



THE ROLE OF INFORMED CONSENT IN PAEDIATRIC SURGERY IN INDONESIA

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ABSTRACT

Informed Consent (IC) plays an important role in determining the fate of pediatric patients, especially children who require medical treatment in the form of surgery. Children are considered legally incapable of giving legal consent to medical procedures because they have not reached adulthood, so the responsibility is given to a parent or legal guardian. Without the consent of the parents, medical procedures cannot be performed on pediatric patients. The purpose of this article is to find out how the regulation and role of IC in the practice of Paediatric Surgery in Indonesia is based on applicable regulations. The research method used is a normative juridical method. The findings obtained are that IC in the practice of Paediatric Surgery in Indonesia is regulated in Law No. 29 of 2004 concerning Medical Practice and Permenkes No. 290/Menkes/Per/III/2008 concerning the Approval of Medical Measures. In pediatric surgical procedures, IC is given by parents as the closest family based on the consideration of the best efforts for the benefit of the child, as well as protection for medical personnel in carrying out their duties. However, existing regulations do not yet regulate the protection of children's rights against parents who reject IC. In the future, it is hoped that IC pediatric surgical practice will be carried out with full understanding and wise decisions from all parties involved, in accordance with legal principles and medical ethics.

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1. INTRODUCTION

The relationship between doctors and patients in the health sector has its own characteristics. This relationship is a therapeutic transaction [1]. A therapeutic transaction is an agreement between a patient and a healthcare provider and/or doctor where the healthcare provider and/or doctor agrees to make every effort to treat the patient [2]. Legal doctor-patient agreement refers to a legal relationship that is based on an agreement to provide medical services [3]. This agreement has a certain legal nature that involves the rights and obligations of both parties. Law Number 17 of 2023 concerning Health states that legal relationships in therapeutic transactions give rise to rights and obligations for each party [4]. These rights and obligations are a balance of power in the form of individual rights which are reflected as obligations to other parties [5]. Therapeutic

transactions are included in the category of *verbintenis inspannings* business engagements which are based on maximum business commitment and not on the guarantee of results or the engagement of *verbintenis* results [6]. During rapid developments in the health sector, Informed Consent is very important in its function for the safety and benefit of the parties involved, ensuring that all parties carry out their rights and obligations accordingly [7].

Informed Consent (IC) is a patient's consent that is given after obtaining clear, complete, and understood information regarding the medical procedure to be performed. IC has a legal basis and principles that are in line with treaty law [8]. IC in therapeutic transactions has an important role because it gives patients the right to know enough information about their health conditions and medical actions to be carried out by doctors [9]. This allows the patient to make an informed decision regarding the medical action to be taken on them. In addition, IC also protects doctors from lawsuits that may arise because of medical actions they perform. Informed Consent, approval of medical or dental procedures is regulated in Law No. 29 of 2004 concerning Medical Practice (Medical Practice Law) [10]. Article 45 number (1) of the Medical Practice Law states that: "Every medical or dental action to be carried out by a doctor or dentist on a patient must be approved" [11]. Approval of medical measures is given after the patient has received a thorough explanation, including the diagnosis and administration of the medical procedure, the purpose of the medical procedure performed, other alternatives that can be performed, the risks and complications that may occur, and the prognosis of the action to be performed [12].

Informed Consent is further regulated in the Regulation of the Minister of Health of the Republic of Indonesia Number 290/Menkes/Per/III/2008 concerning the Approval of Medical Actions (Permenkes Approval of Medical Actions). In line with the Law on Medical Practice, Article 2 number (1) of the Regulation of the Minister of Health on the Approval of Medical Actions states: "All medical actions that will be carried out on patients must be approved". This contains the meaning of all medical actions that doctors will take on their patients, must first be approved by the patient or their immediate family, both orally and in writing. Furthermore, Article 13 number (1) of the Permenkes on the Approval of Medical Actions states: "Approval is given by a competent patient or a close family". Child patients are not included in the competent patients, so Informed Consent is given by parents as the closest family as regulated in the Regulation of the Minister of Health on the Approval of Medical Measures [13]. Incompetent patient refers to a condition in which a patient is deemed incapable of giving legal consent (Informed Consent) for medical decisions. This is usually related to certain cognitive, emotional, or condition limitations that prevent the patient from understanding relevant information, evaluating options, or making decisions based on that information [14]. For example, in patients with neurological or mental disorders, conditions of decreased consciousness, severe emotional or psychological stress that hinder rational decision-making and minor patients. The extent of the patient's decision-making competence depends on his or her understanding of the information and communication between the patient and the doctor. The key to the most effective relationship between patient and doctor is good communication.

Pediatric surgical services are specialized medical services that handle surgical procedures on pediatric patients, from infants to adolescents. This service is carried out by pediatric surgeons who are trained to perform surgery, considering the special needs of the child, both physically and psychologically. Pediatric patients are not miniature adults, so they require specific medical treatment [15]. In the context of pediatric medical care, no medical procedure may be performed without the consent of a parent or legal guardian. This requirement aligns with the principle of Informed Consent, which entails written or verbal approval granted after a comprehensive explanation by medical personnel regarding the procedure, its benefits, risks, and available alternatives. Children are deemed legally incompetent to make independent medical decisions due to their limited cognitive and emotional development. Accordingly, parents or guardians act as the child's legal and moral representatives in granting or refusing consent, with the paramount consideration being the child's best interests. Although the legal authority rests with the parent or guardian, older children typically those aged 12 and above are often involved in discussions as part of efforts to respect their rights and promote health education [16].

Informed consent of parents to children plays an important role in determining the fate of pediatric patients, especially children who need medical treatment in the form of surgery. Children are considered legally incapable of giving legal consent to medical procedures because they have not reached adulthood, so the responsibility is given to a parent or legal guardian. The parent or guardian gives consent on behalf of the child by fully understanding the information provided by the doctor regarding the medical procedure. Without the consent of the parents, medical procedures cannot be carried out on the child, even if it is considered necessary for his health. Therefore, this article explores the following research questions; how is the regulation and role of Informed Consent in the practice of paediatric surgery in Indonesia based on applicable regulations?

2. RESEARCH METHODS

The method used is a normative juridical approach (doctrinary approach), namely a statutory approach. The legislative approach in this case is the Law on Medical Practice and the Regulation of the Minister of Health on the Approval of Medical Actions, especially those related to the approval of medical actions by parents against biological children, which are also closely related to the Indonesian Medical Code of Ethics. The normative

approach includes legal principles, legal systematics, synchronization (legal adjustment) to know in detail, systematic and comprehensive about the use of Informed Consent in pediatric surgical patients.

3. RESULT AND ANALYSIS

Informed Consent in Pediatric Surgery in Indonesia

Informed consent

Informed Consent comes from two words, namely Informed (having received an explanation/description/information and Consent (giving consent/permission). Informed Consent is an agreement given after obtaining information [17]. Informed Consent in the medical profession is a statement of consent or permission from a patient that is given freely, rationally, without coercion (voluntary) about the medical action that will be taken against him after obtaining sufficient information about the medical action in question. Informed Consent according to the General Provisions of Article 1 number 1 of Permenkes No. 290 of 2008, is consent given by the patient or his immediate family after receiving a complete explanation of the medical or dental actions to be carried out on the patient [18]. Informed Consent is basically the idea that the decision to provide treatment to patients must be based on cooperation between doctors and patients. Medical measures, both diagnostic and therapeutic, require Informed Consent, which is the construction of conformity of the will after each of them reciprocally expresses information. Therefore, Informed Consent can be interpreted as consent after information [19]. The essence of Informed Consent is to protect patients from any possible medical actions that are not approved or not authorized by the patient, as well as to protect the doctor (legally) against the possible unexpected, undesirable and negative consequences of the medical actions carried out.

The background of Informed Consent is in principle that every human being has the right to participate in decision-making that concerns him/her. This is then described as [20]:

- a. The patient must understand and have sufficient information to make decisions about his or her treatment.
- b. The patient must give consent to the treatment of him/herself, either orally or in writing, explicitly or implicitly.

Principles Underlying Informed Consent

The Oxford English Dictionary defines the term "consent" as "voluntary agreement to, or acquiescence in, what another proposes or desires; compliance, competition, permission". Informed Consent is intended as the free consent given by the patient to a medical procedure, after he or she has obtained all the important information about nature and consequences of the action [21]. The principle of Informed Consent is rooted in human dignity where the autonomy and personal integrity of the patient must be protected. Human integrity demands that everyone acts according to what he knows and according to his free choice. Such choices are personally sourced from within oneself, and not from internal impulses or from external pressures [22]. The principle of Informed Consent is the right and obligation of every competent individual to improve his or her spiritual life and physical well-being through his or her free consent, or by refusing to consent to certain medical procedures based on sufficient knowledge of the associated benefits, harms and risks. For an incompetent individual, these rights and obligations must be interpreted by the individual's legitimate guarantor (the patient) to the extent of his or her knowledge or rational wishes [23].

Informed Consent is the free consent given by the patient to a medical procedure, after he or she has obtained all the necessary information about the nature and consequences of the procedure. Informed Consent is based on the principles of autonomy (respecting the patient's autonomy), beneficentia (doing good), non maleficentia (no harm) and Justice (fair), which are rooted in human dignity where the autonomy and personal integrity of the patient are protected and respected [24]. If the patient is incompetent, then approval is given by the family or legal guardian. If the family/guardian is present but is also incompetent, then the medical personnel must decide on their own to carry out certain medical measures according to the patient's circumstances. Especially in emergency situations where immediate medical action must be taken to save lives, proxy consent is not needed. Informed Consent functions to protect and increase patient autonomy, protect patients and research subjects, prevent manipulative and coercive actions, increase self-awareness of the medical team, improve rational decision-making, and involve the public in the development of autonomy as a social value and control over biomedical research [25].

The explanation/information that must be provided before a medical procedure is carried out is [26]:

- a. Established diagnosis.
- b. The nature and extent of the action to be taken.
- c. The benefits and urgency of taking these actions are real.
- d. The risk of risks and complications that may occur from such medical measures.

- e. The consequences are that if these actions are not taken and are there other alternative treatment methods.
- f. The cost of the medical procedure.

Informed Consent is considered valid when [27]:

- a. The patient has been given an explanation/information.
- b. The patient or legal representative is in a state of competence to give a decision/consent.
- c. Consent must be given voluntarily

Legal Aspects of Informed Consent

Article 39 of Law Number 29 of 2004 concerning Medical Practice states: "Medical practice is organized based on an agreement between a doctor or dentist and a patient in an effort to maintain health, prevent disease, improve health, treat diseases and restore health." What is meant by medical practice in this provision is a series of activities carried out by doctors and dentists to patients in carrying out health efforts. The legal relationship between a doctor or dentist and a patient in the practice of medicine arises, because of an agreement between the two parties, or is based on an agreement between them [28]. The agreement between a doctor or dentist and a patient is known as a Therapeutic Agreement. For the occurrence of a therapeutic agreement, Article 45 of the Law on Medical Practice specifies that every medical or medical action that will be carried out by a doctor or dentist on his patient, must be approved and such approval is given after the patient has received a complete explanation at least including the diagnosis and procedures of medical procedures, the purpose of the medical procedure performed, other alternative measures and the risks, risks and possible complications as well as the prognosis of the actions taken.

Informed Consent can be given either in writing or orally. High-risk medical procedures must obtain written consent signed by the party entitled to give consent. An agreement in a therapeutic transaction occurs when the patient or the right party gives consent to the medical procedure to be performed by the doctor or dentist is signed. Article 1233 of the Civil Code states that the agreement is the legal source of the agreement. Informed Consent from the legal principle of the agreement functions as a fulfillment of the principle of consensualism which contains the meaning that since the agreement (consensus) between the parties regarding the subject matter of the agreement, the agreement has occurred [11]. Both parties have been bound since the conclusion of the agreement, are obliged to fulfill the obligations arising from the agreement and obtain their rights in accordance with the agreement or according to the provisions of applicable law.

Therapeutic agreements have their own characteristics that are different from agreements in general, namely located in the object of the agreement. The object of this agreement is in the form of efforts or therapies for the healing of the patient. So according to the law, the object in the agreement in the therapeutic transaction is not the healing of the patient, but the appropriate and maximum effort for the healing of the patient. A therapeutic agreement between doctors and patients does not include a resultats agreement because the object of the agreement is not the result of medical services by doctors, but the efforts, behaviors or treatment of medical services carried out by doctors. A doctor-patient legal bond is a type of inspannings verbintenis engagement, which is an agreement in which the doctor promises the best effort in accordance with his field of expertise to carry out a series of actions that can be held accountable for the healing and restoration of the patient's health. The best measure of effort in this relationship is in accordance with professional standards, standard operating procedures, patient medical needs, and medical or dental service standards [29].

Approval of medical actions is a mandate from Permenkes No. 290 of 2008 concerning Approval of Medical Actions which is the implementation of Law No. 29 of 2004 concerning Medical Practice Article 45. The Regulation of the Minister of Health on the Approval of Medical Actions Article 2 paragraph (1) states that all medical actions that will be carried out on patients must be approved [30]. This regulation is a representation of the state's efforts to prevent the arbitrariness of doctors that allow for violations of patients' human rights. Article 13 number (1) of the Regulation of the Minister of Health on Approval of Medical Actions states: "Approval is given by a competent patient or close family." So here it is clear that all medical procedures require Informed Consent from the competent patient or his family.

Stages in the implementation of Informed Consent:

- a. Process of Providing Explanations

The process of providing an explanation in the approval of the medical procedure must be given in full about everything related to the medical procedure to be performed on the patient/family by the doctor who will perform the procedure, so that the patient/family understands and can understand, and the explanation can be used as a consideration for making a decision. Thus, the approval of medical measures is the result of a communication process between the doctor and the patient/family.

- b. Decision Making Process

Decision is a complete knowledge of right or wrong, decision declaring yes or no. Always makingions can be right and can also be wrong, in humans there is a desire to always make the right decisions. To

make the right decision, a correct explanation is needed. So, the decision to approve or disapprove of medical actions is largely determined by the correct explanation of the action to be taken as well as the patient's freedom in determining his own fate. The legal force of medical procedure approval lies in the implementation of the medical procedure approval in accordance with applicable provisions. If the implementation of the approval of medical measures is in accordance with the rules of law, the approval of the medical procedure will provide legal certainty for the parties. A review of the legal aspects of "agreement". R. Subekti in the Law of Agreements, states that a contract is an event where one person makes a promise to another person or two people promise each other to perform something. From this event, a legal relationship arises between the two people called an engagement. The covenant published an alliance between the two people who made it. Furthermore, Article 1320 of the Civil Code (KUHPercivil) states that for the validity of an agreement, four conditions are required that must be met, namely the agreement of those who bind themselves, the ability to make an agreement, a certain subject matter and a cause that is not prohibited.

According to Cecep Triwibowo, Health Ethics and Law is an alliance between doctors and health workers and patients, in the form of a legal relationship that gives birth to rights and obligations for both parties. Referring to the conditions for the validity of the agreement that have been described, the Therapeutic Agreement must be carried out by capable people. The recipient of medical services is the patient, while the provider of medical services is the doctor and health workers. Therapeutic Agreements have an object, namely medical services or healing efforts. In this case, healing efforts are the maintenance and improvement of health oriented on family principles, including activities to improve the quality of health (promotive), disease prevention (preventive), cure of diseases (curative), and health restoration (rehabilitative). Basically, Informed Consent is necessary to ensure that the patient has understood all the information needed to decide, the patient is able to understand the relevant information and finally the patient gives consent.

In the therapeutic agreement, the agreement is an effort, with a real effort (inspanning verbintenis) and not an alliance of results (resultaat verbintenis). No doctor can guarantee the success of a medical procedure because all medical procedures are sure to contain risks known as medical risks. Therefore, even if the medical procedure does not yield the expected results, as long as the doctor does it seriously and in accordance with what should be done, then the doctor who performs the medical procedure cannot be said to have committed a violation or a crime that can be punished. Any medical action is legally justified when [14]:

- a. It is done because there is a legal relationship between the doctor and the patient
- b. Performed by a doctor according to his competence
- c. Performed according to medical indications
- d. Carried out in accordance with Service Standards and Standard Operating Procedures.
- e. It is carried out after there is consent from the patient/family based on Informed Consent

Analysis of the Role of Informed Consent in Therapeutic Transactions in Pediatric Surgical Practice Regulation of Informed Consent in Therapeutic Transactions in Paediatric Surgery Practice in Indonesia

Children's rights are part of human rights, which are clearly stated in Indonesian legislation and are more strictly regulated in the Child Protection Law. Parents are obliged and responsible in nurturing, nurturing, educating, and protecting children. The state must also ensure the implementation of protection for all Indonesian children, including the protection of their rights. Paying special attention to the future of children means maintaining and saving the future of the nation and state. The rules that govern the obligations and responsibilities of child protection management in Indonesia are very important. The Child Protection Law has confirmed the existence of these obligations and responsibilities. The state, government, community, family and parents are obliged and responsible for the implementation of child protection. The state and the government are obliged and responsible to respect and guarantee the human rights of every child regardless of ethnicity, religion, race, class, gender, ethnicity, culture, language, legal status of children, order of birth, or physical and/or mental condition [25]. The state and the government are obliged and responsible to support facilities and infrastructure in the implementation of child protection. The state and the government ensure the protection, maintenance, and welfare of children by paying attention to the rights and obligations of parents, guardians, or other people who are legally responsible for the child [31]. The state and the government must also guarantee the rights of children to express their opinions according to their age and level of understanding.

Health is a child's human right and is an element of welfare that must be realized in accordance with the ideals of the Indonesian nation. In line with the spirit of Pancasila and other national patriots, all efforts to raise the highest level of public health must be carried out with the principles of non-discrimination, participation, protection, and sustainability. This is very important for the formation of resilient Indonesian human resources, to increase the nation's resilience and competitiveness, and as the basic capital for national development. Child

protection is an action that seeks to create situations and conditions that allow the implementation of children's rights and obligations in a humanly positive manner [30]. This means that children receive protection to obtain and maintain their right to life, to have survival, to grow and develop, as well as protection in the exercise of their own rights and obligations or with their protectors. Child protection is not a new matter, it is part of the child from birth, including rights in the health sector.

Child protection in Indonesia is regulated based on the Law. Law Number 23 of 2002 concerning Child Protection was made against the background because the Indonesian nation guarantees the welfare of each of its citizens, including the protection of children's rights which are part of human rights, as stated in the 1945 Constitution and the United Nations Convention on the Rights of the Child. Child Protection Law was subsequently updated to Law Number 35 of 2014 [29]. The reason for the changes and updates, based on the explanation of Law Number 35 of 2014, is because Law Number 23 of 2002 is not seen as effective as a legal regulation that aims to provide protection and fulfillment of children's rights. Child protection measures must be carried out as early as possible, namely from the time the fetus is in the womb, until the child is eighteen years old. Focusing on the concept of child protection that is complete, comprehensive, and comprehensive, the Child Protection Law emphasizes the obligation to protect children based on the following principles:

- a. The principle of non-discrimination
The principle of non-discrimination is a principle that does not discriminate, limit or exclude children, either directly or indirectly based on religion, ethnicity, race, social status, economic status, culture or gender that can affect the fulfillment and protection of children's rights
- b. The basis of the best interests for the child
The principle for the best interests of the child is a principle that emphasizes that in all actions related to children, the best interests of the child must be the main consideration, whether it is carried out by the government, the community or the legislative and judicial bodies
- c. Basic rights to life, survival and development
The fundamental principle, namely the right to life, survival and development, is a principle that emphasizes that every child has the right to live safely, peacefully, happily, prosperously in birth and mind, as well as the right to the fulfillment of their basic needs, in order to grow and develop properly, as well as the right to achieve a decent standard of living for the physical, mental, spiritual, moral and social development of children. All of them must be fulfilled by the parties mentioned in the Child Protection Law. They are parties who have obligations and responsibilities to carry it out, including parents, the community and the government
- d. The principle of respect for children's views/opinions
The principle of respect for children's views/opinions is a principle that gives children the right to express their opinions in all matters that affect the child, consisting of:
 - 1) The right to express one's opinion and to have one's opinion considered
 - 2) The right to receive and know information and to express
 - 3) Right to union, to establish a relationship to join
 - 4) The right to obtain appropriate information and to be protected from unhealthy information.

Informed Consent is a form of respect for the rights of patients, including pediatric patients. Doctors understand that before carrying out medical procedures, both diagnostic, therapeutic, and rehabilitative, Informed Consent is required, consent given after explanation. This cannot be applied to pediatric patients. Children are not competent patients. Competent patients are adult patients or non-children according to laws and regulations or have been/have been married, are not disturbed by their physical consciousness, are able to communicate reasonably, do not experience mental developmental retardation and do not experience mental illness so that they are able to make decisions freely. Therefore, in pediatric patients, another party needs someone who can "represent" the pediatric patient for this purpose. Children are not part of their parents. He is a separate human being who has the same rights as adults. Neither doctors nor parents can negate children's rights. If a father or mother checks his child with a doctor, the patient is the child, not the parent. Therefore, the primary responsibility of the doctor is to the patient, namely the child, not to the parents. The interests of children must be the top priority of doctors. In other words, the decision to do or not to do something must refer to the child's priorities, not the parents or guardians who bring the child for treatment. Doctors do not have the right to make decisions for their patients solely because of the wishes of others, even if the other person is the patient's parents, let alone to the point of ignoring the impact on the patient. The right of parents to decide whether medical services can be carried out for their children must be limited and based on decisions that benefit the child. Understanding children's rights also contains recommendations that actions that are not too important can be postponed until the child is able to give his consent [32]. Children must be protected from unnecessary actions, and as much as possible included in the decision-making process. Doctors are obliged to always ask for parental permission, although in certain circumstances they can ask for legal opinions if the parent's decision poses a substantial risk to the child [17].

Patient autonomy as an important principle in the ethics of doctor-patient relations means a correct and complete explanation, openness, and informed consent. In most pediatric patients, this has not been enforced. Children are not yet able to make decisions about potential things in their lives. Because of these limitations, pediatric patients are represented by parents as the closest family in making decisions. Informed Consent can only be given by adults who can accept and digest explanations from doctors properly. Infants and children obviously cannot give Informed Consent [33]. Therefore, the decision-making process in the world of health involving pediatric patients is a shared responsibility between doctors and parents. In general, parents are considered to have the legal and ethical right to determine the best medical course for their child. In these conditions, doctors must try to obtain parental permission to perform medical procedures on pediatric patients if it is based on the principle of the best interests for the child [34].

Based on the theory of legal certainty by Sudikno Mertokusumo, which states that legal certainty is a guarantee that the law must be implemented in a good way, through efforts to regulate the law in laws made by the authorities and authorities, so that the rules have a juridical aspect that must be obeyed. Law Number 29 of 2004 concerning Medical Practice has regulated Informed Consent, approval of medical or dental procedures. Approval is given after the patient or their immediate family has obtained the necessary information, at least including the diagnosis and procedures of medical procedures, the purpose of the medical procedure performed, other alternative measures, risks and complications that may occur, and the prognosis of the actions taken. Likewise, the Regulation of the Minister of Health on the Approval of Medical Actions which reregulates the approval of medical measures more completely, shows that there is legal certainty that guarantees that the law is carried out in a good way, namely the delivery of information at the beginning and then continued with the granting of approval. Those who have the right according to the law can obtain their rights, namely the patient and their immediate family, have the right to information before medical treatment is performed, have the right to give consent or rejection of the medical procedure to be performed [35]. If in practice there are still patients who do not understand the explanation presented by the doctor, generally due to limited knowledge, level of education, it can also be due to the doctor's explanation using medical terms that are difficult for the patient and his family to understand, plus the reluctance of the patient and his family to discuss problems that they do not understand, or are not able to accept with the doctor who will carry out the medical procedure.

The Role of Informed Consent in Therapeutic Transactions in Pediatric Surgical Practice in Indonesia

Informed Consent is an agreement, so it has the subject and object of the agreement. The subjects in the agreement are the parties to the agreement. There are two kinds of subjects, namely a human being or a legal entity that is burdened with obligations or gets the right to carry out those obligations. The subject in the form of a human being must meet the legal requirements to take legal action, namely being an adult and not under guardianship. In the case of a therapeutic agreement, the subject is the doctor and the patient represented by the parents as the immediate family. While the object in the agreement is in the form of achievement, which is to give something, do something, and not do something. In therapeutic agreements, motorcycle taxis are medical procedures. An agreement to give something is a person's obligation to give or hand over something, either juridically or in real terms. Commitment to doing something, which is an achievement, can lead to doing something or doing certain positive deeds. Meanwhile, the commitment not to do something is to not do certain deeds that have been promised. In line with that, the Informed Consent for Pediatric Surgery must be signed by the doctor who will carry out the procedure and the patient's parents as the representative of the pediatric patient.

A therapeutic agreement is an agreement between a doctor and a patient that authorizes the doctor to carry out health services to patients based on the expertise and skills possessed by the doctor. In the Preamble to the Indonesian Medical Code of Ethics attached to the Decree of the Minister of Health of the Republic of Indonesia Number 434/MenKes/X/1983 concerning the Enactment of the Indonesian Medical Code of Ethics for Doctors in Indonesia, it is stated about therapeutic transactions as follows: "Therapeutic transactions are the relationship between doctors and patients that is carried out in an atmosphere of mutual trust (confidential), and always overwhelmed by all emotions, The legal relationship in therapeutic transactions arises the rights and obligations of each party, both for the patient and the doctor. An agreement is said to be valid if it meets the requirements as stipulated in Article 1321 of the Civil Code which explains: "There is no valid agreement if the agreement is given due to mistake or obtained by coercion or fraud". In accordance with the above article, it can be concluded that juridically the validity of an agreement is determined by the agreement of the parties who bind it, without any error, coercion or fraud. This agreement is an agreement made by both parties where both parties have an agreement of will in the therapeutic transaction as the patient's side, namely the parents agree that their child is treated by a doctor, and the doctor agrees to treat the patient. In order for this agreement to be valid according to the law, the parties must be aware (there are no mistakes) of the agreement made, there must be no coercion from either party, or there must be no fraud in it. For this reason, Informed Consent is required.

The requirements for having the ability to make an engagement/agreement are regulated in Articles 1329 and 1330 of the Civil Code as follows:

- a. Article 1329: Everyone can make alliances, if he is not declared by law to be incompetent.
- b. Article 1330: Failure to make an agreement is:
Immature people.
Those who are placed in the pardon.
Women, in matters prescribed by law and generally all persons to whom the law has forbidden the making of certain treaties.

Based on the reading of Article 1329 of the Civil Code above, juridically what is meant by the ability to make an engagement is a person's authority to bind himself, because it is not prohibited by law. The doctor who provides an explanation in the Informed Consent is a competent doctor, master's the information conveyed regarding the medical action to be performed and also meets the administrative requirements as a doctor (for example, having a Practice License). The patient, in the case of the recipient of medical services represented by the parents, is also confirmed to be eligible to make an agreement. Medical service recipients can include various age groups, and different types of patients, consisting of those who can act and those who are not capable of acting. This must be realized by the doctor as one of the parties who finds himself in the therapeutic transaction, so as not to cause problems in the future. Medical services recipients who are incapable of acting (may not make an agreement, or the agreement made may be considered invalid) include:

- a. Adults who are incapable of acting (e.g., insane, drunk, or unconscious), then the consent of the caregiver is required (who may make an engagement with the doctor is the caregiver)
- b. Minors are required to have the consent of their guardians or parents.

The Civil Code (KUHPercivil) regulates the definition of Children in Article 330 of the Civil Code which states that "Immature are those who have not reached the age of 21 (twenty-one) years and have been married before." From this, it can be interpreted that adulthood is when a person is 21 years old or has been married or has been married. Article 330 of the Civil Code defines a child as a minor and a person who has not reached the age of legal legitimacy as a subject of law or as a subject of national law as determined by civil legislation. Article 1320 of the Civil Code, the object of the agreement, consists of "a certain thing" and must be "a cause that is lawful or permissible to be agreed". In therapeutic transactions, regarding certain things that are agreed upon or as the object of the agreement are efforts to cure diseases that are not prohibited by law. The nature or characteristics of therapeutic transactions as mentioned in the Preamble to the Indonesian Medical Code of Ethics are:

- a. Special therapeutic transactions regulate the relationship between the doctor and the patient.
- b. The relationship in this therapeutic transaction should be carried out in an atmosphere of mutual trust (confidential) which means that the patient must trust the doctor who performs the therapy, and vice versa the doctor must also trust the patient. Therefore, to maintain this mutual trust, doctors must also make maximum efforts for the recovery of patients who have entrusted health to him, and patients must also provide clear information about their illness to doctors who are trying to treat him and obey the doctor's orders that are necessary to achieve the expected recovery.
- c. This hope is also stated as "always overwhelmed by all the emotions, hopes and worries of human beings". Given the condition of patients who are sick, especially patients with chronic diseases or patients with severe illnesses, the patient's emotional condition, worries about the possibility of being cured or not of the disease accompanied by the hope of wanting to live longer, give rise to a special relationship that distinguishes this therapeutic transaction from other transactions in general. In the context of pediatric surgery in Indonesia, Informed Consent has an important role in providing protection for the rights of patients and families. Informed Consent guarantees the right of parents or guardians of children to obtain clear, complete, and understandable information about surgical procedures, including the risks, benefits, alternatives, and consequences of not acting. The parent or guardian has the right to give or deny consent after understanding all aspects of the medical procedure.

Informed Consent serves not only as a communication process but also as a tool to respect parental autonomy. In certain situations, if the refusal is potentially life-threatening, the doctor may involve a third party such as the hospital's ethics committee or legal authority to find the best solution for the child's welfare, although the decision-making rights holder remains the child's parent. This shows that Informed Consent is not just an administrative formality, but a process that upholds human rights while protecting the professional integrity of doctors. By providing information transparently, doctors and parents can collaborate to make the best decisions that take into account the medical, ethical, and needs aspects of the child. The low level of medical understanding among the public is often an obstacle in providing understandable explanations. Some societies have certain traditional views or beliefs that influence medical decision-making. The existence of good Informed Consent from doctors is expected to minimize these obstacles. The decision taken by the parent or guardian of the child must consider the balance between family autonomy and the protection of the child from unnecessary risks and is based solely on the welfare of the child. Informed Consent has an important role in the practice of pediatric surgery in Indonesia, especially to protect the rights of children, parents, and medical personnel. This process

ensures that the surgical procedure is performed with full understanding and a wise decision from the child's guardian, in accordance with legal principles and medical ethics. In its effectiveness, good communication, clear education, and a comprehensive approach to family culture and needs are needed.

4. CONCLUSION

The regulation of Informed Consent in therapeutic transactions in the practice of Paediatric Surgery in Indonesia is regulated in various laws and regulations, including Law No. 29 of 2004 concerning Medical Practice, the Civil Code (KUHPerduta), Permenkes No. 290/Menkes/Per/III/2008 concerning the Approval of Medical Actions. In pediatric surgical procedures, Informed Consent is given by parents as the closest family based on consideration and best efforts for the benefit of the child. Informed Consent in therapeutic transactions in the practice of paediatric surgery in Indonesia plays a role in providing protection for the rights of children's patients and families as well as protection for medical personnel in carrying out their duties. This process ensures that the agreement on the surgical procedure is carried out with full understanding and a wise decision from the child's guardian, in accordance with the principles of medical law and ethics.

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