

DISCOURSE OF INFORMED CONSENT IN THE APPLICATION OF CARDIAC SURGERY TECHNIQUES IN INDONESIA

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Abstract

Informed Consent is an important thing in medical services, recently there have been cases of problems that start from the incompatibility of Informed Consent with factual actions carried out by the hospital. This has been explained in Jo Law No. 44 of 2009 concerning hospitals Article 37 paragraph 1 which states that every medical action taken in the hospital must obtain the consent of the patient and his family. The purpose of this article is to analyze the Informed Consent Relationship between Doctors and Patients Legally in the Application of Cardiac Surgery Techniques in Indonesia and to analyze the Application of Informed Consent in the Application of Cardiac Surgery Techniques. The method used in this research is the normative juridical method. The normative juridical approach is carried out by conducting a study of the principles, regulations and legislation in force with regard to the legal issues to be discussed. The results of this study are the existence of an informed consent relationship between doctors and patients and the application of informed consent in heart surgery in Indonesia.

Keywords: Doctor, Informed Consent, Patient

A. Introduction

Health Law covers all regulation related laws in a way direct with maintenance and provision service health. This involve rights and responsibilities answer recipient service health, good individual nor group society, as well maintenance service health and various aspect other. Giving service health done For treat the disease suffered by the patient, and in the treatment process This involve various parties, incl House Sick (Rikomah, Setya Enti, 2017)

House Sick is A institution service health sector focused society health. Law no. 44 of 2009 concerning House Sick explain that House Sick is institution service health that provides service comprehensive health, incl _ maintenance stay in, take care of road, and it's serious emergency (Koto, Ismail, and Erwin Asmadi, 2021). In context service medical, home Sick it's not entity that is direct give action medical; rather, action medical administered by a doctor appointed by the house Sick. Service process medical This often called as transaction therapeutic (Mahila, Sharifa, 2018). Connection between doctor and patient in transaction therapeutic This is based on two aspect right basic man. Right For determine fate Alone (*The Right to self determination*) Right on information (*The Right to Information*). With second right base the, doctor and patient together find the most appropriate therapy that would be used.

Because in the relationship between doctor and patient, the patient's position is equal to the doctor. Even the patient's status in medical science is no longer as an object, but assubjects who have the same status as doctors. Therefore before attempting healing is carried out, it requires Informed Consent. Based on Law no. 29 Year 2004 about Practice Medical, there is a number of principle Which must There isrelated with *Informed Consent* the, that is:

1. Every Action medical must get agreement patient .
2. Agreement given after patient get explanation in a way complete .

Explanation the at least includes , Diagnosis and procedures follow medical , Purpose of medical action taken , Alternative actions and their risks , Risk And complications Which Possible occur , Prognosis to Action Which done , Approval can given Good in a way written nor verbal , Every Medical procedures that involve pregnancy risk tall must given with agreement written Which signed by Which entitled give agreement .

Informed Consent is an important thing in medical services, these days There are cases of problems that start from non-compliance with *Informed Information Consent* with factual actions taken by the hospital (Mustikasari, 2023). This has been explained in Juncto . Act No. 44 year 2009 about House Sick chapter 37 paragraph 1 Which States that every medical procedure carried out in a hospital must be get patient and family consent.

Informed Consent is agreement provided by the patient or family nearest after get explanation in a way complete about action medical or medical tooth Which will done to patient. *Informed Consent* or agreement action medical in Indonesia arranged in a number of regulation legislation, including Law Number 29 of 2004, concerning Practice Medical, Constitution Number 17 Year 2023 about Health, Regulation of the Minister of Health of the

Republic of Indonesia 290/ Menkes /PER/III/2008 concerning Accept medical action goals . In Jo . Law Number 17 of 20 23 About Health in Chapter 2 mentioned that development health held with based humanity, keseimbangan, benefit, protection, respect to right And obligation, justice, gender And non-discriminatory and norms religion.

Whereas in Chapter 3 mentioned development health aim For increase awareness, will and ability to live healthily for everyone so that realizing the highest degree of public health, as an investment for development source Power man Which productive in a way social And economical. Validity law is rule law Which has applies, real And Certain.

Legal validity in Indonesia means that it has been stated in a written rule such as statutory rules, government regulations, circulars and several rule other written laws (Ayurini, dkk, 2023). Law present in society is to integrate and coordinate interests Which contradictory One The same other. Coordination interest done with method limit And protect interests the. Law must give protection to all party in accordance with their legal status because everyone has the same position in front of law. Apparatus enforcer law must straighten up law And with the function of legal rules, then indirectly also the law or all aspects in Community life is regulated by law.

In conveying *Informed Consent* The explanation given by the doctor to The patient must be complete and clear regarding the diagnosis, procedures for medical treatment, goals the procedure carried out, treatment alternatives, risks, possible complications happen (Gosal, dkk, 2024). So if the presentation of approval for medical treatment is incomplete can be classified as an unlawful act because it does not comply with the procedures delivery information medical Which

Correct. Validity action medical in should be in accordance with Standard Operating Procedures (SOP) in the service sector health as regulated in the Regulation of the Minister of Health of the Republic of Indonesia Number 1438/Menkes/PER/IX/2010 about Standard Service Medical. Objective made Standard Procedure Operational (SPO) that is so that various process Work Which routine carried out efficiently, effectively, uniformly and safely in order to improve quality service through standards Which applies.

The Normative Juridical Approach is carried out by conducting a study of principles, regulations And regulation legislation Which applies Which regarding with legal issues to be discussed. Data collection which is used in This research includes writing carried out in 2 (two) ways, namely Primary Data and Secondary Data. Studies Literature is collection procedures data with how to search, read, study, understand and cite various literaturerelate with problem Which discussed in study This, form regulation legislation Which applies, books law, article, journals, jurisprudence and strong court decisions law remains and also materials other laws. The data collected and processed above can be analyzed with method descriptive analytical, that is intended For describe and analyze data Which obtained from research results .

B. Discussion

1. Connection *Informed Consent* Doctor And Patient By Law On Implementation Technique Operation Heart in Indonesia

Along increasing service health and care medical , role law becomes very important. Service health can realized through various approach like promotion, prevention, treatment and rehabilitation , good For individual nor community in public in a way whole (Suntana, William, 2022) .This matter arranged in Constitution Number 17 of 2023, Article 52, which is related with field health. Progress knowledge knowledge and technology in the field health has push achievement health optimal society . By Simultaneously , practitioners health, especially doctor, have potency big in face issues emerging law connection with action their medical do in operate his profession . Use technique surgery heart latest or even those who haven't Once used previously in a House Sick can become source problem If patient No own alternative other .

One of frequent problem appear is caused by differences in perception between explanation given by the doctor , hope patient , and the reality of what happened (Pratama, dkk, 2022). Especially when results from application technique new cause loss or death patients , especially in operation with risk tall . In framework this , agreement action medical or " *Informed Consent* " becomes very important in every action medical . Based on right basic , every patient own right For know procedure care will be they live it , incl necessary risk they not quite enough as consequence from method maintenance certain. Patients also have right For know is There is other possible alternatives there are , incl the risk .

A number of expert opinion that patient own right For know related information with action medical , incl factors related social. Draft This often called as *Informed Consent* or agreement after get information complete . *Informed Consent* This Can given in a way oral or written by the patient after doctor give explanation detailed about action medical information , associated risks , and other relevant information . Patient or his family own right For decide is they will accept or reject action medical This with method sign form agreement information .

Give information in form *Informed Consent* is obligation doctor . However , in situation certain , doctor can divert authority This to power other health , however still responsible answer in a way law . From perspective the law , actually nurse No own authority For carry out the *Informed Consent* process (Purwandi, Agustri, 2019). Task This is not quite enough answer doctor , and if There is delegation authority , doctor must ensure that given nurse task truly competent in field that and is capable give explanation that the patient understands . Therefore that , in fact law , bear it answer related *Informed Consent* still be with a doctor .

Informed Consent is consent given by the patient and/ or his family after accept explanation about action medical will done to patient (as appropriate with Article 1a Regulation of the Ministry of Health of the Republic of Indonesia No. 585 of the Year 1989). Medical treatment This covers Good action diagnostic nor therapeutic . Right patient For accept information and rights For own control on his fate Alone is two right base as humans strengthened by *Informed Consent* , which becomes condition subjective in the process of action medical . Doctor running action medical without agreement from patient or his family will violate law , and he will responsible answer on all possible risks arise consequence action.

Relevant patients own right full For give agreement or rejection to action medical . If the patient the is under guardian or guardianship , then *Informed Consent* can given to member family nearest like parents or you birth . However , in situation threatening emergency _ life patient , consent No required so that action medical can quick done For save life patient . After circumstances patient stable and possible , explanation and agreement medical can given . In case patient children , education medical can given to family or companion patient . However , if No There is member family present , *Informed Consent* can given to patient the child concerned . This matter Because children Not yet own ability For understand information medical delivered and for make decision best for self they Alone . So, deep case patients below guardian is a children , family nearest own right For give agreement after get information proper medical care .

Decision given can allow or reject action , even when patient has give agreement For action the patient Still own right For unplug consent and declare rejection in a way written when action will done . Article 16 regulates matter This . Therefore that , everything consequence from rejection the fully become not quite enough answer patient , accordingly with doctrine “ *Volenti nonFit Inuria* ” which is principle the law states that someone who with consciously and voluntarily , without compulsion , giving consent and be ready take risk , no can submit claim to injury or possible losses happen. As example , p This applies For patients returning home with forced after doctor explain all the risk in detail.

In service medical , one expert surgery heart initially will start interaction with patient through stage interview or anamnesis, which aims For delve into it history health patient as well as identify related factors with the operating process (Ampera, 2018) . The next step involve inspection physical , which is supported by tests diagnostic like radiology and analysis blood . Through steps that , doctor can make a diagnosis and plan appropriate handling For patient . Entire interaction between doctor and patient will noted in a way detailed in notes medical patient , accordingly with standard applicable medical , and all doctor own not quite enough answer full in take notes related results and decisions with maintenance patient .

In determine steps in practice surgeon , one doctor considered in accordance with applicable law If his actions fulfil criteria following :

- a. There are real clues in step medical For reach objective or specific results
- b. Medical measures applied obey applicable norms and ethics in field medical
- c. Before do the action in question , doctor must obtain agreement from patient , which is normal noted in a way written in form agreement information (*informed consent*).

Interaction process between doctor and patient in context therapy must carried out with careful and careful . A doctor surgery own not quite enough answer full For explain all aspect operations , incl considerations used in taking decisions , steps to be taken taken during the operation process , potential associated risks with procedures , as well plan post operation until patient recovered . Specifically , when doctor surgery will apply technique yet Once used before , risk error become more tall compared to with procedure already routine often done . Although so , if technique the considered as step critical in save patient , doctor own right For carry it out with agreement patient .

In the process of explanation about decision action that will taken , one expert surgery the heart is also expected For give clear and comprehensive education . This important Because part big the patient will undergo operation heart tend feel worried to every action invasive that will done , and p This can be one obstacle in reach agreement therapeutic . According to research conducted by Joanna and her colleagues , approximately 90% of patients will undergo operation experience worry before operation (yankes.kemkes.go.id/view_article/1202). Fear and anxiety This Of course can influence connection therapeutic between doctor and patient . Patient moment This own opportunity big For utilise right they in understand all over the procedure will be they go through . Connection between doctors and patients today different with connection paternalistic dominant in the past , where patients only follow decision doctor and undergo procedures that have been done planned .

Patient own right For request as well as accept as much Possible information before they make decision about action that will taken by a doctor (Citra Aditya Bakti, 2009). This No only beneficial For get details complete about what is possible happen during procedures , but also for understand level complexity action that , especially in field surgery heart . With so , though fair relationship between doctor and patient has intertwined , mutual awards among both of them still awake , and risk frequent dissatisfaction appear If the result No in accordance with what was expected can pressed .

Patient own chance For determine action that will they live it , incl look for opinion addition from doctor with the same specialization or different before make decision (Kristiawan, Ardityo Purdianto, 2021).Need For get opinion second , which is also known as *second opinion* , becomes very important when action planned medical own risk high , like operation heart . The same thing applies If action or therapy offered Still relatively new and have little support data available , either for doctor nor patient . In the process of searching *second opinion* , patient No need worry about injure feeling doctor main caretaker they moment This is because right For getting a second opinion is guaranteed by Law no. 44 of 2009 concerning House Sick . Through effective communication between doctor and patient , agreement therapeutic between both of them can intertwined in a way harmonious , creating impactful trust and optimism positive .

With intertwined effective communication between doctor and patient, appointment process therapeutic between both of them will become more conducive. This will create Trust and optimism are very important when face operation big like operation heart. A doctor surgery heart will feel more comfortable in do his task when patient give belief or not make it worry will possibility demands medical, esp remember risk very high operation. This is the end will give benefit for patient during the therapy process they.

2. Application Informed Consent in Application of Operational Techniques Surgery Heart

In the medical world, surgery heart Can considered as one of the most complex procedure. Besides that's surgery the heart also raises risk tall to disability and death, more tall compared to with discipline surgery other (Junaidi, Iskandar, 2011). Circumstances This demand level optimal performance isn't it only from the doctor did it surgery, but also requires Work The same from all over team medical personnel involved. Sometimes, one expert surgery heart can faced with a very complicated case that requires adoption or use technique suitable new one For guard well-being patient. Therefore that, approval absolute from the patient is very important in matter This.

In the Surgical Unit The Heart of Our Hope Child, which is House Sick reference leading in field service surgery heart in Indonesia, has apply Lots innovation in technique operation heart. Connection between doctor and patient started since patient register yourself at home Sick This. Abnormalities heart experienced by a person need various examination and analysis. During this process, the patient and his family join in as well as in team preparation purposeful operation reach success procedure the. Each stage preparation operation done as good as maybe, and if There is problem, doctor will give guide For action corrective To use ensure preparation operation become complete and perfect.

Preparation process prolonged surgery, patients and their families often interact with the doctor who treated him. Regardless from preference personal, relationship This create strong bond. With involve patients and their families, all information about patient can accessible to them Alone. Patients and their families always get information about condition his health and the procedures to be carried out carried out, so they can more Ready. This is commitment a doctor For try maximum maybe for healing patients, incl adopt technique new in operation. Therefore that's important For guard honor This through A Strong *Informed Consent*, which in turn will create justice in profession medical. In context Indonesian culture is based on faith to Almighty God Yes, we are understanding that effort medical best Possible No always succeed If That No will Lord. During doctor operate action in accordance standard profession medical, this show fulfillment obligation they. In situation This is a risk possible medical happen must accepted by the patient as part from treatment that is not involve error medical. Therefore _ that's important *Informed Consent* written in the planning process maintenance medical always emphasized.

This matter in accordance with view from Soejatmiko, where when do procedure medical without get agreement action medical from patient. This can increase risk demands malpractice criminal Because negligence and lack understanding patient about What will happened to him (Divine, Wahyu Rizki Kartika, 2018). In effort make it easier delivery information This is available various method like brochures, explanatory videos, or meeting direct with staff consultant at Harapan Kita.

Information important This start spread in a way gradually to patients and their families. Although patient has understand various possible risks happens , still required for doctor For give explanation and get agreement before operate action medical . This is provisions that have been determined by Harapan Kita management . Problem malpractice is moderate issue widespread moment This . Indonesia, knowledge and understanding public about technique operation still very limited . However , society own high hopes related recovery from procedure This . Gaps between level knowledge and hope This can produce misunderstanding If No overcome through giving good information through *informed consent*.

Although Thus , *Informed Consent* it's not guarantee safety absolute in solution conflict between doctor and patient . Although procedures *Informed Consent* has implemented , conflict between doctor and patient Still can appeared , esp when results therapy No in accordance with hope patients and their families . Through *Informed Consent* , patient given complete information , possible they For make decision about step treatment next will be influence fate they . In context this , *Informed Consent* own role double , useful Good for doctor nor patient That Alone . With *Informed Consent* , doctor own obligation For obtain agreement patient with explain the procedure will be done in a way detailed and comprehensive . There is reference about obligation this is what can be done used as base theoretical For obtain agreement patient , that is as following :

- a. *Informed Consent* must give more benefits wide than only For patient That Alone . This is also purposeful For give readiness to all parties involved in maintenance patients , and also for give trust to doctor For Work without worry will demands law from patient.
- b. *Informed Consent* required patient try understand useful information related with plan treatment that has been prepared by a doctor
- c. *Informed Consent* give ability for patient For make decision in a way independent without exists pressure from party anywhere .

Informed Consent own more relevance wide than simply become condition written . This covers aspect protection for second split parties , esp patients and doctors . Therefore that , doctor own obligation For ensure completeness of this process from beginning . With exists *Informed Consent* is to be base action a doctor , hopefully intertwined connection harmonious doctor -patient in the therapy process . However , after achieved agreement , factor important other is safety patient .

Principle '*do no harm*' which is part from oath Hippocrates become guidelines important (Suryadi, dkk, 2009). This means that a doctor own not quite enough answer For give maintenance medical provider more benefits big than risk injury or possible losses arise from action the . This matter often become issue important , esp in case undergoing patients operation heart , especially If the condition not optimal. Doctor surgery heart must consider principle This with careful and explain with clear to patients and their families about risks and benefits every step action that will taken . It's also important to noted that safety patient regulated by Law No.44 of 2009 concerning House Sickness in Indonesia. According to provision law that , home Sick required give protection fully to patient , with safety patient as principle main in maintenance service health at home Sick the . Besides that , home Sick must capable give guarantee law and protection to patient . House ill also have not quite enough answer For fulfil all condition *Informed Consent* as part important in guard safety patient .

Informed Consent is mandatory be delivered in a way written with sign hand from patients and families / guardians , as well documented in notes medical . If requirements *Informed Consent* No filled , home Sick entitled enforce penalty administrative to treating doctor patient .

Error medical , an incident that is not desired , and event almost is type regulated incident in Constitution . If incident sort of That happens , home Sick own obligation For quick report incident the to committee safety patient . Reporting must done in a way anonymous so you can give input and corrections to system House Sick To use increase safety patient . Standard safety the patient is also regulated in regulation minister .

In case application technique operation heart , a doctor must consider with carefully potency risks and benefits from action that will done . Doctor must explain all related aspects _ with risk action , start from the worst until possibility success operation . Therefore _ that , with apply Appropriate *Informed Consent* , while still prioritize safety patient , one doctor can avoid practice medical that is not in accordance or detrimental negligence _ patient .

C. Closing

In implementation technique operation surgery heart , important very For apply Comprehensive and understood *Informed Consent* with Good . *Informed Consent* This must made in a way written and signed by the patient or his family , then saved in record medical House Sick . Based on the Decree of the Minister of Health No.436/Menkes/SK/VI/1993 concerning Standard Home Services Sick , home pain too responsible answer if Informed Consent is not provided done with correct and complete . Failure in get *Informed Consent* For action medical can result penalty administrative , like unplug permission practice the doctor concerned . Signing *Informed Consent* show that the signing party (okay patient nor his family) has understand , realize , and accept all action that will carried out by the doctor concerned , along with possible risks arise consequence action the .

Bibliography

- Astuti, Endang Kusuma, and M. SH. *Therapeutic Transactions in medical service efforts in hospitals* . Citra Aditya Bakti, 2009.
- Ampera, Ampera. "The hospital's responsibility towards patients in the implementation of health services." *Al-Ishlah: Legal Scientific Journal* 21, no. 2 (2018): 59-74.
- Ayurini, Safira Lia, and Muhammad Faiz Mufidi. "Legal Responsibility for Medical Services Based on Informed Consent Post-Surgery at Hospital In *Bandung Conference Series: Law Studies* , vol. 3, no. 1, pp. 684-689. 2023.
- Gosal, Vini HR, Aaltje E. Manampiring, and Caecilia Waha. "The professional behavior of medical personnel regarding ethical responsibilities and therapeutic transactions in carrying out clinical authority." *Medical Scope Journal* 4, no. 1 (2022): 1-9.
- Divine, Wahyu Rizki Kartika. "Medical risks and medical negligence in the aspect of criminal liability." *Volkgeist Law Journal* 2, no. 2 (2018): 170-186.

- Junaidi, Iskandar. *Stroke, be aware of the threat* . Andi Publisher, 2011.
- Koto, Ismail, and Erwin Asmadi. "Legal Liability for Malpractice Actions by Medical Personnel in Hospitals." *Volksgeist: Journal of Legal and Constitutional Studies* (2021): 181-192.
- Kristiawan, Ardityo Purdianto. "The Legal Position of Informed Consent in Fulfilling Patient Rights in Hospitals." *Scientific Journal of Law and Community Dynamics* 19, no. 1 (2021): 1-15.
- Mahila, Sharifa. "Civil Aspects of Therapeutic Transactions in the Legal Relationship Between Doctors and Patients." *Batanghari University Jambi Scientific Journal* 11, no. 1 (2018): 61-69.
- Mustikasari, Aidha Puteri. "Informed Consent and Medical Records in Telemedicine in Indonesia." *Journal of Law and Economic Development* 8, no. 2 (2021): 89. <https://doi.org/10.20961/hpe.v8i2.49759>.
- Pratama, Mohammad Alvi, Ahnav Bil Aufaq, and Rr Yudiswara Ayu Permatasari. "Optimizing the Informed Consent Paradigm from to Disclose to Understand as Respect for Individual Autonomy." *Journal of Health Research" Forikes Voice"* 13, no. 4 (2022): 1011-1016.
- Purwandi, Agustri. "Legal Force of Transfer of Medical Authority and Infoconsent by Doctors to Nurses Based on Law Number 38 of 2014 concerning Nursing." *Yustitia Journal* 20, no. 1 (2019).
- Rikomah, Setya Enti. *Hospital Pharmacy* . Deepublish, 2017.
- Suntana, William. "Study of Informed Consent (Consent to Medical Actions) According to Law No. 36 of 2009 concerning Health." *Lex Privatum* 5, no. 5 (2017).
- Suryadi, Taufik, and Bioethics Team. "Ethical and legal principles in the medical profession." *V JBHKI 13th National Meeting* (2009).
- [https://yankes.kemkes.go.id/view_article/1202/bayar-studi-terkait-seft-spiritual-emotional freedom-technique-dalam-menurunkan-kecemasan-patient-prior-operation](https://yankes.kemkes.go.id/view_article/1202/bayar-studi-terkait-seft-spiritual-emotional-freedom-technique-dalam-menurunkan-kecemasan-patient-prior-operation) , accessed on 05 October 2023, 11.30 WIB