Medical Action, informed consent is the consent given by the patient or the next of kin who are competent after getting a complete explanation of the medical action that is going to be carried out to the patient. Informed consent contains the understanding of an agreement or rejection of medical actions given by patients or competent closest family after being informed of medical actions to be carried out and any risks that may occur. Article 1 paragraph (3) of the Regulation of the Minister of Health of the Republic of Indonesia Number 290/MENKES/PER/III/2008 concerning the Approval of Medical Action, medical action is a medical action in the form of preventive, diagnostic, therapeutic or rehabilitative conducted by the doctor on the patient.

Informed consent is very important considering the success of medical action is not a certainty. The success of medical action is influenced by many factors. The results of medical action are not always the same, can differ from case to case. The community, especially patients, now wants to be more involved in taking care decisions for themselves.



Well-obtained consent, through good and correct information, can facilitate the patient's wishes. Informed consent will ensure that the relation between the doctor and the patient is based on beliefs.

Informed consent or translated as an approval of medical action is the consent given by the patient or the competent family after being fully explained about the medical action to be carried out on the patient. Medical action is a preventive, diagnostic, therapeutic or rehabilitative medical action performed by a doctor to his patient (Sugiarti, 2010).

Attempts to obtain informed consent can take a long time. The time to obtain informed consent in various circumstances will be different from each other, because each patient has individualized attention and needs. And even though there is little time available, there is still no reason not to obtain informed consent.

The function of informed consent is (Thohari, 2013):

1. Promotion of the right of individual autonomy;
2. Protection from patients and subjects;
3. Prevent fraud or coercion;
4. Causing stimulation to the medical profession to conduct introspection towards themselves;
5. Promotion of rational decisions; and
6. Community involvement (in advancing the principle of autonomy as a social value and conducting supervision in biomedical investigations).

Informed consent according to expert J. Guwandi is to have the following objectives (Thohari, 2013):

1. Protect the patient from any medical action that is taken without the patient's knowledge; and
2. Provide legal protection to doctors of any unexpected and negative consequences, for example the risks of treatment that are impossible to avoid even though the doctor has tried as much as possible and treated with a good treatment carefully.

Informed consent basically relies on two individual basic rights, namely The Right of Information and the Right to Self-Determination. Article 28F of the Constitution of the Republic of Indonesia of 1945, the right to obtain information is that everyone has the right to communicate and obtain information. The right to information in informed consent is the right to obtain more information before a medical action. While the right to self-determination is that everyone has the right to maintain his/her life, Article 28A of the Constitution of the Republic of Indonesia Year 1945. The right to self-determination is the right to privacy and the right to his/her own body.

The existence of informed consent plays an important role in providing protection of patient rights. The right of the patient is to get full explanation before the medical action. The purpose of a complete explanation is for the patient to have the freedom to make his own decisions. The patient has the right to approve or reject the recommended medical action. Patients are also entitled to ask for the opinion (second opinion) of other doctors (Syafrudin, 2015).

Informed consent can be written or orally. Article 45 paragraph (5) of the Law of the Republic of Indonesia Number 29 of 2004 concerning the Practice of Medicine, informed consent which is in writing form are given to any high-risk medical action. A high-risk medical act is a medical act that with some probability may result in death or disability (loss of limbs or damage to the function of certain organs), for example, certain surgical and invasive treatment. The General Medical Council (GMC) in the UNITED KINGDOM, written consent is required in the following circumstances: when a high-risk medical action, not in the framework of therapy, has an impact on personal life and when the medical action is carried out as part of a study (Utja, 2006).

Informed consent is based on the principles of autonomy, beneficentia and non-maleficentia. Informed consent is rooted in human dignity, autonomy and personal integrity of patients protected and respected (Felenditi, 2009). Based on the moral autonomy of the patient, the doctor is obliged to provide information to obtain consent but must not force such consent. Based on clinical autonomy, it does not mean that doctors can act rashly without regard to the opinions of others. The functions of informed consent are to protect patient autonomy, prevent manipulative and coercive actions, improve self-care and improve rational decision-making from doctors (Felenditi, 2009).

Based on therapeutic agreements that give rise to rights and obligations for the parties, doctors also have rights and obligations as a professional. The rights of doctors as a professional can be formulated as follows:

1. The right to obtain complete and honest information from the patient that will be used for the purposes of diagnosis and therapeutic;
2. The right to the reward of services or honorarium for the services that has been given to the patients;
3. The right to good faith of the patient or his family in carrying out therapeutic transactions;
4. The right to defend oneself from the patient's claim or lawsuit for the health services it provides; and
5. The right to obtain medical action approval from the patient or his/her family.

The right of the patient which becomes the doctor's duty in informed consent is the right of information and the right of consent. Article 45 of the Law of the Republic of Indonesia Number 29 of 2004 on The Medical Practice, the minimum limitation of information that must be provided is the diagnosis and procedure of medical action, the purpose of medical actions that is carried out, alternative actions and risks, risks and complications that may occur and the prognosis of the actions taken. At Muhammadiyah Gresik Hospital the information provided includes reasons, risks, objectives, other alternatives, prognosis and cost of medical action (Nasichin, 2017).

The right of consent is the human right of the patient to accept or reject medical action that is offered by the doctor, after the doctor has provided the information. The doctor has done the duty to provide information and obtain consent. Doctors have fulfilled

their obligations in respecting the patient's right of information and the patient's right of consent (Rokhim, 2012).

An agreement is considered valid if (Utja, 2006):

1. The patient has been given an explanation/information;
2. The patient or who is legally representing him/her are in a competent state to give a decision/approval; and
3. Approval must be given voluntarily.

Informed consent in writing must be signed by a competent patient or next of kin. Competent means able to receive, understand, analyze information and use it in making approval or rejection of medical actions (Utja, 2006).

According to Article 1 paragraph (1), (2) and (3) of the Regulation of the Minister of Health of the Republic of Indonesia Number 290/MENKES/PER/III/2008 concerning the Approval of Medical Action, those who are considered as competent if they are 21 (twenty-one) years old or have/ever married, are not disturbed of their physical awareness, are able to communicate normally and are able to make decisions freely and do not experience developmental retardation (mental retardation). While competent according to the Indonesian Medical Council means being able to understand the information that has been given to him in a clear way, using simple and understandable language. Be able to trust the information that has been given. Able to maintain understanding of the information for a considerable time and able to analyze it and use it to make free decisions (Utja, 2006).

Consent must be given by a competent individual. According to Utja, in terms of age, a person is considered competent if he is 18 years old or older or has been married. Children who are 16 years old or older but not yet 18 years old can make approval of certain medical actions that are not at high risk if they can demonstrate their competence in making decisions. The underlying legal reasons are:

1. Under the Civil Code, a person who is 21 years old or older or has been married is considered as an adult and therefore may give consent;
2. Based on the Law of the Republic of Indonesia Number 23 of 2002 on Child Protection, everyone aged 18 years old or older is considered as a person who is no longer a child. Thus they can be treated as competent adults, and therefore may give consent; and
3. Those who are 16 years old but not yet 18 years old are still classified as children according to the law, but by respecting the right of individuals to argue as also stipulated in the Law of the Republic of Indonesia No. 23 of 2002 on Child Protection, then they can be treated like adults and can give approval to certain medical actions, especially those that are not at high risk. For that they must be able to demonstrate their competence in receiving information and making decisions freely. In addition, their consent or refusal may be annulled by a parent or guardian or court appointment.

As described above, everyone who is 18 years old or older is considered competent. A patient with a mental disorder who is 18 years old or older should not be considered incompetent until later proven incompetent by examination. Conversely, a person who is

normally competent can become temporarily incompetent as a result of severe pain, shock, the influence of certain medications or the state of his or her physical health.

The House of Lords (UK) publishes two main principles in terms of competence, namely:

1. The right of parents to make consent on behalf of their children ends when the child has sufficient intelligence and is able to understand the context to give approval of medical action for him/herself; and
2. It is the doctor who decides whether a child has reached that level.

Children are considered incapable of making decisions due to their immaturity, difficulty in understanding medical actions or the impact of their condition. If important decisions are to be made regarding medical action, then both parents (father and mother) should be asked for their opinions. For the best of the child, the court may overturn the refusal of medical action by a person as parental responsibility (Utja, 2006).

The person who is considered to have responsibility as a parent is the parent of the child, that is, if the child is born as the child of a legal married couple. The child's mother, that is, if the child is born to an unauthorized partner so that the child only has a civil relation with the mother. Guardians, foster parents, or legal caregivers under the Law on the Elimination of Domestic Violence, as well as persons who are customarily/culturally considered as the representatives of the child. A guardian is a person who is legally considered legitimate to represent the urgency of another incompetent person (in this case an incompetent patient). A master is a person or entity designated by the court as a party representing the urgency of a particular person (in this case the patient) who is declared to be under the board. The closest family is a husband or wife, a legitimate parent or a competent child and his or her siblings. While other family relationships such as uncles, aunts, grandfathers, in-laws, brothers-in-law, nephews and others are not considered as the closest family. Doctors are not burdened with the obligation to prove a familial relationship to the approval of medical action (Utja, 2006).

Doctors in providing explanations or information to patients should note that information provided in the context of their values, culture and background, may use tools such as leaflets or other forms of publication. Offer the patient to bring the next of kin at the time of providing information. Ensuring the information conveyed does not make the patient depressed (distress), given empathy, should include other health workers (e.g. nurses). Providing information in discussions, strive to provide support to patients, answer all patient questions correctly and clearly, and provide enough time for patients to understand information (Utja, 2006).

The doctor who does the medical action is responsible for ensuring that informed consent has been obtained correctly and properly. Doctors who does medical actions can indeed delegate the process of providing information and receiving approvals, but the responsibility remains on the doctor who does the medical action that delegate to ensure that informed consent is obtained correctly and properly. If a doctor is going to provide information and receive the patient's consent on behalf of another doctor, then the doctor

must be confident that he or she is able to fully answer any questions the patient asks regarding the medical action that will be taken over the patient to ensure that the approval is made correctly and appropriately (Utja, 2006).

Based on medical record data of Jember Lung Hospital, Jember Lung Hospital Emergency Room in January to March 2020 serves 956 emergency patients. There were 952 emergency patients with informed consent. From general observation and the results of an interview with Samsul Anas, S.Kep., Ns. (Head of Emergency Room of Jember Lung Hospital) on February 3, 2020, The implementation of informed consent in the Emergency Room of Jember Lung Hospital has referred to the mandate of the Law of the Republic of Indonesia Number 29 of 2004 on The Medical Practice, Regulation of the Minister of Health of the Republic of Indonesia Number 290/MENKES/PER/III/2008 on Approval of Medical Action and The Indonesian Medical Council on Medical Action Approval Manual.

Jember Lung Hospital already has Standard Operating Procedures on informed consent contained in the list of Standard Operating Procedures of Jember Lung Hospital. The implementation of informed consent at Jember Lung Hospital is contained in the Standard Operating Procedure Number ST - IGD - 013 on Guidelines for the Use of Informed Consent. Standard Operating Procedure is a written work order to guide activities so that a job can be in accordance with regulations or standards. This procedure is expected to be a foundation in the work, evidence of conformity with procedures and regulations that apply somewhere in the hopes of reducing the number of errors in work and can increase efficiency and effectiveness (Farhatani, 2014).

Explanation of medical actions by doctors to patients in the Emergency Room of Jember Lung Hospital has been implemented in language that is easily understood by the patient. After getting an explanation from the doctor of the Emergency Room of Jember Lung Hospital, the nurse will ask the patient or the next of kin who are competent to sign the Form of Approval or Rejection of Medical Action of Jember Lung Hospital. The form lists the date, time, name and signature of the explanatory and the explanatory recipient. The form was then documented in the medical record file of Jember Lung Hospital as an informed consent document.

The explanation of medical actions in the Emergency Room of Jember Lung Hospital is carried out by duty doctor of the Jember Lung Hospital Emergency Room as medical action givers who treat patients. However, because of the work and busyness of duty doctor of the Jember Lung Hospital Emergency Room, sometimes this explanation is delegated to senior nurses. According to the Indonesian Medical Council, it is the responsibility of the doctor who does the medical action to ensure that the approval has been obtained correctly and appropriately. Doctors can delegate explanations and acceptance of approval, but the onus remains with the delegate doctor (Utja, 2006). According to Article 10 paragraphs (2), (3) and (4) of the Regulation of the Minister of Health of the Republic of Indonesia Number 290/MENKES/PER/III/2008 concerning the Approval of Medical Action, delegation of explanations to patients is allowed as long as the explanation is those who provide health services directly to patients.

In accordance with the provisions of Article 13 paragraph (1) and (2) of the Regulation of the Minister of Health of the Republic of Indonesia Number 290/MENKES/PER/III/2008 concerning approval of medical actions, consent is given by patients or competent closest family. The next closest family of the approval of medical action at the Emergency Room of Jember Lung Hospital is the husband or wife, father or biological mother and the siblings of the competent patient' biological or siblings. At Jember Lung Hospital, patients are considered competent if they are 18 years old or have been married, able to communicate and are able to make decisions freely. This is in accordance with Article 1 paragraph (1) and (2) of the Regulation of the Minister of Health of the Republic of Indonesia Number 290/MENKES/PER/III/2008 concerning the Approval of Medical Action.

The implementation of written informed consent at the Emergency Room of Jember Lung Hospital is requested for any high-risk medical action. A high-risk medical action is a medical act that can result in death or disability. For the operation, approval of the medical action is requested to the next of kin who are competent. Written informed consent at the Jember Lung Hospital Emergency Room is made in the form of a statement contained in the Jember Lung Hospital Medical Action Approval or Rejection Form. The implementation of written informed consent form of the Jember Lung Hospital Emergency Room is especially in line with Article 3 paragraph (1) and (3) regulation of the Minister of Health of the Republic of Indonesia Number 290/MENKES/PER/III/2008 concerning the Approval of Medical Action. But it is not as complete as the example of the documentation form of providing information of the Medical Action Approval Manual, Indonesian Medical Council.

The service of Jember Lung Hospital Emergency Room in January to March 2020, got 4 (four) cases of emergency patients who have taken medical action without informed consent. The first case, January 25, 2020, Mrs. T, 43 years old, with an acute asthma attack and respiratory failure, was escorted to the Jember Lung Hospital Emergency Room by neighbors. The second case, February 8, 2020, Mr. P, 26, who was in a traffic accident with moderate head injuries and a fractured left leg, was escorted to Jember Lung Hospital Emergency Room by friends. The third case, February 16, 2020, Mr. D, 54 years old, with Chronic Obstructive Pulmonary Disease acute exacerbation and respiratory failure, was delivered to the Jember Lung Hospital Emergency Room by neighbors. The fourth case, March 14, 2020, Mr. K., with impaired heart function and decreased consciousness, was delivered to the Jember Lung Hospital Emergency Room by a neighbor. These four cases are cases of emergency patients in the Emergency Room of Jember Lung Hospital with a high risk of life-threatening if not done medical action immediately but not accompanied by informed consent. These four patients are incompetent and not accompanied by next of kin who can provide informed consent.

In an emergency situation, to save the patient's life and/or prevent disability for the patient, and if no one competent can give consent, then medical action is not required with any informed consent. Medical action in an emergency room is decided by a doctor

without the consent of a competent patient or next of kin. All medical action is recorded in the medical records of Jember Lung Hospital. This is in accordance with Article 4 paragraph (1) and (2) of the Regulation of the Minister of Health of the Republic of Indonesia Number 290/MENKES/PER/III/2008 concerning the Approval of Medical Action.

Article 13 paragraph (1) and (2) of the Regulation of the Minister of Health of the Republic of Indonesia Number 290/MENKES/PER/III/2008 concerning Approval of Medical Action, informed consent may be excluded for emergency patients. Law of the Republic of Indonesia No. 29 of 2004 on The Medical Practice explains in emergency situations, to save the life of patients, it doesn't need any approval of medical action. But after the patient is conscious and being aware, the patient will immediately be given an explanation and made approval. All of this is done on the basis of healing and the safety of the patient itself. Handling emergency patients is the application of the principle of patient protection and safety stipulated in the Law of the Republic of Indonesia Number 36 of 2009 on Health.

### **Legal Aspects of Medical Action Without Informed Consent in Handling Emergency Patients**

Legal aspects in informed consent include three aspects of law, namely aspects of administrative law, aspects of civil law, and aspects of criminal law. If a doctor performs a medical action without obtaining approval of a valid medical action or informed consent, it will face problems in terms of administrative legal sanctions, civil law sanctions, or criminal law sanctions.

Administrative law sanctions in the form of discipline by the Honorary Council of Indonesian Medical Discipline (MKDKI). If the Honorary Council of Indonesian Medical Discipline receives a complaint about a doctor who performs medical action without informed consent then they will take it to the trial and give medical discipline sanction in the form of a reprimand until the recommendation of the revocation of registration certificate (Utja, 2006). The responsibilities of the doctor in the aspect of administrative law relates to administrative requirements that concern the authority of the doctor in carrying out his professional duties.

Civil law sanctions in the form of damages lawsuits against the doctor if the patient can show that he or she was not warned in advance about the specific end result of the action. Or if the patient can show that the doctor has performed a medical action without consent (Utja, 2006). In the aspect of civil law, medical actions are carried out without the consent of the patient, while the patient is conscious and able to give consent, the doctor can be blamed and sued for committing an act against the law or *onrechtmatigedaad* based on Article 1365 of the Civil Code. If medical action harms the patient, then it can be held legally accountable by providing compensation. Without the approval of medical action, doctors can be punished with criminal assault. This can be a reason for patients to complain the doctor to the police investigator (Utja, 2006). In the criminal law of a medical action (e.g. surgery) committed by a doctor without the consent of the patient, the doctor

can be charged with committing a criminal act of persecution and committing a violation of Article 1351 of the Criminal Code.

There is a presumption by some doctors that informed consent is a means that can free them from legal responsibility in the event of malpractice. Assumptions like this are false and misleading. Malpractice is the implementation of medical services that are not in accordance with the standards of the medical profession. Article 6 of the Regulation of the Minister of Health of the Republic of Indonesia Number 290/MENKES/PER/III/2008 concerning the Approval of Medical Action, states that the approval of medical action does not eliminate the legal liability in the case that there is proven negligence in performing medical acts that cause harm to patients.

The medical actions given by doctors in hospitals are not always gives satisfactory results. There are times when doctors make negligence or errors in performing medical actions that result in disability, paralysis, or even death. Based on Article 58 of the Law of the Republic of Indonesia Number 36 of 2009 concerning Health, states that everyone has the right to claim damages against a person, health worker, and/or health organizer who causes harm due to error or negligence in providing medical action (Wahyudi, 2011).

Generally applicable law also applies to the medical profession, but there are still special factors such as: risk of treatment, in certain medical actions there is always an inherent risk (e.g. allergic reactions, complications, etc.), medical accidents, accidents of medical actions that are completely unpredictable and are not the purpose of action, non-negligent error of judgment, a doctor is not considered to be negligence if he chooses one of the methods/way of treatment recognized in the world of medicine, *volenti non fit inura*, if a person knows that there is a risk and voluntarily willing to bear the risk, he can no longer sue if the risk is true and contributory negligence, unnatural actions of patients who harm themselves (Felenditi, 2009). In the situation of the special factors above the doctor cannot be blamed if he has acted carefully and fulfilled the standards of the medical profession and request informed consent from competent patients/closest family. Informed consent is an absolute requirement for a doctor before performing medical action. Informed consent is also an absolute requirement for a doctor to stop medical action. Such action can be in the form of termination of treatment and/or medical therapy (Nurdiyanningrum, 2018).

Without informed consent medical action can be blamed for violating Article 45 of the Law of the Republic of Indonesia Number 29 of 2004 concerning the Medical Practice. However, in dealing with emergency patients, the doctors may face a difficult choice, to save the life of patients, the doctor have to do medical action without providing information and do not ask for prior approval to the patient/his family. Just like the medical action carried out by doctors of jember Lung Hospital Emergency Room on four emergency patients who are life-threatening but not accompanied by informed consent. The four patients are old enough but in a state of decreased consciousness and not accompanied by next of kin so that no one is competent to provide informed consent.



Medical action without informed consent can be categorized as persecution in accordance with Article 1351 of the Criminal Code. But according to Article 45 of the Law of the Republic of Indonesia Number 29 of 2004 on The Medical Practice and Article 4 paragraph (1) of the Regulation of the Minister of Health of the Republic of Indonesia Number 290/MENKES/PER/III/2008 on approval of medical actions, for patients with emergency situations, informed consent can be excluded. In emergency situations the stressed medical action is to provide assistance on humanitarian grounds. Medical action on the basis of patient protection and safety in accordance with Article 2 of the Law of the Republic of Indonesia Number 29 of 2004 concerning the Medical Practice.

## **Conclusion**

1. Implementation of medical actions for emergency patients in the Emergency Room of Jember Lung Hospital to save the patient's life and/or prevent disability for the patient, if no one competent can give approval to medical action then no informed consent is requested. Medical action in an emergency room is decided by the doctor without the consent of the patient or next of kin. All medical actions are recorded in the medical records of Jember Lung Hospital. This is in accordance with Article 4 paragraph (1) and (2) of the Regulation of the Minister of Health of the Republic of Indonesia Number 290/MENKES/PER/III/2008 concerning the Approval of Medical Action, in this case informed consent can be excluded for emergency patients.
2. Legal aspects of medical action without informed consent in handling the emergency patients include three aspects of law, namely aspects of administrative law, aspects of civil law and aspects of criminal law. Informed consent is something that must be provided by health workers related to medical actions over patients. If not provided, there are legal consequences in the form of administrative sanctions, civil sanctions or criminal sanctions. Medical action without informed consent is excluded in emergency patients as stipulated in Article 45 paragraph (1) of the Law of the Republic of Indonesia Number 29 of 2004 on The Medical Practice and Article 4 paragraph (1) of the Regulation of the Minister of Health of the Republic of Indonesia Number 290/MENKES/PER/III/2008 on approval of medical actions. Informed consent of emergency department patients is excluded on the basis of the principle of protection and safety of the patient itself in accordance with Article 2 of the Law of the Republic of Indonesia Number 29 of 2004 concerning the Medical Practice. The granting of approval of medical action (informed consent) does not eliminate the legal liability in the case that is proven negligence in performing medical actions that result in harm to patients.

## **Suggestions**

1. Doctors should act carefully and meet the standards of the medical profession and ask for informed consent. The doctor must provide a complete explanation of the medical

actions that will be carried out to the patient using language that can be understood by the patient.

2. Patients should understand that the legal relation between doctors and patients does not promise definite results (cure) but promises maximum efforts made by doctors carefully in accordance with the standards of the medical profession.

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