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Position informed consent of on the reasons for medical abolition of criminal

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Abstract
Informed consent is a form of agreement and agreement is one of the terms of the agreement, then the revocation of *informed consent* will greatly affect the therapeutic agreement between the doctor and patient. Before signing the approval for the action, it must be preceded by the delivery of information to the patient or the husband/wife or the patient's parents about the action to be taken and possible complications if it occurs. This procedure is standard, problems sometimes arise for the patient or the patient's husband/wife or parents who feel that there is an abnormality at the time of the procedure or after the procedure. Then a problem arises, namely what is the position of *Informed Consent* on the risk of rejection of medical action by patients?. In addition, the author has the aim of writing this to understand the position of *Informed Consent* against the risk of refusing medical action that is not approved by the patient. The approach method used in this research is normative juridical, namely by reviewing or analyzing secondary data in the form of secondary legal materials by understanding the law as a set of regulations or positive norms in the applicable legislation, so this research is understood as library research, namely research on secondary materials. Thus the position of *Informed Consent* to the risk of rejection of medical action by the patient is legally recognized because the patient has factually died, but if there is no element of 'severe negligence' then the status remains as *on recht matige daad*, therefore legal action (*legal action*) can be taken against doctors is a lawsuit for damages (*civil action for damages*) so that the position of *informed consent is* very strong as evidence in the trial to be able to acquit doctors in all lawsuits.

Keywords: informed consent, medical, deletion, criminal

Introduction
The legal relationship between doctors and patients can occur with or without the intention of the parties involved (Mufidi, 2012) [12], which relies on 2 (two) kinds of human rights guaranteed in international documents and conventions. The two rights are *the right to self-determination* and *the right to information.* These two basic rights stem from *the right to health care*, which is an individual human right. International documents that guarantee these two rights are *The Universal Declaration of Human Rights* in 1948, and *The United Nations International Covenant on Civil and Political rights* in 1966 (Yunanto, 2009) [27]. The state must strive to realize the principles of Indonesia as a state of law (Suseno, 2011) [25], and guarantee human rights in the life of society and the state (Suahrdin, 2007) [23].
In order to fulfill the right to access health resources as well as the right to safe and quality health services, it is necessary to make provisions governing the agreement between a doctor or dentist and a patient. *Informed Consent* or approval of medical action is given by the patient before the doctor performs medical action. It is the initial form of a doctor-patient legal relationship, which is very likely to continue in an agreement (Mufidi, 2012) [12]. The patient agrees (*consent*) or refuses (*refusal*), is a personal right that should not be violated, after receiving information from the doctor or dentist on things that will be done by the doctor or dentist in connection with the medical services provided to him, as stated in Article 56 of Law Number 36 of 2009 concerning Health which reads; "Every person has the right to accept or reject part or all of the relief measures that will be given to him after examining and fully understanding the information regarding such actions".
Regarding *informed consent* as a patient's right, the patient also has the obligation to provide a complete and honest explanation about his illness. Given that *informed consent* is a form of agreement and agreement is one of the terms of the agreement, the revocation of *informed consent* will greatly affect the therapeutic agreement between the doctor and patient (Mufidi, 2012) [12]. *Informed Consent is* regulated in Law Number 36 of 2009 concerning Health, Article 8, Law Number 29 of 2004 concerning Medical Practices Article 45, then also regulated in Regulation of the Minister of Health Number 290 of 2008 concerning Approval of Medical Actions.
Positive law in Indonesia has regulated medical crimes as a preventive effort, especially in the legal protection of both parties, in this case doctors and patients or victims (Mariyanti, 1988) [10], so that unwanted things do not happen, because this medical crime is related to closely related to human life (Satria, 2018) [18]. In every criminal act there must be an element of unlawful nature, whether explicitly stated or not. In general, the unlawful nature of medical malpractice lies in the violation of the patient's trust in the therapeutic contract.
In principle, there is no one who does not apply to him the criminal provisions contained in criminal law. Anyone who commits a crime must be held accountable for the crime he has committed, unless there is no mistake in that person. Chairul Huda said that guilt and criminal responsibility are

institutions contained in criminal law, both contained in criminal law theory, and in criminal law enforcement (Huda, 2006) [4]. Errors that determine whether or not a person can be convicted.

Even though criminal law recognizes the abolition of crime in health services, namely justification and excuses as contained in jurisprudence, it does not necessarily remove the justification and forgiveness of a crime for the medical profession. One of the jurisprudence that contains justifications and excuses in health services is the jurisprudence in the case of "Natanson BV. 1960's Clients". This jurisprudence contains *"Informed Consent"* as a criminal waiver. However, this does not mean that the medical profession is freed from all criminal responsibility, because justifications and excuses for doctors' actions are only found in certain exceptions (Nasution, 2005; Pontoh, 2013) [13, 16].

The reason for the abolition of the crime is a special condition (which must be stated but not proven by the defendant) which, if fulfilled, results in even though all the written elements of the formulation of the offense have been fulfilled and sentenced to a sentence. The Criminal Code does not explain what is meant by the reason for the abolition of a crime and the difference between justification and excuse. The Criminal Code only mentions things that can abolish criminals. Discussion on this matter develops through doctrine and jurisprudence.

According to van Bemmelen, what can make an offender unpunished is not only because the act he has committed in a *noodtostand* has met the requirements of proportionality and subsidiarity but also if the act he has committed is an act that has occurred as a result of the existence of a*noodtostand-exces.* The reasons for the abolition of this crime are reasons that allow people who commit acts that actually have fulfilled the formulation of the offense, but are not punished. Unlike the case with reasons that can abolish prosecution, the reason for the abolition of a crime is decided by the judge by stating that the unlawful nature of the act of erasing or the error of the author of the write off is due to the provisions of laws and laws that justify the act or forgive the author. So in this case the right to prosecute from the prosecutor remains, not lost, but the defendant is not sentenced by the judge (Chazawi, 2002) [1].

In the health system, the medical profession often gets quite scathing criticisms from various levels of society, some mass media have also brought this news to the surface (Mariyanti, 1988) [10]. The increasing public spotlight on the medical profession is caused by various changes, including advances in the field of health science and technology, changes in the characteristics of the health worker community as service providers and changes in health service users who are more aware of their rights. If these changes are not accompanied by increased communication between health workers as service providers and the community as recipients of health services, this can lead to misunderstandings, dissatisfaction and conflict between the two (Wijono, 2000) [26].

In essence, *informed consent* is a tool to enable self-determination to function in a doctor's practice. Self-determination is a value, a goal in *Informed Consent*. Concretely, therequirement *Informed Consent* is for both diagnostic and therapeutic actions, in principle, the patient's consent is required in a definite form in this case an agreement (Soewono, 2006) [20].

Before signing the approval for the action, it must be preceded by the delivery of information to the patient or the husband/wife or the patient's parents about the action to be taken and possible complications if it occurs. Such a procedure is standard, problems sometimes arise for the patient or the patient's husband/wife or parents who feel that something is wrong at the time of the procedure or after the operation, for example, the patient does not immediately wake up (coma). Then the patient asked it which then got an unsatisfactory answer, this is where the "dispute" began to emerge (Pakendek, 2012) [15].

The regulation of medical practice aims to provide protection to patients, maintain and improve the quality of medical services provided by doctors and dentists, and provide legal certainty to the public, doctors and dentists.

In the civil aspect of health law, the doctor's relationship with the patient is intertwined in a transactional bond or a therapeutic contract. The results of Veronica Komalawati's research show that the role of *informed consent* in therapeutic transactions is as a means to increase awareness, willingness, and ability to participate in medical efforts carried out, and *informed consent is* not only needed in therapeutic transactions but also in medical research on humans (Komalawati, 2002) [6]. The need for *informed consent is* not only based on moral obligations associated with individual human rights and individual responsibilities for their health, but also serves to protect humans from being manipulated as objects for personal gain.

Conflicts in the doctor-patient relationship are often initiated due to a lack of transparency in *informed consent*, causing a mismatch between doctors and patients, which leads to medical disputes. The increasing number of medical disputes that occur sometimes also lead to *criminalization in health care.* The public is still unable to distinguish malpractice due to negligence from medical risk (Kuntardjo, 2017) [7].

Signing theform *informed consent* in writing is only a confirmation of what has been previously agreed. The purpose of a complete explanation is for the patient to make his own decision according to his own choice (*informed decision*). Therefore, the patient also has the right to refuse the recommended medical treatment. Patients also have the right to seek the opinion of another doctor (*second opinion*) from the doctor who treats them. The task of providing explanations or information to patients is the person in charge of care for patients is the duty of a doctor.

The problem that arises in the approval of medical actions between doctors and patients which leads to legal problems is the failure or result of medical actions that are not in accordance with the expectations of the patient and or family, in the form of disability or even death even though the action is carried out after *informed consent* (Jusuf Hanafiah, 2007) [5].

Another *informed consent* case is the case of doctor Elisabeth Susana, M. Biomed in Makassar City. This case began with a report on an alleged crime committed by the defendant dr. ELISABETH SUSANA, M.Biomed with criminal charges filed by the Public Prosecutor against the defendant, namely imprisonment for 4 (four) years and a fine of Rp. 30,000,000,- (thirty million rupiah) provided that if the fine is not paid, it will be replaced with imprisonment for 3 (three) times, for injecting *filler* into the nose of the victim AGITA DIORA FITRI without making written*informed consent.*) to witness AGITA DIORA FITRI

as a patient before committing the act, which caused the victim's left eye to be unable to see. Even though it is known that every medical action must obtain written consent (*informed consent*) from the patient or the patient's closest family as regulated in Article 45 paragraph (1) of the Republic of Indonesia Law Number 29 of 2004 concerning Medical Practice and Article 1 point 1 and Article 3 paragraph (1) Regulation of the Minister of Health of the Republic of Indonesia Number 290/MENKES/PER/III/2008 concerning Approval of Medical Actions. Against this criminal case by the Makassar District Court Number: 1441/Pid.Sus/2019/PN.Mks.

Especially about the actions taken by doctors in their profession. That the actions of doctors cannot be included in the sense of intentionally causing pain as referred to in Article 351 of the Criminal Code, because what they did was not against the law (PAF & Lamintang, 2012) [14]. Noyon and Langemeijer argue that the exclusion of acts committed by doctors in the sense of persecution is reflected in the word persecution itself, because in order to be called an act of persecution, the act committed by a person must be a goal and not a means. To achieve a justifiable goal (PAF & Lamintang, 2012) [14].

Noyon and Langemeijer, as well as German writers in general have written that the acts committed by these doctors cannot be included in the meaning of persecution, especially because the acts they committed in their position as doctors were *tat be stand massig* or actually not. is a *konperverletzung* as intended above but is an effort *tot het welzijn van het lichaan* or an effort for body health (PAF & Lamintang, 2012) [14]. In German jurisprudence it is argued that doctors can justify the actions they have taken with their patients on the consent they have obtained from their patients, whether expressly or tacitly given. silenced by these patients, which can essentially be viewed as *korperverletzung* (PAF & Lamintang, 2012) [14].

In the aspect of civil law the principle applies; *"Whoever harms another person must provide compensation"*. While in the criminal aspect, the benchmark used is "grave error" (*culpa lata*). Therefore, the existence of a small error (*culpa levis*) in the implementation of medical actions cannot be used as a benchmark for imposing criminal sanctions (Suarda, 2011) [24].

Based on previous research conducted by Beni Satria with the title Legal Protection Against Doctors on Allegations of Committing Medical Crimes after the Supreme Court Decision Number 14/PUU-XII/2014 associated with the Doctrine of Unlawful Material Law, that with the rejection of the lawsuit against the Material Examination article 66 paragraph (3) through Supreme Court Decision No. 14/PUU-XII/2014 the rights of doctors and dentists to obtain legal protection on suspicion of committing medical crimes based on fair Indonesian laws and regulations have not been realized to provide justice, order and legal certainty (Satria, 2018) [18]. So with this the author has a difference in terms of the object studied, namely the abolition of criminal law against doctors and the legal position of *informed consent*. In criminal law, a person who is accused of committing a criminal act can be punished if he fulfills two things, namely the act is against the law and the perpetrator of a criminal act can be held accountable for the act that was charged (there is a mistake by the perpetrator) or the act can be blamed on the perpetrator and there is no excuse for forgiveness. In criminal law, the reasons for criminal law are distinguished in the reasons for the general criminal abolition and are referred to in articles 44, 48, 49, 50, 51 of the Criminal Code, and the reasons for the abolition of special crimes. The theory of criminal law is usually the reasons that abolish the crime are divided into reasons of justification, reasons for forgiveness, and reasons for the abolition of the crime.

Based on the description above, to focus more on this study, what is the position of *Informed Consent* on the risk of patient refusal of medical action? In addition, the author has the aim of writing this to understand the position of *Informed Consent* against the risk of refusing medical action that is not approved by the patient.

Method

The approach method used in this research is normative juridical (Hanitjo, 1990) [3]. The normative juridical approach is to examine or analyze secondary data in the form of secondary legal materials by understanding the law as a set of regulations or positive norms in the applicable legislation, so this research is understood as library research, namely research on secondary materials (Soekanto, 1985) [19]. This study uses an approach to legal norms in the laws and regulations relating to the issue of the implementation of *informed consent* on the implementation of rights and protection between doctors and patients in realizing a balanced legal relationship.

Discussion

In Indonesian criminal law, the teaching of causality is applied to material crimes, crimes qualified by their consequences and *omissions* impure. This means that outside the three types of criminal acts it is impossible to use the teaching of causality to be able to hold the perpetrators of criminal acts accountable.

Crime Requires Teachings on Causality

Material of Crimes

One of the elements of an objective crime is its unlawful nature. An unlawful act means that a person violates or violates or is contrary to the material rules that apply to him. Material crimes are criminal acts whose formulation is aimed at the emergence of prohibited consequences (Spier, 1996) [22], the elements of the consequences are determined in the formulation of the article. Indirect effects appear immediately, but are separated by time, in other words, the emergence of new effects has occurred since the act was committed (Moeljatno, 2002) [11]. Theoretically, formal criminal acts are also found, but the form of the prohibited acts has been carried out without having to wait for the consequences. In material crimes discussed are "*constitutive*" consequences, namely consequences that are clearly stated in the formulation of criminal acts, while in criminal acts that are formally formulated, certain consequences can be aggravating or lighten the crime, but without consequences that are prohibited from appearing, the perpetrator has can be convicted (D. Schaffmeister, N. Keijzer, 2003) [2].

In relation to the formulation of this crime, theoretically it is found that there are two functions of the criminal formulation, namely related to the concrete application of legality where criminal sanctions can only be given to actions that have been formulated in the legislation. The second function of the formulation of a crime is as a

function of evidence clues known in criminal procedural law. In other words, all elements listed in the formulation of a crime must be proven according to the rules of criminal procedure law. These elements as written requirements to be convicted, all elements must be proven (D. Schaffmeister, N. Keijzer, 2003) [2].

Criminal Acts Disqualified by Consequences An

Offense that is qualified by its consequences is where due to the emergence of a certain result, the criminal threat against the offense is increased. For example, ordinary persecution is punishable by a maximum imprisonment of 2 years and 8 months (Article 351 paragraph (1) of the Criminal Code), but if the abuse results in serious injuries to the victim, the threat of punishment is increased to 5 years (Article 351 paragraph (2) of the Criminal Code). and if it causes death to the victim, the maximum penalty is 7 years (Article 351 paragraph (3) of the Criminal Code) (D. Schaffmeister, N. Keijzer, 2003) [2].

The weighting of a crime is not based on the guilt of the defendant but the emergence of aggravating consequences which are objectively determined by his actions. In this case, Van Hamel gave specific comments related to the criminal acts qualified by the consequences, namely;

1. It is wrong to carry out a criminal charge without seeing the error, even though what is important in modern criminal law is the mental attitude of the defendant.
2. If we still maintain the existence of the type or type of offense, it is sufficient if the criminal threat for the offense is abandoned so that the judge can impose a heavier sentence than an ordinary offense if there are consequences arising from it (D. Schaffmeister, N. Keijzer, 2003) [2].

Hazewinkel Suringa has no doubt that in the offenses qualified by the consequences there is a “pure causal relationship, that is, to a complete and sufficient amount of criminal conviction.” Noyon Lengemeyer was of the opinion that the legislators wanted at that time that it must be proven that the result was intended to be *inconcreto* (Saleh, 1994) [17].

Roeslan Saleh has a different view, persecution that ends in death cannot be qualified as murder. The fact that there is an unintended consequence of death by the perpetrator acts as an aggravating situation. Such crimes still qualify as persecution, with the unintended consequence of being aggravating circumstances. Pure causal relationships have been built perfectly to account for unwanted consequences in different ways (Saleh, 1994) [17].

In closing this debate, it is worth mentioning the view of Hans Schultz, a Swiss writer who says that the consequences can be a burden to the maker, even though he does not want these things, does not know them and cannot expect them, or perhaps needs to expect them not. it is doubtful that the principle of error has been violated by the maker (Saleh, 1994; Sofian, 2018) [17, 21].

The Crime of Impure Omission

In a murder offense, the criminal law provides legal threats to crimes that result in the death of a person. However, the criminal law does not specify what actions are prohibited which resulted in the death of the person. Criminal law generally punishes someone who commits an act so that his act causes death, but criminal law also punishes someone who fails to prevent an act that results in the death of a person. In this case, it has entered an area that is better known as *commissioning* and not doing *omissions* (Leavens, 1988) [8].

In general, *omission is* defined as someone who has a legal obligation to prevent crime/harm to others but does not do so, he can be punished as with people who cause crime/danger (Leavens, 1988) [8]. Almost the same as this conception, Satochid Kartanegara states that if a person does not act, while he has an obligation to do so, then such a situation is considered a cause rather than an effect. Meanwhile, according to D. Schaffmeister, the crime of impure omission (*commission per omission*) means causing consequences due to negligence. The crime of *omission* impureonly has a limited scope, where the maker has an obligation to act (Sofian, 2018) [21].

The Doctrine of the Relationship between Causality and Criminal Responsibility

Doctrinally, causality is in the area of action, not in the area of error (Sofian, 2018) [21]. Although some legal scientists such as Van Hamel said that causality could also be in the area of error, even other legal scientists such as Barda Nawawi Arief said that causality is subjective and some is objective. Conceptually, causality can only occur if there is an act or series of actions that cause certain consequences that are prohibited by law. Before the 18th century in *common law countries, it was* difficult to state “error” as one of the elements that contributed to causality. It is common practice that causality exists in the area *actus reus.* Furthermore, causality is also associated with the objective element of an action. Therefore, there is not much literature that discusses in depth the relationship between the teaching of causality and the teaching of error (Sofian, 2018) [21]. However, Remmelink said that in the discourse of criminal law, the possibility of causality in terms of wrongdoing is no longer in question, although in the development of causality in the 19th century there is still a view that legitimizes that causality exists in the context of actions.

Criminal acts only refer to the prohibition of the act. Whether the person who has committed the act is then also punished, depends on the question of whether he or she has committed the crime or not. If the person who committed the crime did have an error, then of course he would be punished (Saleh, 1994) [17]. Sudarto stated that it is not enough to punish a person if that person has committed an act that is against the law or is against the law. So, even though his actions meet the formulation of offenses in the law and are not justified, they do not meet the requirements for criminal prosecution. For punishment, there is still a requirement that the person who commits the act has a fault or is guilty. In other words, the person must be accountable for his actions or if viewed from the point of view of his actions, he can only be held accountable to that person. Here applies what is called the principle of "No Crime Without Error" (*Nulla Poena Sine Culpa*). The

principle of no crime without guilt has a long history. In criminal law, the emphasis for the existence of a crime is on the act and its consequences, although the shift in the existence of elements in the maker has influenced the act and its consequences. It can be said that the current criminal law is called a criminal law that favors the act and the person. Today's criminal penalties require that in order to be able to impose sanctions on someone there must be an error

on the part of the maker. To give the meaning of error, the following is a summary of the notion of error quoted by Sudarto:

1. Mezger said: "Error is the whole condition that provides the basis for personal reproach against the criminal".
2. Simons interprets the error as a "Social-ethisch" understanding, and says, among other things: "As a basis for liability in criminal law it is in the form of the psychological state (soul) of the maker, and its relationship to his actions and in the sense that it is based on the psyche (soul). It is a disgrace to the maker.
3. Van Hamel said that, "Error in an offense is a psychological understanding, the relationship between the state of the soul of the maker and the realization of the elements of the offense due to his actions. Mistakes are legal liability."
4. Pompe said, among other things: "In violation of norms committed because of his fault, usually the nature of being against the law is an external aspect. What is against the law is his actions. The aspect of it which relates to the will of the maker is error. This error can be seen from two angles according to its consequences, it is something that can be reproached and according to its essence it is something that unlawful acts can be avoided.

Based on the description above, for an error there must be an element of reproach against someone who commits a crime, meaning that a criminal act committed by a person must be reproachable to that person. According to Muladi, the reproach meant was not a censure of decency but a censure of the law. Meanwhile, Sudarto said that the criticism meant was ethical criticism, no matter how small the criticism was, at least the maker could be reproached for not respecting the rules in society. Regarding this error, Sudarto then distinguishes between psychological (inner) errors and normative errors.

In subsequent developments the placement of causality is associated with error. The placement of causality is motivated by the results of the perpetrator's actions which are also influenced by the element of error. For example, a consequence of a crime that was never intended by the perpetrator, meaning that the perpetrator never thought about the consequences or results of the crime occurring, or the perpetrator did not have any bad intentions for an act that resulted in a prohibited act. This concept does not only apply in *Common law countries,* but also implicitly applies in Germany and the Netherlands. A concrete example that shows how difficult it is to separate error from causality is that an actor is given a weapon to kill a criminal. Unbeknownst to the gun, it turned out to be filled with real ammunition instead of rubber ammunition. Of course the villain died because of the actor's shot. The question is whether the cause of the death of the criminal is, of course, the act of the actor who fired the firearm. Is the actor guilty? (Saleh, 1994) [17].

Errors in Welzel's view also determine causality for special cases. Errors associated with causality indicate the predictability of the consequences easily and significantly by the perpetrator. The predictability of the consequences by the perpetrator implies that the consequences that arise are easily predictable by the perpetrator. The inclusion of an element of predictability is nothing but the view of Von Kries' theory on the doctrine of subjective-adequate causality. This teaching requires consideration of the knowledge of the perpetrator on the emergence of prohibited consequences. The knowledge of the actor is related to the probability of the consequences of the events that occur which according to Von Kries is called no mological knowledge. In addition, knowledg ealso needed *ontological* (understanding of facts/empirical situations) is for these events.

In determining criminal liability for the actions of the perpetrators that cause prohibited consequences, it is necessary to limit them to the teachings of error. The limitation in question is that the perpetrator can guess the consequences that may arise from the act. If the perpetrator cannot predict the consequences that will happen, then the perpetrator cannot be held accountable. This is a form of exception in the teaching of causality in order to protect the perpetrator for something that happens, due to coincidence or factors that are not attributions of his actions. In principle, criminal law was made not to punish people because of the bad luck factor but to punish people because of the error factor (Sofian, 2018) [21].

The position of Informed Consent on the Reason for the Abolition of Criminal

Therapeutic Contracts creates rights and obligations for the parties bound in it, namely doctors and patients. This shows the existence of an engagement that is regulated in civil law regarding an engagement that is born out of an agreement. The rights and obligations of doctors and patients give rise to achievements and contra-achievements that must be fulfilled by each party.

The rights of patients as written in Article 52 of Law Number 29 of 2004 concerning Medical Practices, include: The

a. Right to obtain a complete explanation of medical actions, at least including;
1. Diagnosis and procedures for medical action;
2. The purpose of the medical action taken;
3. Other alternative actions and risks;
4. Risks and complications that may occur;
5. Prognosis of the action taken.

b. The right to seek the opinion of a doctor or other doctor. The
c. Right to get services according to medical needs. The
d. Right to refuse medical action, and the
e. Right to obtain the contents of the medical record.

The term Therapeutic is not known in the Civil Code but is included as explained in Article 1319 of the Civil Code, that for all agreements, whether a special name or not subject to an engagement in general (Chapter I Book III of the Civil Code) and sourced from an agreement (Chapter II Book III of the Civil Code). Thus, for a therapeutic transaction to be valid, the conditions contained in Article 1320 of the Civil Code and the consequences thereof are regulated in Article 1338 of the Civil Code.

In essence, or what is known as *informed consentInformed Consent* is a tool to enable self-determination to function in a doctor's practice. Self-determination is a value, a goal in *Informed Consent*. Concretely, therequirement *Informed Consent* is for both diagnostic and therapeutic actions, in principle, the patient's consent is required in a definite form

in this case an agreement (Soewono, 2006) [20].

An agreement can be made orally or in writing. This is confirmed in Book III of the Civil Code which adheres to an open system with the principle of freedom of contract. Even though there is the principle of freedom of contract, the conditions for the validity of the agreement contained in Article 1320 of the Civil Code, it is stated that for the validity of the agreement four conditions are needed, namely: agreeing those who bind themselves, the ability to make an agreement, a certain thing and a cause lawful. With the fulfillment of the specified conditions, according to Article 1338 of the Civil Code, it is stated that all agreements made legally apply as law for those who make them.

According to the Regulation of the Minister of Health Number 36 of 2012 it can be seen that the approval to take medical action can be made in written form or orally. The obligation to give written approval for medical actions that have a high risk is regulated in the Regulation of the Minister of Health Number 36 of 2012 namely: "Every medical action that contains a high risk must be with a written agreement signed by the person entitled to give consent".

Approval of medical actions against patients who do in written form (*Written Consent*) must have a form that has been standardized. This is in accordance with what is required by the legal regulations that govern it, namely the Regulation of the Minister of Health Number 36 of 2012 in Article 3 paragraph (1); "That every medical action that contains a high risk must be with a written agreement signed by the person who has the right to give consent. Medical action is one of the medical actions that can directly affect the integrity of body tissues and contains a high risk, so *Informed Consent* of all medical actions must be done in written form and this must be done by the Hospital.

The method of conveying information must be in accordance with the patient's level of knowledge. A doctor must take care that the explanation given does not cause fear, and conversely the doctor must not lie to the patient so that he will give his consent. If the patient is experiencing fear or shock, in this case the information must be given to the next of kin.

In such a situation, the patient does have the right. The right of a patient to waive his right to obtain information or refuse to be given information and refuse to make his own decisions. The legal regulations also regulate this condition in Ministerial Regulation Number 36 of 2012 concerning Approval of Medical Actions in Article 4, namely:

1. Information about medical actions must be given to patients, whether requested or not.
2. Doctors must provide complete information, except when the doctor considers that the information can harm the health interests of the patient or the patient refuses to be given information.
3. In cases as referred to in paragraph (2), the doctor in the patient's consent can provide the information to the closest family accompanied by a nurse/other medics as a witness.

In this case the patient has the right, this right is contained in Article 4 paragraph (2) of the Regulation of the Minister of Health Number 36 of 2012 concerning Approval of Medical Action which states "Doctors must provide complete information, except if the doctor considers that the information may harm health interests. patient refuses to be given information.

So if the information conveyed by the doctor has explained the risks and the patient has received an explanation and has understood and then signed it and the actions taken have met ethical and professional standards, then a risk arises that is unexpected, then the doctor should be released from prosecution.

If then the patient or the patient's family who has been given the information refuses to take medical action, the patient is asked to sign a letter of refusal of medical action whose content format is exactly the same as the format of the medical action approval letter. In the treatment process, if the patient and his family have given consent for medical treatment, the doctor is not justified in severing the relationship unilaterally, before the therapeutic relationship ends.

Doctors have a moral obligation to remind patients of the importance of continuing treatment to another doctor or hospital and to submit important notes to patients so that they can be forwarded to a new doctor or hospital. This note is important for the substitute doctor to avoid re-examination that requires a lot of time and money and to avoid administering drugs that are ineffective or even can cause anaphylactic reactions.

The patient's uncooperative attitude or resistance to the only possible therapeutic method can indeed be considered as an opportunity that can be used by the doctor to unilaterally terminate the legal relationship, but the patient's condition and the opportunity to obtain a substitute doctor or hospital must be taken into consideration. Before a replacement doctor or hospital is obtained, the doctor or hospital still has the obligation to treat.

Medical engagement that is born from a medical agreement is a reciprocal legal relationship. As a reciprocal legal relationship, a medical agreement always has two aspects which contain rights on the one hand and obligations on the other. In other words, the rights of the first party are the obligations of the second party and vice versa the obligations of the first party are the rights of the second party. Likewise, the legal relationship between doctors and their patients also has rights and obligations.

It has been discussed that prior to any medical action, the patient's consent is required. Why a patient is required to give that consent; such as an operation. When viewed from the criminal aspect, this can be related to Article 351 of the Criminal Code concerning persecution. If someone stabs a knife into another person's body causing a wound, this is abuse. If someone drugged another, this too was abuse. If the person who drugged it happened to be a doctor, then the act was still persecution (Soewono, 2006) [20].

These actions do not constitute persecution according to the Criminal Law, if (PAF & Lamintang, 2012) [14];

a. The injured person gives consent;
b. The medical action is based on a medical indication, and is aimed at a concrete goal; and the
c. Medical action is carried out according to medical science.

The injured person gives consent, it has been stated that the obligation to give consent is required by providing prior information. It has also been explained that only in certain circumstances, such consent is not required, for example the patient is unable to express his wish or in an emergency. In

the latter case, it does not matter which theory will be used, namely with regard to the issue of whether the medical action constitutes an abuse or not, especially about how the action should not be included in the definition. If an agreement generally does not justify a deviation from professional medical standards, then only in one case can the existence of an agreement make a medical action that is not indicated a justifiable action, namely if the action is not ethically prohibited.

The medical action is based on a medical indication, and is aimed at a concrete goal, which means that medical care in accordance with applicable medical professional standards, must be aimed at the goals of medical science. It must also be ethically justified. Furthermore, the method used must be in accordance with the objectives to be achieved, the instruments used are indeed necessary, and there is a balance between the methods used and the objectives to be achieved. Instrumental use is considered non-existent, for example: if a serious medical action has been applied to a mild feeling of pain; if an unnecessary medical action is taken; if the patient has not been given adequate amounts of "pain relief" and so on. A treatment that cannot be accounted for instrumentally or according to that purpose should qualify as abuse. As an exception it can happen that for a patient there is a difference between goals and services, for example in human trials, but if people want that action cannot be called an act that is materially against the law, then the action must comply with the law. Conditions for an experiment.

The medical action is carried out according to medical science, the problem in this case is related to the accuracy of carrying out medical actions, both at the time of conducting an examination to make a diagnosis and during therapy, and with regard to the accuracy of providing pain prevention facilities and providing services.

The loss of a person's life due to negligence by a doctor is a very important issue to be studied and researched. However, the occurrence of unwanted events in medical actions carried out by doctors is not necessarily caused by negligence by doctors. Doctors and other medical personnel are ordinary people who are full of limitations in carrying out their duties full of risks, because the possibility of a patient dying after being treated by a doctor can occur, even though the doctor has carried out his duties according to standard operating procedures (SOP). This situation should be called a medical risk and this risk is sometimes interpreted by parties outside the medical profession as *medical malpractice*. (Machmud, 2008) [9].

Conclusion

Refusal of medical action by the patient after obtaining the explanation stated in the *informed consent is* considered as an effort by the doctor to prove his sincerity in complying with *primum non nocere*, professional standards, service standards and the principle of prioritizing the interests of patients. Thus, even though the patient is factually dead, if no element of 'severe negligence' is found, the status remains as *onrechtmatige daad*, therefore*legal action*that can be taken against doctors is a*civil action for damages*. The position of *informed consent is* very strong as evidence in the trial to be able to acquit doctors in all lawsuits.

It is necessary to revise the Regulation of the Minister of Health Number 290 of 2008 concerning Approval of Medical Actions, which does not explicitly and clearly state the age limit and ability of a person to give consent for medical treatment and also regarding the refusal of medical treatment.

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