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Discourse on the Application of Cardiac Surgery Techniques in Indonesia and Consent for Medical Actions in Health Law

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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 cardiac surgery in Indonesia.

Keywords: Dokter, Informed Consent, Pasien

Introduction

Health Law covers all legal regulations directly related to the maintenance and provision of health services. It involves the rights and responsibilities of health service recipients, both individuals and community groups, as well as the organization of health services and various other aspects. The provision of health services is carried out to treat the illness suffered by the patient, and in this treatment process involves various parties, including hospitals. Health law is a field of law that regulates various aspects related to public health, health services, and rights and obligations in a medical context. It encompasses various regulations related to the provision of health services, including licensing of medical personnel, standards of medical services, patient protection, and regulation of drugs and medical devices. Health law aims to ensure that health services are provided safely, effectively, and fairly, and to protect the rights of individuals in receiving medical care.

One important aspect of health law is the protection of patients' rights. These rights include the right to clear and complete information regarding their health condition, available treatment options, and the risks and benefits of any medical procedure. Patients are also entitled to privacy and confidentiality of their medical information. In the event of a violation of these rights, health law provides mechanisms for enforcement and dispute resolution, either through the courts or other dispute resolution institutions.

A hospital is a public health service institution that focuses on the health sector. Law No. 44 of 2009 on Hospitals explains that a hospital is a health care institution that provides comprehensive health services, including inpatient, outpatient, and emergency care.² In the context of medical services, hospitals are not entities that directly provide medical actions; instead, medical actions are provided by doctors appointed by the hospital. This medical service process is often referred to as a therapeutic transaction.³ The relationship between

¹ Rikomah, Setya Enti. Farmasi Rumah Sakit. Deepublish, 2017.

² Koto, Ismail, and Erwin Asmadi. "Pertanggungjawaban Hukum Terhadap Tindakan Malpraktik Tenaga Medis di Rumah Sakit." Volksgeist: Jurnal Ilmu Hukum dan Konstitusi (2021): 181-192

³ Mahila, Syarifa. "Aspek Perdata Transaksi Terapeutik Dalam Hubungan Hukum Antara Dokter Dengan Pasien." *Jurnal Ilmiah Universitas Batanghari Jambi* 11, no. 1 (2018): 61-69.

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doctors and patients in this therapeutic transaction is based on two aspects of human rights.

- 1. The right to self-determination.
- 2. The right to information. With these two basic rights, doctors and patients together find the most appropriate therapy that will 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 as a subject who is equal to the doctor. Therefore, before healing efforts are made, Informed Consent is required. Based on Law No. 29 of 2004 concerning Medical Practice, there are several principles that must exist with regard to Informed Consent, namely:

- 1. Every medical procedure must have the patient's consent.
- 2. Consent is given after the patient has received a complete explanation.

The explanation at least includes, Diagnosis and medical procedures, Purpose of the medical action performed, Alternative actions and their risks, Risks and complications that may occur, Prognosis of the action performed, Consent can be given either in writing or orally, Every medical action that contains high risk must be given with written consent signed by those entitled to give consent. Informed Consent is an important thing in medical services, recently there have been cases of problems that start from the mismatch of Informed Consent with factual actions taken by the hospital.⁴ This has been explained in Juncto. Law No. 44 of 2009 concerning hospitals article 37 paragraph 1 which states that every medical action performed in a hospital must obtain the consent of the patient and his family.

Informed Consent is an agreement given by the patient or next of kin after receiving a complete explanation of the medical or dental treatment that will be performed on the patient. Informed Consent or approval of medical action in Indonesia is regulated in several laws and regulations, including Law Number 29 of 2004, concerning Medical Practice, Law Number 36 of 2009 concerning Health, Regulation of the Minister of Health of the Republic of Indonesia 290 / Men kes / PER / III / 2008 concerning Approval of Medical Action. Law

⁴ Mustikasari, "Informed Consent Dan Rekam Medis Dalam Telemedicine Di Indonesia."

Number 36 of 2009 Concerning Health in Article 2 states that health development is organized based on humanity, balance, benefits, protection, respect for rights and obligations, justice, gender and nondiscrimination and religious norms. Meanwhile, Article 3 states that health development aims to increase awareness, willingness, and ability to live healthy for everyone in order to realize the highest degree of public health, as an investment for the development of socially and economically productive human resources. Legal validity is a legal rule that has been valid, real and certain.

The validity of law in Indonesia means that it has been outlined in a written rule such as laws, government regulations, circulars and several other written legal rules.⁵ Law is present in society to integrate and coordinate interests that conflict with each other. Coordinating interests is done by limiting and protecting these interests. The law must provide protection to all parties in accordance with their legal status because everyone has the same position before the law. Law enforcement officers are obliged to enforce the law and with the functioning of the rule of law, then indirectly the law or all aspects of community life are regulated by law.

In the delivery of Informed Consent, the explanation given by the doctor to the patient must be complete, clear regarding the diagnosis, procedure for medical action, the purpose of the action, alternative treatment, risks, complications that may occur.⁶ So if it is incomplete in the exposure of medical action approval, it can be classified as a tort because it is not in accordance with the correct procedure for conveying medical information. The validity of medical actions should be in accordance with the Standard Operating Procedures (SPO) in the field of health services as stipulated in the Regulation of the Minister of Health of the Republic of Indonesia Number 1438/Menkes/PER/IX/2010 concerning Medical Service Standards. The purpose of making Standard Operating Procedures (SPO) is so that various routine work processes are

⁵ Ayurini, Safira Lia, and Muhammad Faiz Mufidi. "Pertanggungjawaban Hukum Layanan Medis Berdasarkan Informed Consent Pasca Tindakan Operasi di Rumah Sakit X Jakarta Ditinjau Dari Undang-Undang Nomor 29 Tahun 2004 Tentang Praktik Kedokteran." In *Bandung Conference Series: Law Studies*, vol. 3, no. 1, pp. 684-689. 2023.

⁶ Gosal, Vini HR, Aaltje E. Manampiring, and Caecilia Waha. "Perilaku profesional tenaga medis terhadap tanggung jawab etik dan transaksi terapeutik dalam menjalankan kewenangan klinis." *Medical Scope Journal* 4, no. 1 (2022): 1-9.

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carried out efficiently, effectively, uniformly and safely in order to improve service quality through applicable standards.

Research Methods

The Normative Juridical Approach is carried out by conducting a study of the principles, regulations and legislation in force relating to the legal issues to be discussed. Data collection used in this research includes this writing is done in 2 (two) ways, namely Primary Data and Secondary Data. Literature Study is a procedure for collecting data by searching, reading, studying, understanding and quoting various literature related to the issues discussed in this study, in the form of applicable laws and regulations, law books, articles, journals, jurisprudence and court decisions that have permanent legal force and also other legal materials. The data collected and processed above can be analyzed in a descriptive analytical way, which is intended to describe and analyze the data obtained from the research results.

Discussion

1. The Relationship between Informed Consent of Doctors and Patients in the Application of Cardiac Surgery Techniques in Indonesia

As health services and medical care increase, the role of the law becomes very important. Health services can be realized through various approaches such as promotion, prevention, treatment, and rehabilitation, both for individuals and communities within society as a whole. This is regulated in Law No. 17 of 2023, Article 52, which deals with the health sector. Advances in science and technology in the health sector have encouraged the achievement of optimal public health. At the same time, health practitioners, especially doctors, have great potential to face legal issues that arise in connection with the medical actions they take in the course of their profession. The use of the latest or even unprecedented heart surgery techniques in a hospital can be a source of problems if the patient has no other alternative.

⁷ Suntana, William. "Kajian Tentang Informed Concent (Persetujuan Tindakan Medik) Menurut Uu No. 36 Tahun 2009 Tentang Kesehatan." *Lex Privatum* 5, no. 5 (2017).

One of the problems that often arise is caused by the difference in perception between the explanation given by the doctor, the patient's expectations, and the reality that occurs.⁸ Especially when the outcome of the application of a new technique leads to patient harm or death, especially in high-risk surgeries. In this framework, informed consent becomes very important in every medical procedure. Based on human rights, every patient has the right to know the treatment procedures they will undergo, including the risks they have to bear as a result of certain treatment methods. Patients also have the right to know if any other alternatives may exist, including the risks. Some experts argue that patients have the right to know information relating to medical treatment, including the social factors involved. This concept is often referred to as informed consent. Informed consent can be given verbally or in writing by the patient after the doctor provides a detailed explanation of the medical procedure, associated risks, and other relevant information. The patient or his/her family has the right to decide whether to accept or reject the medical treatment by signing the informed consent form.

Providing information in the form of Informed Consent is the doctor's obligation. However, in certain situations, doctors can transfer this authority to other health workers, but are still legally responsible. From a legal perspective, nurses do not actually have the authority to carry out the Informed Consent process.⁹ This task is the responsibility of the doctor, and if there is a delegation of authority, the doctor must ensure that the nurse assigned to the task is truly competent in the field and able to provide explanations that are understood by the patient. Therefore, legally, the responsibility for informed consent remains with the doctor.

Informed Consent is the consent given by the patient and/or his/her family after receiving an explanation of the medical action that will be performed on the patient (in accordance with Article 1a of the Regulation of the Ministry of

⁸ Pratama, Mohammad Alvi, Ahnav Bil Aufaq, and Rr Yudiswara Ayu Permatasari. "Optimalisasi Paradigma Informed Consent dari to Disclose Menuju to Understand Sebagai Penghormatan Individual Autonomy." *Jurnal Penelitian Kesehatan" SUARA FORIKES" (Journal of Health Research" Forikes Voice")* 13, no. 4 (2022): 1011-1016.

⁹ Purwandi, Agustri. "Kekuatan Hukum Penyerahan Wewenang Medis dan Infoconsent Oleh Dokter Kepada Perawat Berdasarkan Undang-Undang Nomor 38 Tahun 2014 tentang Keperawatan." *Jurnal Yustitia* 20, no. 1 (2019).

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Health of the Republic of Indonesia No.585 of 1989). This medical action includes both diagnostic and therapeutic actions. The patient's right to receive information and his/her right to have control over his/her own fate are two basic human rights that are reinforced by Informed Consent, which is a subjective requirement in the process of medical action. A doctor who performs a medical procedure without the consent of the patient or his/her family will be violating the law, and he/she will be liable for all risks that may arise from the procedure.

The relevant patient has the full right to give consent or refusal to medical treatment. If the patient is under guardianship or trusteeship, then Informed Consent can be given to the next of kin such as parents or siblings. However, in emergency situations that threaten the patient's life, consent is not required so that medical action can be taken immediately to save the patient's life. Once the patient's condition is stabilized and possible, medical explanation and consent can be given. In the case of pediatric patients, medical education can be provided to the patient's family or companion. However, if no family members are present, Informed Consent can be given to the pediatric patient in question. This is because children do not have the ability to understand the medical information presented and to make the best decision for themselves. Thus, in case the patient under guardianship is a child, the next of kin has the right to give consent after obtaining appropriate medical information.

The decision given may authorize or refuse the action, even when the patient has given consent for the action, the patient still has the right to revoke the consent and express refusal in writing when the action is about to be performed. Article 16 regulates this. Therefore, any consequences of such refusal are entirely the responsibility of the patient, in accordance with the doctrine of "Volenti nonFit Inuria" which is a legal principle stating that a person who knowingly and voluntarily, without coercion, gives consent and is willing to take risks, cannot make a claim against any injury or loss that may occur. For example, this applies to a patient who goes home involuntarily after the doctor has explained all the risks in detail.

In medical care, a cardiac surgeon will initially start interacting with the patient through an interview or history taking stage, which aims to explore the patient's medical history as well as identify factors related to the surgical process. ¹⁰ The next step involves a physical examination, supported by diagnostic tests such as radiology and blood analysis. Through these steps, the doctor is able to establish a diagnosis and plan the appropriate treatment for the patient. All interactions between the doctor and the patient will be recorded in detail in the patient's medical record, in accordance with applicable medical standards, and all doctors have full responsibility in recording the results and decisions relating to the patient's care.

In determining the steps in surgical practice, a doctor is considered to be in compliance with the applicable law if his or her actions meet the following criteria:

- a. There is a clear direction in the medical steps to achieve a specific goal or outcome.
- b. The medical measures applied comply with the prevailing norms and ethics in the field of medicine.
- c. Before performing the intended action, the doctor must obtain consent from the patient, which is usually recorded in writing in the form of informed consent.

The process of interaction between doctor and patient in the context of therapy must be undertaken with care and caution. A surgeon has the full responsibility to explain all aspects of the surgery, including the considerations used in decision-making, the steps to be taken during the surgical process, the potential risks associated with the procedure, as well as the post-operative plan until the patient recovers. In particular, when the surgeon is about to apply a technique that has never been used before, the risk of error is higher compared to routine procedures that have been performed frequently. Nonetheless, if the technique is considered a critical step in saving the patient, the doctor has the right to perform it with the patient's consent.

In the process of explaining the decision, a heart surgeon is also expected to provide clear and thorough education. This is important because most patients

¹⁰ Ampera, Ampera. "Tanggung jawab rumah sakit terhadap pasien dalam pelaksanaan pelayanan kesehatan." *Al-Ishlah: Jurnal Ilmiah Hukum* 21, no. 2 (2018): 59-74.

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who will undergo heart surgery tend to feel anxious about every invasive action that will be taken, and this can be one of the obstacles in reaching therapeutic agreement. According to research conducted by Joanna and her colleagues, around 90% of patients who will undergo surgery experience preoperative anxiety. This fear and anxiety can certainly affect the therapeutic relationship between doctors and patients. Patients today have a great opportunity to utilize their right to understand the entire procedure they are going through. The relationship between doctors and patients today is different from the paternalistic relationship that was dominant in the past, where patients only follow the doctor's decision and undergo the planned procedure.

Patients have the right to request and receive as much information as possible before they make a decision regarding the action to be taken by the doctor. ¹² This is not only beneficial to get full details of what may happen during the procedure, but also to understand the level of complexity of the procedure, especially in the field of cardiac surgery. Thus, while an equitable relationship between doctor and patient has been established, mutual respect between the two is maintained, and the risk of dissatisfaction that often arises if the outcome is not as expected is minimized.

Patients have the opportunity to decide on their course of action, including seeking additional opinions from doctors of the same or different specialties before making a decision.¹³ The need to get a second opinion, also known as a second opinion, becomes especially important when the planned medical action has high risks, such as heart surgery. The same applies if the procedure or therapy being offered is relatively new and has little supporting data available to both the doctor and the patient. In the process of seeking a second opinion, patients need not worry about hurting the feelings of their current primary physician, as the right to a second opinion is guaranteed by Law No. 44 of 2009

¹¹ https://yankes.kemkes.go.id/view-artikel/1202/pandangan-studi-terkait-seft-spiritual-emotional-freedom-technique-dalam-menurunkan-kecemasan-pasien-sebelum-operasi, diakses pada 05 Oktober 2023, 11.30 Wib

¹² Astuti, Endang Kusuma, and M. SH. *Transaksi Terapeutik dalam upaya pelayanan medis di Rumah sakit.* Citra Aditya Bakti, 2009.

¹³ Kristiawan, Ardityo Purdianto. "Kedudukan Hukum Informed Consent Dalam Pemenuhan Hak Pasien di Rumah Sakit." *Jurnal Ilmiah Hukum Dan Dinamika Masyarakat* 19, no. 1 (2021): 1-15.

on Hospitals. Through effective communication between doctors and patients, the therapeutic agreement between the two can be established harmoniously, creating trust and optimism that has a positive impact.

With effective communication between doctor and patient, the therapeutic agreement process between the two will become more conducive. This will create trust and optimism which is crucial when facing a major surgery such as heart surgery. A cardiac surgeon will feel more comfortable in performing his or her duties when the patient confides in him or her and does not worry him or her about possible medical demands, especially considering the very high risks of the surgery. This will ultimately benefit the patient throughout their treatment process.

2. The Application of Cardiac Surgery Techniques in Indonesia and Consent for Medical Actions

In the medical world, heart surgery can be considered one of the most complex procedures. In addition, cardiac surgery also poses a high risk of disability and death, higher than any other surgical discipline.¹⁴ This situation demands an optimal level of performance not only from the doctor performing the surgery, but also requires the cooperation of the entire medical team involved. At times, a cardiac surgeon may be faced with very complicated cases that require the adoption or use of new techniques that are appropriate to safeguard the patient's well-being. Therefore, the absolute consent of the patient is crucial in this regard.

At Harapan Kita Pediatric Cardiac Surgery Unit, which is a leading referral hospital in the field of cardiac surgery services in Indonesia, has implemented many innovations in cardiac surgery techniques. The relationship between doctor and patient starts from the moment the patient registers at this hospital. The heart defect experienced by a person requires various examinations and analysis. During this process, the patient and his family participate in the surgery preparation team that aims to achieve a successful procedure. Each stage of the surgery preparation is done to the best of their ability, and if there are any problems, the doctor will provide guidance for corrective actions to ensure the surgery preparation is complete and flawless.

¹⁴ Junaidi, Iskandar. Stroke, waspadai ancamannya. Penerbit Andi, 2011.

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Due to the prolonged process of preparing for surgery, patients and their families often interact with their treating doctors. Regardless of personal preferences, this relationship creates a strong bond. By involving the patient and their family, all information about the patient is accessible to them alone. Patients and their families are kept informed about their health condition and upcoming procedures, so they can be better prepared. It is a doctor's commitment to do everything possible for the patient's recovery, including adopting new techniques in surgery. Therefore, it is important to maintain this honor through a strong Informed Consent, which in turn will create justice in the medical profession. In the context of Indonesian culture, which is based on belief in God Almighty, we understand that the best medical efforts may not always succeed if it is not God's will. As long as doctors carry out actions according to the standards of the medical profession, this demonstrates the fulfillment of their obligations. In this situation, any medical risks that may occur should be accepted by the patient as part of the treatment that does not involve medical error. Therefore, the importance of written Informed Consent in the medical treatment planning process is always emphasized.

This is in accordance with the view of Soejatmiko, where when performing medical procedures without obtaining informed consent from the patient, this may increase the risk of criminal malpractice claims due to negligence and the patient's lack of understanding of what will happen to them. ¹⁵ In an effort to facilitate the delivery of this information, various means are available such as brochures, explanatory videos, or direct meetings with consultant staff at Harapan Kita. This important information is gradually being disseminated to patients and their families. Even though patients understand the risks involved, it is still mandatory for doctors to provide explanations and obtain consent before carrying out medical procedures. This is a provision that has been set by Harapan Kita's management. Malpractice is an issue that is currently rife.

In Indonesia, the public's knowledge and understanding of surgical techniques is still very limited. However, people have high expectations regarding the recovery from these procedures. This gap between the level of knowledge and

¹⁵ Ilahi, Wahyu Rizki Kartika. "Resiko medis dan kelalaian medis dalam aspek pertanggungjawaban pidana." *Jurnal Hukum Volkgeist* 2, no. 2 (2018): 170-186.

expectations can result in misunderstandings if not addressed through the provision of good information through informed consent. However, informed consent is not an absolute guarantee of safety in resolving conflicts between doctors and patients. Although informed consent procedures have been implemented, conflicts between doctors and patients can still arise, especially when the outcome of therapy does not match the expectations of the patient and their family. Through informed consent, patients are provided with complete information, enabling them to make informed decisions about the next steps of treatment that will affect their fate. In this context, Informed Consent has a dual role, benefiting both the doctor and the patient themselves. With Informed Consent, the doctor has an obligation to obtain the patient's consent by explaining the procedure to be performed in detail and comprehensively. There are references to this obligation that can be used as a theoretical basis for obtaining patient consent, which are as follows:

- a. Informed Consent should provide broader benefits than just for the patient themselves. It also aims to provide readiness to all parties involved in the patient's care, and also to give doctors the confidence to work without worrying about lawsuits from patients.
- b. Informed Consent requires the patient to make an effort to understand useful information related to the treatment plan that has been prepared by the doctor.
- c. Informed Consent provides the ability for patients to make decisions independently without pressure from any party.

Informed Consent has a wider relevance than just being a written requirement. It encompasses aspects of protection for both parties, particularly the patient and the doctor. Therefore, doctors have an obligation to ensure the completeness of this process from the start. With Informed Consent being the basis of a doctor's actions, it is expected that a harmonious doctor-patient relationship will be established in the therapeutic process. However, once an agreement is reached, another important factor is patient safety.

The principle of 'do no harm', which is part of the Hippocratic oath, is an important guideline. This means that a doctor has a responsibility to provide

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¹⁶ Suryadi, Taufik, and Tim Bioetika. "Prinsip-prinsip etika dan hukum dalam profesi kedokteran." *Pertemuan Nasional V JBHKI* 13 (2009).

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medical care that provides benefits that outweigh the risk of injury or harm that may arise from the action. This is often an important issue, especially in the case of patients undergoing cardiac surgery, especially if their condition is not optimal. Cardiac surgeons should carefully consider this principle and clearly explain to the patient and his or her family the risks and benefits of each action step to be taken. It is also important to note that patient safety is regulated by Law No.44 Year 2009 on Hospitals in Indonesia.

According to these legal provisions, hospitals are required to provide full protection to patients, with patient safety as the main principle in the delivery of health services in the hospital. In addition, hospitals must be able to provide legal guarantees and protection to patients. Hospitals also have responsibility to fulfill all Informed Consent requirements as an important part of maintaining patient safety. Informed Consent must be submitted in writing with signatures from the patient and family/guardian and documented in the medical record. If the Informed Consent requirements are not met, the hospital has the right to impose administrative sanctions on the doctor treating the patient. Medical errors, adverse events, and near misses are the types of incidents regulated under the Act. If such incidents occur, the hospital has an obligation to immediately report the incident to the patient safety committee. Reporting must be done anonymously in order to provide feedback and corrections to the hospital system to improve patient safety. Patient safety standards are also regulated in ministerial regulations. In the case of applying cardiac surgery techniques, a doctor must carefully consider the potential risks and benefits of the action to be performed. The doctor is obliged to explain all aspects related to the risks of the action, ranging from the worst to the possible success of the operation. Therefore, by applying appropriate Informed Consent, while prioritizing patient safety, a doctor can avoid inappropriate medical practice or negligence that harms the patient.

Conclusion

In the practice of applying cardiac surgical operation techniques, it is important to implement a comprehensive and fully understood Informed Consent. The Informed Consent must be prepared in writing and signed by the patient or his/her family representative, then stored in the medical records at the hospital.

of Minister accordance with the Decree the of Health Ĭη No.436/Menkes/SK/VI/1993 on Service Standards in Hospitals, hospitals also have the responsibility of ensuring that Informed Consent is done correctly and completely. Failure to obtain Informed Consent for medical procedures may result in administrative sanctions, such as revocation of the relevant doctor's license to practice. The signature of the Informed Consent indicates understanding, awareness, and acceptance by the signing party (patient or his/her family representative) of the procedure to be performed by the doctor, along with the risks that may occur as a result of the procedure. The discourse on the application of cardiac surgery techniques in Indonesia shows that developments in medical technology and the expertise of health workers have enabled increasingly sophisticated and effective procedures to treat various heart diseases. However, challenges include limited access to quality medical facilities, uneven distribution of cardiac surgeons, and high costs for such surgical procedures. Therefore, efforts to improve health capacity and infrastructure, as well as comprehensive subsidy and health insurance policies, are needed to ensure that all segments of society are able to receive adequate cardiac surgery services.

Informed consent for medical procedures, including cardiac surgery, is a crucial aspect of medical practice that emphasizes the importance of the patient's right to information and autonomy. The informed consent process must be carried out by providing a complete and easy-to-understand explanation of the purpose, procedure, risks, and treatment alternatives available. In Indonesia, the implementation of the principle of informed consent needs to be continuously strengthened through education and training for medical personnel, as well as increasing patients' awareness and understanding of their rights. Thus, a more transparent and trust-based relationship between medical personnel and patients can be realized, supporting better and ethical health outcomes.

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