

The Principle of Best Interest and Harm Principle as the Basis for Limitation of the Role of Informed Refusal by Surrogate Consent in Pediatric Patient

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ABSTRACT--This research starts from the problem of ethical dilemma that occurs due to informed refusal by parents or guardians of pediatric patients which has the potential to cause disability or death in children as an implementation of unlimited authority delegation to the family / guardian of pediatric patients in Indonesia towards fulfilling the patient's right to accept or reject medical treatment. There is a conflict between the decision of the medical team based on the principle of beneficence for life of pediatric patients with the obligation to respect the family / guardian of pediatric patients autonomy who provide informed refusal. The question is whether the medical team should respect the patient's family autonomy or let the patient die? This study uses normative juridical research with a statutory approach that is supported by a conceptual approach and comparative law with the United Kingdom and the Netherlands in the application of Informed Refusal involving children in the Practice of Medical Services. The results of the study show that it is necessary to regulate the position of third parties in the principle of autonomy of pediatric patients to create a balance against efforts to protect the autonomy of pediatric patients. Limitation of family or guardian authority on pediatric patients is carried out on the basis of 2 important principles namely that positively health services must respect the best interests of patients, and negatively health services must avoid situations that endanger the safety (harm principles) of pediatric patients, as an effort to fulfill human rights for health services.

Keywords: informed refusal, principle of best interest, harm principle

I. INTRODUCTION

Indonesia is a constitutional state [1], and in a constitutional state, human rights is protected [2]. Health is part of human rights [3] and one of the elements of welfare that must be realized in accordance with the ideals of the Indonesian nation as referred to in the Pancasila and the Preamble of the 1945 Constitution. Health is the basic right of every individual and citizen, as guaranteed in Article 28 H and Article 34 (2) of the 1945 Constitution which must be realized by efforts to improve the highest level of public health.

Recognition and protection of the right to health as part of human rights such as the above provides recognition of the right to health care as part of the rights of Indonesian citizens, where as human rights, the right to health services must be protected and fulfilled by the State as stated in Article 28 I of the 1945 Constitution.

Support for patient autonomy has led to a fundamental change in the pattern of relationships between doctors and

patients in health care, from doctor-focused to patient-focused health services[4].

One manifestation of patient-focused care is a belief that the results of service to patients will be better if the right patient and family or those who are entitled to make decisions are involved in making service decisions and processes that are in line with expectations, values and culture. One of many attempts to get patients involved in decision making in the care process is by giving consent [5].

A patient must receive an explanation of the factors related to the care plan to be given before deciding to give his consent. This is called informed consent. The patient has the right to decide whether to give consent or refusal of a treatment. The patient's decision must be respected regardless of the doctor's belief that the treatment is appropriate and important for the patient concerned [6].

Protection of the patients's rights, especially informed consent and informed refusal in Indonesia is outlined in the trilogy of legislation in the health sector [7]. Protection of the rights of recipients of health services is regulated in Article 52 of Medical Practice Act 2004 which states that patients in receiving services in medical practice, have the right to refuse medical treatment; Article 56 of Health Act 2009, in the case that every person has the right to accept or refuse part or all of the relief measures that will be given to him after receiving and understanding information about such actions in full. Article 32 of Hospital Act 2009 also regulates the patient's right to give consent or refuse actions to be taken by health provider for their illnesses; This informed consent is absolutely necessary because medical actions carried out without the patient's permission can be classified as battery. Furthermore, a medical action carried out by a doctor is carried out without the patient's permission, while the patient is fully conscious and able to give consent, the doctor can be blamed and prosecuted on the basis of a lawsuit for breach of contract and an act against the law (onrechtmatige daad) [8].

The legal relationship between providers and recipients of health services also raises the obligations of service providers, as regulated in Article 51 of the Medical Practice Act 2004 which states that doctors or dentists in carrying out medical practices have an obligation to provide medical services in accordance with professional standards and operational procedure standards as well as the patient's medical needs. Likewise Article 24 of the Health Act 2009 states that health

provider who are authorized to administer health services must meet the provisions of the code of ethics, professional standards, the rights of users of health services, service standards, and operational procedure standards. The obligation to administer health services in accordance with the standards and professional code of ethics and protection of the rights of patients, especially the right to consent or refuse to act against the disease to be carried out by health provider often cause conflicts of interest in daily practice.

Problems arise when the patient is incompetent and the incompetent patient is represented by his family or guardian. Is the principle of autonomy delegated to parents or guardians of incompetent patients also unlimited? A case of a 2-year-old child experiencing respiratory failure due to aspiration pneumonia (inflammation of the lung parenchyma, distal to the terminal bronchus which includes respiratory bronchioles, and alveoli, as well as causing lung tissue consolidation and disruption of local gas exchange caused by foreign body aspiration both from inside the body and from outside the patient's body)[9] where the parents (after being given information about the patient's condition and medical action plan) refuse to do an intubation action (Endotracheal intubation is the act of inserting a tracheal tube into the trachea through the rhyme glottides by developing a cuff, so that the distal tip is approximately in the middle of the trachea between the vocal cords and tracheal bifurcation)[10] for the safety of his life, but the refusal brings death to the patient. Many cases are found that medically require certain medical procedures which if performed medical measures it is believed (based on science) will bring improvement or healing to the patient, but the proposal is refused by the family or guardian, which then the rejection is fatal (disability or death). Decision making by family or guardians on these incompetent patients is possible because it is regulated in Article 13 of the Approval of Medical Action Regulation 2008 which states that the Approval is given by competent patients or the closest family. This also confirmed the statement issued by the Indonesian Medical Association, that is, if the patient's age is less than 18 years must obtain the approval of parents or guardians[11]. In reality in the field, doctors may not dare to do medical actions without the patient's permission (in this case delegated family or guardian) because the act without permission is included in the category of battery that is included in the criminal sphere. In civil terms, the adagium "volenti non fit inura", which means that someone who already knows the risks and will also be willing to bear them if they arise, cannot then file another lawsuit, cause doctors and hospitals to feel safe and do not want to dispute the informed refusal, despite knowing that the informed refusal will cause the patient to experience disability and even death. This action actually violates Article 62 of the Human Rights Act which states that every child has the right to obtain proper health services, according to his physical and mental spiritual needs. Every child has the right to be raised, nurtured, cared for, guided by the life of his parents or guardians until

adulthood. The child's rights at the same time give birth to obligations for each parent or guardian to carry out obligations as a real parent.

adesire to protect and respect the patient's autonomous rights often negates the patient's autonomous rights by surrendering fully without limitations to the family or guardian, any decision to be imposed on the patient is entirely in the hands of his family or guardian. This is precisely different from what is applied in western countries. European countries such as France and Italy[12], in the case of refusing blood transfusions caused by reasons of the belief of the Jehovah's witnesses for example, does not necessarily follow the wishes of a family or guardian, especially in child patients. It is said that children over 12 years of age can give consent for their own medical treatment without the help of a parent or guardian. On the other hand, for children under 12 years old, parents or guardians may not refuse blood transfusions that will be given to their children only for reasons of belief or religion, unless they can show an alternative that is acceptable to the medical[13].

The problem of informed refusal taken by the family or guardian as a manifestation of the patient's autonomy rights that cause disability or death of the patient actually brings a conflict between juridical and empirical facts. At the normative level, there is a mismatch between the application of legal norms with the application of medical ethics principles, namely the application of the principle of unlimited autonomy by family or guardians with the principle of therapeutic goals (the principle of beneficence). On one hand Article 23 of the Health Act 2009 requires aspects of patient safety as a benchmark for health services by prioritizing medical and non-discriminatory indications in the best interests of patients and in accordance with medical indications, Article 24 of the Health Act 2009 and Article 51 of the Medical Practice Act 2004 also state that health provider (including doctors) must meet the provisions of the code of ethics, professional standards, the rights of users of health services, service standards and standard operating procedures. But on the other hand, Article 52 of the Medical Practice Act 2004 and Article 32 of the Hospital Act 2009, in which regulates the patient's right (without limits) to give consent or refuse actions to be taken against him, including the rights of parents or guardians to patients who are not competent. this often creates conflict in the practice of health services in hospitals.

There are no restrictions on the rights of patients in Indonesia as stipulated in Article 52 of the Medical Practice Act 2004 and Article 32 of the Hospital Act 2009, in giving consent or refusing actions to be taken against him, including when those rights are delegated to parents and guardians due to incompetent patients (for example because the age is less than 18 years) causes a lot of disability and deaths that can actually be prevented. The responsibility of the Indonesian state as constitutional state which is obliged to protect the rights of its citizens to health as mandated in Article 28 of the 1945 Constitution. Recognition that the right to health is part of universal human rights stated in the general explanation of the

Health Act 2009 has given the responsibility of the government / state to realize this[14]. This unrestricted right has the potential to violate the human rights of others. The patient's autonomy rights (including by family or guardian) should be limited in accordance with human rights arrangements in Indonesia that every human rights of a person creates a basic obligation and responsibility to respect the rights of others reciprocally and it is the duty of the government to respect, protect, uphold and promote it.

There is a conflict between the principle of autonomy with the principle of therapeutic goals (beneficence principle) and the conflict between the value of individual freedom and the value of benefits (social) at the level of values, as well as the existence of vague norms, especially in regulating the patient's consent-refusal rights (including family or guardian) require comprehensive and integrated legal study. The obligation and responsibility of the government to respect, protect, uphold and advance human rights, including in taking effective implementation steps in the field of law and politics as stipulated in Articles 71-72 of the Human Rights Act, including child protection.

Based descriptions above and challenges that must be faced, encourage this scientific writing with the title: *The Principle of Best Interest and Harm Principle as the Basis for Limitation of The Role of Informed Refusal by Surrogate Consent in Pediatric Patient.*

II. RESEARCH METHOD

This study uses normative juridical research with a statutory approach that is supported by a conceptual approach and comparative law with the United Kingdom and the Netherlands in the application of Informed Refusal involving children in the Practice of Medical Services. This research is a normative juridical research because this study describes the ambiguous of norms in articles that have the potential to cause multiple interpretations and cause legal problems in the practice of medical services, namely Article 52 of the Medical Practice Act 2004; Article 32 of the Hospital Act 2009; Article 13 of Approval of Medical Action Regulation 2008 as implementing regulations Article 45 of the Medical Practice Act 2004. This study also outlines the conflict between Article 23 and Article 24 of the Health Act 2009; Article 51 of the Medical Practice Act 2004 in one side. And Article 52 of the Medical Practice Act 2004 and Article 32 of the Hospital Act 2009 in other side.

There are no restrictions on rights as stipulated in Article 52 of the Medical Practice Act 2004 and Article 32 of the Hospital Act 2009, in giving approval or refusing actions to be taken against him, including when those rights are delegated to parents and guardians because of incompetent patients (for example due to age less than 18 years old) causes a lot of disability and deaths can be prevented. This unrestricted right has the potential to violate children's rights as regulated in the Human Rights Act and the Child Protection Act.

III. FINDINGS AND DISCUSSION

It is well established in Indonesia law that a patient must give in-formed consent before a physician may administer treatment. a competent person has a constitutionally protected right in refusing unwanted medical treatment. This right to refuse treatment and grant informed consent does not disappear for individuals who are incompetent. Rather the right is one that must be exercised for them[15]. Under Indonesia law, minors are generally considered incompetent to provide legally binding consent regarding their parents or guardians are generally empowered to make those decisions on their behalf, and the law has respected those decisions.

The Approval of Medical Action Regulation provides arrangements regarding the right to give consent, namely:

- a. Consent was given by a competent **patient or family**
- b. Assessment of patient competencies as referred to in Paragraph (1) Can be performed by a doctor or dentist before a medical action is taken
- c. In the event that there is doubt as to the consent given by the patient or his family, the doctor or dentist can make a request for re-approval.

The Hospital Act provides the following arrangements:

- a. Every medical action performed at a hospital must be approved by the **patient or family**.
- b. Provisions regarding approval of medical measures as referred to in paragraph (1) shall be implemented in accordance with statutory provisions.

Article 13 of the Approval of Medical Action Regulation as a follow-up to the Medical Practice Act and Article 37 of the Hospital Act gives the patient or family the same status as the party who has the authority to exercise patient autonomy in the form of refusal or approval of proposed medical interventions. The use of the word "**or**" in the second formulation of the article means that the family can replace the patient in making decisions in medical care. The two regulations never stipulate what qualifications must be met before the family can be involved in making the decision. This was also confirmed by a statement issued by the Executive Board of the Indonesian Doctors Association that is, if the patient is less than 18 years old, he must obtain the approval of a parent or guardian. Without a qualification regarding the terms of involvement of the family in making medical decisions, this has the potential to violate the patient's autonomy itself (in this case pediatric patients).

Specifically, the Approval of Medical Action regulation regulates the refusal of medical measures including: "Refusal of medical action can be done by the patient **and / or** his immediate family after receiving an explanation of the medical action to be performed".

Regulation in Indonesia has not yet created a balance against efforts to protect patient autonomy when patients lack competence. Efforts to protect the interests of pediatric patients in upholding the principle of autonomy become important when there is a conflict between the will of the family or guardian with the proposed medical treatment from the health service provider. There is no regulation of which party is responsible for supervising medical decisions made by parents / family when the medical decisions are detrimental to pediatric patients. Indonesian law does not provide an opportunity for doctors to be involved in overseeing the use of the principle of autonomy for parties outside the patient in the event that the outside party makes a medical decision that does not reflect the patient's best interests or is contrary to the provision of good medical services.

1. Application of Informed Refusal by Family or Guardian Against Child Patients in dr.Bratanata Hospital.

The description of the application of informed refusal by family or guardian to pediatric patients in Indonesia is obtained from research conducted at the Army hospital Dr.Batanata Jambi with class C classifications with 200beds. for 6 months at the Army Hospital dr. Bratanata Jambi in the period October 2018 - March 2019. The method of data collection is done by using the hospital data management system as part of hospital quality indicators (in this case effective communication). It is carried out directly by using the unit in charge of the data unit coordinated by the deputy head of each hospital inpatient room who will record any informed refusal that occur and then report to the data management system to the hospital's communication and information media. The data collected will be verified by the hospital data verification team which also involves 16 internship doctors at the hospital who come down every day to each room to validate and re-educate the patient or family / guardian of the patient to ensure that the patient and / or family / guardian have get adequate information to give a decision.

In this paper, it is shown data of informed refusal in October 2018 period only.In October 2018, there were 90 cases of Informed Refusal, 10 of which were refused by parents or guardians of pediatric patients.The consequence of informed refusal has the potential to endanger the lives of patients as much as 32.2%, the potential to cause disability in patients as much as 25.5% and not potentially cause disability and the danger of the patient's life as much as 42.4%.

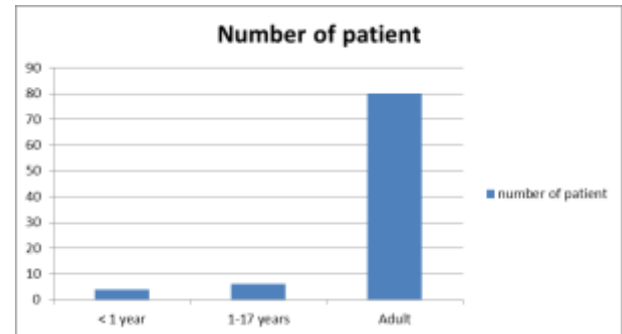


Figure 1. Informed refusal diagram.In dr. Bratanata hospital, October 2018 Period.

2. Role of family in decision Making in Indonesia Contexts

The discourse of human rights and bioethics in Asia, establishes the family as the central unit of autonomous rationality.the family plays a greater role in Asian contexts (including Indonesia) than would be found for example in Northern Europe[16].The Asian values discourse is ideologically tied to an outdated notion of culture as essence, tied to place and determining action. In the triangle of physician, patient and relative, the patient is usually the weakest, whereas the dynamic power structure between the other two actors is intensely negotiated to determine the course of action. In this process, the role of the family is important.

The family remains factually important, because it more often than not has to find the resources to pay for medicine and medical investigations, and because the patient is dependent on family support before, during and after treatment. There are several good reasons for this presumption to respect parental autonomy and family privacy[17]. First, because most parents care about their children, they will usually be better situated than others to understand the unique needs of their children, desire what's best for their children, and make decisions that are beneficial to their children. Second, the interests of family members may sometimes conflict, and some family members may be subject to harms as a consequence of certain decisions. Parents are often better situated than others outside of the family to weigh the competing interests of family members in making a final decision. Third, parents should be permitted to raise their children according to their own chosen standards and values and to transmit those to their children. Finally, in order for family relationships to flourish, the family must have sufficient space and freedom from intrusion by others.

For all of these reasons, we must begins with the assumption that parents are the persons best suited and most inclined to act in the best interests of their children[18], and that in most cases they will do so[19]. In most situations, parents are given wide latitude in terms of the decisions they make on behalf of their children[20].

The intrinsically Western notion and promotion of the individual as the centre of decision-making, which is the basis for the concept of patient autonomy, is not necessarily universally meaningful, possible or desirable,

and that grounded explorations are required to guide a bioethics discourse that is often naïvely ethnocentric, but the straightforward acceptance of family autonomy as a normative bioethical principle may be repressive, dangerous and against the interests of the patient.

3. *Beneficence vs Autonomy in Informed Refusal Which is Taken by Family or Guardian in Child Patient*

There is a conflict between the principle of autonomy with the principle of therapeutic goals (beneficence principle) and the conflict between the value of individual freedom and the value of benefits (social) at the level of value in the application of unlimited informed refusal by family or guardians in pediatric patients requiring ontological, epistemological and axiological studies of the existence of informed refusal by the parent or guardian of the pediatric patient. What is the true nature and purpose of the existence of informed refusal by parents or guardians in pediatric patients? Why does the existence of unlimited refusal informed by the family or guardian have the potential to violate the rights of the child concerned?

Informed refusal exists because of the realization of the patient's autonomy rights. The term autonomy comes from Greek, which is "autos" which means self and "nomos" which means rule, governance, or law[21]. Jhon Stuart Mill defines autonomy as liberty, that is, the sovereignty of the individual over his body and mind[22]. According to Ruth R.Faden and Tom L. Beauchamps, autonomy is rooted in a liberal western tradition that emphasizes the importance of individual freedom and freedom of choice[23]. In the context of legal rights, Ruth R.Faden and Tom L. Beauchamps categorize patient autonomy as a personal right that respects aspects of self-determination. In the world of health services, patient autonomy which is also often referred to as the right to self-determination (The Right of Self Determination) is a basic right or primary right in the health sector. The autonomy rights of these patients come from human rights which then give birth to the right to informed consent and the right to Informed Refusal. Patient autonomy is the main goal in explaining the doctrine of informed consent.

The fact that the practice of health services that promotes the principle of patient autonomy as part of human rights and is even seen as part of justice raises the question of which principle of autonomy will be applied? In situations where the patient does not have the competence because he is a child, it requires the will of the family or person who supervises the child. The problem of informed refusal in pediatric patients by surrogate consent as a manifestation of the patient's autonomy rights that cause disability or death of the pediatric patient brings a conflict between the principle of autonomy with the principle of therapeutic goals (beneficence principle). Beauchamps associates this beneficence element with non-maleficence elements, namely the obligation to perform the best medical action in the best interests of patients. The benefit element is also seen as a form of obligation for doctors / medical service providers in order to maintain and respect human dignity (patients). On the one hand Article 23 of The Health Act

2009 requires patient safety aspects as a benchmark for health services by prioritizing medical and non-discriminatory indications in the best interests of patients and in accordance with medical indications, Article 24 of the Health Act 2009 and Article 51 of the Medical Practice Act 2004 also states that health provider (including doctors) must meet the provisions of the code ethics, professional standards, user rights for health services, service standards and operational procedure standards. But on the other hand, Article 52 of the Medical Practice Act 2004 and Article 32 of the Hospital Act 2009, in which regulates the patient's right (without limits) to give consent or refuse actions to be taken against him, including the rights of parents or guardians to patients who are not competent. This often creates conflict in the practice of health services in hospitals. The desire to protect and respect the patient's autonomous rights that occur at this time often actually negates the patient's autonomous rights by surrendering completely without restrictions to the family or guardian, every decision to be imposed on the patient is entirely in the hands of the family or guardian.

From the perspective of utilitarianism, where the moral value of an action is determined by the consequences of that action, it can be analyzed that unlimited informed refusal by family or guardian that has the potential to endanger lives or cause disability violates the moral rules. Perspective Deontology where the moral quality of an action is determined by the right or duty, actually the duty of the family or guardian to protect (and not just replace) the autonomy rights of the child patient. Likewise with doctors, who have the task of reducing suffering or prolonging the lives of their patients (as a manifestation of the principle of beneficence).

The medical profession has its own autonomous nature which has a certain value system that binds the behavior of doctors, both fellow colleagues and members of the community. This value system branched up to medical ethics. The basic ethics of the medical profession are derived from the time of Hippocrates: "The health of the sufferer will always be my priority" (The health of my patient will be my first consideration) remains a principle that has never changed, and is a series of words that unites the doctors in the world[24]. In relation to patient consent, Besides the principle of respecting patient autonomy, doctors are also bound by the principle of beneficence (The Principle of Beneficence means that all actions taken by a doctor against a patient must benefit the patient in order to reduce suffering or prolong his life) and the principle of justice (The principle of Justice means that doctors must act fairly, do not look at position, do not look at wealth and are impartial in treating patients). Under certain conditions, the two principles serve as a philosophical basis for helping patients, such as in emergencies and unconscious patients, doctors do not need to wait for informed consent to immediately take action that is necessary for the safety of the patient's life (life saving). The basis of the consideration is that medical measures are taken because they are solely to help the soul. Saving the patient's life is of higher

importance than the issue of informed consent. This shows how the doctor in deciding patients who are unconscious and in a state of danger (for example the patient has severe and unconscious bleeding), it is important for him to question and consider whether the patient will agree with actions to be taken if he is conscious (eg giving a blood transfusion). If there is a reason for this, then this fact becomes important in justifying such actions (giving blood transfusions to patients with severe bleeding) even when patients later, perhaps for reasons of belief and religion, blame and prosecute doctors for having performed the blood transfusion procedure[25].

Efforts to protect the interests of patients in upholding the principle of autonomy become important when there is a disagreement between parents or guardians of children and the medical team that treats these patients. The principle of beneficence in medical practice, one of which is manifested in the evidence-based medicine approach (Evidence based medicine (EBM)[26] is the integration of scientific evidence in the form of the best research results with the clinical ability of doctors and patient preferences in the decision-making process of medical services) in providing medical care to evidence-based patients (Evidence-based health care is health care for an individual by using the best current evidence in making clinical decisions. The best current evidence is to update information from valid and relevant research on the effects of sharing forms of health care)[27]. The application of EBM that results in evidence-based medical care is an effort to fulfill the principle of beneficence to patients. In application in the field, often the principle of beneficence is difficult to apply because it is prevented from an informed refusal conducted by parents or guardians as the implementation of unlimited delegation of authority to parents or guardians in making the decision on the pediatric patient. The principle of beneficence in pediatric patient health services is prioritized, not as an effort to kill the principle of respecting the autonomy of the pediatric patient, but the principle of beneficence is put forward to restore and maintain the autonomy rights of pediatric patients that have not yet had the competence until the child reaches maturity and has the right of full autonomy to be able to make his own decisions as part of the right to determine his own destiny[28]. If a child dies or has a disability due to medical treatment in accordance with his best interests cannot be given due to barrier of his parents' or guardian's refusal, then the child's death or disability has wasted the child's opportunity to have full autonomy rights as a competent individual in later. The principle of beneficence must be present to restore and maintain the autonomy of these pediatric patients, so that the child may be able to grow and develop as they should reach competent and autonomous adult individuals.

The application of unlimited refusal informed by parents or guardians in pediatric patients has also violated the principle of justice, where children cannot get access to quality health services as obtained by adult patients. The law must be present to provide protection for the

rights of children who have been harmed by another party, as a form of legal protection[29].

4. *Comparison of Informed Refusal Law in Pediatric Patients with Netherland Law (Civil Law System)*

N.B.W. regulates qualification terms and conditions related to enforcement of patient autonomy between ages before 12 years, 12 to 16 years, and 16 years and above. Based on Article 7: 465 par. 5 and Article 7: 450 par. 2 N.B.W, from the age of 12 to the age of 16, patients can be considered competent. Competence at that age is limited to that age and is considered to have competence as long as it is able to properly consider and appreciate its interests. The basis used is to assess competence at that age is the suitability of the actions of patients at that age with the standard of providing good medical services. If a patient of that age commits an action that is contrary to the provision of good medical services, the medical service provider can represent the patient in carrying out his competence[30]. Based on the arrangement in N.B.W., patients who are 16 years old are essentially competent in order to declare their will in medical care. Every adult has the capacity to determine his destiny.

In situations where the patient does not have the competence because he is child, it requires the will of the family or person who supervises the child. This need is not absolute if the will of the family or the person supervising is contrary to the provision of good medical services or to prevent more serious consequences for the patient, the medical service provider can perform medical treatment without the consent of the family or supervisor. This can only be done by a medical service provider if medical treatment for the child is intended to prevent serious consequences for the patient. In addition, medical service providers can also ignore the will of the patient's family who is not yet old enough if the will of the family or the child's supervisor is against the provision of good medical services. This was also used by the Netherland in arranging medical care contracts in hospitals as regulated in Article 7: 465 par. 4 N.B.W.

In patients who have limited competence (N.B.W. applies to patients who are aged 12 to less than 16 years), medical care for patients also requires the will of the family or supervisor of the child. This is not absolute. In patients like this, medical service providers must also involve the patient in making decisions. If the patient's will is contrary to the will of the family or the supervisor, the medical service provider can ignore the will of the family and follow the patient's will for several reasons. First, the actions of medical service providers in order to prevent serious consequences on patients. Second, the patient wants medical treatment and his decision does not conflict with the provision of good medical services. Third, the patient does not have the ability to appropriately appreciate the best interests, while the family has stated its will which is contrary to the provision of good medical services. This can be seen from the arrangements in Article 7: 465 par.2 jo.par.4 and Article 7: 450 par.2 N.B.W.

In the Netherlands, based on Article 7: 450 par. 2 N.B.W. , the position of parents does not absolutely replace the autonomy rights of children aged between 12 and before 16 years. The rights of these parents depend on the best interests of the patient. The doctor also has a legal interest to determine the patient at that age. That is part of good medical practice. In patients who have reached the age of 12 years and have not reached 16 years, there is an obligation to also involve the patient in making decisions as much as possible. However, at that age there are some people who can represent their legal interests, namely their parents or those who legally guard it (regulated in article 7: 450 par. 2 N.B.W.). In addition, the party representing them can also be the party whose support or person is appointed as their advisor in relation to their autonomy in medical care, as formulated in Article 7: 465 par. 2 N.B.W. The authority to represent is not absolute. The medical service provider may waive their legal authority to declare their will if there are serious consequences that will arise if not handled or medical refusal from the party concerned will bring serious consequences to patients and their actions are contrary to the provision of good medical services, as stipulated in Article 7: 465 par. 6 N.B.W, Article 7: 450 par. 2 N.B.W and Article 7: 450 par. 4 N.B.W.

In the Netherlands, in pediatric patients aged 0 to before 12 years there is no involvement of the child's role in decision making. The person responsible for representing his legal interests is the parent who is responsible for the child or the person who looks after the child. This is confirmed in Article 7: 465 par. 1 N.B.W. The rights of these people are not absolute. There are situations in which medical service providers do not need to ask the will of the parents or the person looking after the child, which is to prevent serious pain in the patient. In pediatric patients aged 0 to less than 16 years, medical service providers can be legal representatives in making decisions and ignore the wishes of the child's parents or their representatives if the actions carried out by parents or their representatives are contrary to the standards of providing good medical services. , as affirmed Article 7: 465 par. 4 N.B.W. In pediatric patients aged 0 to less than 12 years, it is not necessary to involve the child in making medical decisions, as regulated in Article 7: 465 par. 5 N.B.W.

5. *Comparison of Informed Refusal Law in Pediatric Patients with United Kingdom Law (Common Law System)*

According to the Family Law (Reform) Act 1969 states that children are anyone under the age of 18 years. The law effectively divides pediatric patients into 3 main categories when deciding whether they meet the capacity requirements to provide legal approval, namely Children 16-18 years old, Children under 16 who are Gillick-competent, Children under 16 years who are not Gillick-competent[31].

Children aged 16-18 years: In England and Wales, the 8th Family Law (Reform) Act of 1969 states that:

‘8(1) – The consent of a minor who has attained the age of sixteen years to any surgical, medical or dental treatment which, in the absence of consent, would constitute a trespass to his person, shall be as effective as it would be if he were of full age; and where a minor has by virtue of this section given an effective consent to any treatment it shall not be necessary to obtain any consent for it from his parent or guardian [32].

Thus, pediatric patients older than 16 years but younger than 18 years are considered to have sufficient capacity to provide treatment approval. Children under the age of 16 who are not Gillick competent (in children who do not have sufficient maturity, intelligence and understanding), they cannot give legal approval.

In the case of *Re R (a minor)* [1993] 2 FLR 757, a child aged ten months was suffering from B-cell lymphoblastic leukemia. Her doctors considered that she needed treatment over the next two years which could involve blood transfusions at any time. Her parents were practicing Jehovah's Witnesses with their beliefs preventing them from consenting to such treatment. Application by the local authority was obtained to authorise the use of blood products against the parents' wishes. The parents were concerned that any order made should not give the doctors blanket authority to act without consulting them. The court held that the child's need for blood was so overwhelming that for her welfare, the parents's wishes had to be overridden and the use of blood products authorized. To overcome the parents's fear, the court phrased the order that in imminently life threatening situations the child should be given blood products without the consent of the parents, but otherwise the doctors should consult with the parents and consider other options. Only if there was no reasonable alternative should the doctors be at liberty to administer blood products without the parents's consent. Following the above *Re R* case, you may proceed with blood transfusion only if you believe there are no other reasonable alternative to save the child's life[33].

Handling of pediatric patients where there is a disagreement between parents and the medical team: in the United Kingdom as stipulated in the case of *Re B (A Minor) (Wardship: Medical Treatment)* [1990] 3 All ER 92, the court's decision considers the welfare of children as the most important consideration, although the wishes of parents are taken into consideration. The court puts forward the best interests of the child[34].

6. *Limitation of Informed Refusal By Surrogate Consent In Pediatric Patient*

State intervention is justified not only when a parental refusal is contrary to a child's best interest, but also when the parental refusal places the child at significant risk of serious preventable harm. This article takes as its point of departure the best interest (positively) and harm principles (negatively) concomitantly provides a stronger and comprehensive basis as a threshold for state intervention.

7. Threshold For Intervention : Best Interest

Parental authority is not absolute, however, and when a parent acts contrary to the best interest of a child, the state may intervene[35]. The doctrine of *parens patriae* holds that the state may act as “surrogate parent” when necessary to protect the life and health of those who cannot take care of themselves, including children[36,37].

Brock and Buchanan define best interest as “acting so as to pro-mote maximally the good of the individual.”[38] Beauchamp and Childress define the best interest standard as one in which “...a surrogate decision maker must determine the highest net benefit among the available options, assigning different weights to interests the patient has in each option and discounting or subtracting inherent risks or costs.”[39] the standard requires the surrogate to act so as to always make the decision most favorable to the child.

In pediatric patients, autonomy does not automatically become an absolute right of parents. Vivienne Harpwood believes that the basis for making medical decisions in order to represent pediatric patients must be based on the child's best interests[40]. Irresponsible medical decisions on the part of parents who consciously ignore the child's medical needs are a form of crime. In the Common Law system, this is reflected in the judge's decision in the case *R v. Sheppard*[41] (In the case of *R c. Sheppard*, parents of 16-month-old babies who die from hypothermia with malnutrition. The basis of the accusation in that case was the negligence committed by Sheppard which resulted in the baby-Martin Sheppard- becoming a victim and suffering. Under the law, their actions take the form of negligence (omission), which is failing to provide something appropriate for the baby's needs) and *Gillick v. West Norfolk and Wisbech Area Health Authority* [1986]. Parental status carries the consequences of parental responsibility for the children under their authority. The act of representing the child patient is part of the responsibility of being a parent to the child for the child's benefit. In the case of *R v. Sheppard, F v. West Berkshire Health Authority, R v. Harris and another, and Gillick v West Norfolk and Wisbech AHA and another*, the position of the doctor representing the child in making medical decisions should not be understood as an attempt to take over the responsibilities of parents and children's affairs. In principle, parents and doctors have the right to protect the best interests of the child patient.

The nature of interests are frequently complex. Although medical considerations are important, a child's interests will also be affected by emotional and physical accompaniments of the chosen course. Best interests all too often may be reduced to objective medical interests alone[42]. According to Jo Bridgeman, to assess the best interests of patients is not based solely on medical measures, but also combines medical interests, emotions and other aspects of well-being, namely whether the proposed medical treatment brings benefits to children emotionally, psychologically, and socially. Such construction can be used to control good medical decision making in pediatric patients. The best interests in the child's medical care should not overlap with the parents'

legal responsibilities to the child. The position of parents or guardians cannot replace the patient's right to autonomy.

Circumstances where the family or guardian refuse an action and the hospital and the care giver feel safe and do not make an issue of informed refusal to the pediatric patient may provide teleological or consequentialist justification. Justification that bases on the results it brings benefits or kindness to as many people as possible (the greatest good for the greatest number of people) but sacrifices the best interests of the child. This is unacceptable for a deontologist who holds that the devolution of authority to parents or guardian in pediatric patients is not to sacrifice the best interests of patients, it is the obligation of the parent or guardian of the child to protect and ensure that the best interests of patients should be the main consideration. This view requires all parties to play a role in ensuring that children get their rights to get health services best. Parents or guardians protect the best interests of children through the delegation of authority given, the care giver oversees the decision given by the parent or guardian whether it is in the best interests of the child, so this is in accordance with the pattern of service focusing on patients, not other parties.

The application of informed consent and informed refusal as the implementation of the patient's autonomy rights is very closely related to how the concept of Human Rights is the basis. The view of the Indonesian nation about human rights that human beings as God's creatures bear the aspects of individuality and aspects of sociality should animate the formation and implementation of Informed Refusal related to children in Indonesia. In its application in the Pancasila-based country of Indonesia, the autonomy rights of patients contained in the Informed Refusal by the family or guardian when the patient is not competent, must continue to recognize and respect human rights but must also be limited and adjusted to the values contained in Pancasila.

8. Threshold For Intervention :Harm Principle

State intervention is justified not only because a decision is contrary to the child's best interest, but also because it places the child at significant risk of serious harm. In the medical setting, courts have frequently placed a high burden on the state to show that medical treatment is necessary before compelling treatment over parental objections, and the state is most likely to interfere with a parent's decision when the child is suffering from a serious and potentially life-threatening illness or injury that can be readily managed with medical treatment. The state must establish that parental choices endanger the child and thus fall below the acceptable threshold[43]. In these cases, the state acts in *loco parentis*, in the place of the parents.

In general, courts have gone against parents when the life of a child is endangered, but have typically given great discretion to parents in situations that are not imminently life-threatening[44]. Having identified the harm principle as a basis for state action, the next step is to further define the harm threshold by identifying the level

of harm to be tolerated in parental decisions. It seems clear that not all harms should trigger state intervention. Several of these have further refined the definition of serious harm to include loss of life, loss of health, loss of some other major interest, and the deprivation of basic needs[45]. Defines the harm threshold for state intervention: First, the parental decision to deny treatment will place the child at significant risk of serious preventable harm[46]. Second, the harm standard requires that the harm be imminent, requiring immediate action to prevent it.[47] When a parental refusal does not place a child imminently at significant risk of serious harm, state intervention should be postponed and attempts made to work with the child's parents or guardians in a non-confrontative manner to resolve the issue. Rather, state intervention should require that there be expert consensus, ideally supported by sound evidence, that interference with the parental decision and the provision of treatment has a high probability of being successful[48]. Third, For state action to be justifiable, interference with the parental decision must offer net benefit to the child.[49] The harm prevented must be more substantial than the harm that will result by interfering with parental choice. Fourth, the extent of state intervention and the treatment allowed under the authority of the state should represent the least intrusive alternative that will reduce harm to the child and minimize the impact on parental authority. Most of the time removal of the child from the home will not be necessary, and should not be contemplated unless every other possibility has been considered.

Fifth, the pursuit of state intervention must be generalizable and impartial in the sense that all similar cases would also result in state intervention. The decision to seek state intervention should not be influenced by morally irrelevant considerations (i.e., the religious nature of the decision). For example, state intervention in the case of refusal to consent to a blood transfusion is justified not because the parental refusal has a religious basis, but because the parents are refusing a potentially life-saving therapy that meets the conditions above. A parent's reason for the decision should not be a factor in whether state intervention is sought. Rather, the likely outcome of their decision is the only relevant factor: is it likely to result in serious harm to a child.

IV. CONCLUSION

In ontological, epistemological and axiological studies, Informed refusal exists because of the realization of the patient's autonomy rights. The problem of informed refusal in pediatric patients by Surrogate Consent as a manifestation of the patient's autonomy rights that cause disability or death of the pediatric patient brings a conflict between the principle of autonomy with the principle of therapeutic goals (beneficence principle). Efforts to protect the interests of patients in upholding the principle of autonomy become important when there is a disagreement between the parents or guardians of children and the medical team that handles these patients. however, the principle of beneficence is prioritized to

restore and maintain the autonomy of these pediatric patients, so that the child may be able to grow and develop as they should reach competent and autonomous adult individuals. The position of the parent or guardian does not replace the patient's right to autonomy but ensures and safeguards that the child will get services based on the child's best interests as part of the parents' responsibility towards the child.

In a Comparative study of law in the UK and the Netherlands concerning cases of informed refusal by surrogate in pediatric patients, two problems are found, namely the regulation of age qualifications in determining the competence of pediatric patients and the position of third parties in the principle of pediatric patient autonomy. In Indonesia there is no regulation on age qualifications in determining the competence of pediatric patients. The existence of the Medical Practice Act 2004, The Health Act and Hospital Act 2009, and even the Approval of Medical Action Regulation does not regulate the notion of the qualifications of a patient who is considered to have the competence to carry out his autonomy in a medical care contract.

The rule of law in Indonesia also has not yet created a balance against efforts to protect patient autonomy when the patient lacks competence. Article 13 of The Approval of Medical Action Regulation granting the same position to patients or their families as parties who have the authority / authority to carry out patient autonomy in the form of rejection or approval of proposed interventions medical that actually violates the autonomy of the child's own patient.

Changes are needed in legislation (Health Act, Hospital Act, Medical Practice Act) which regulates the competency qualifications of pediatric patients; It is necessary to regulate the position of third parties in the principle of autonomy of pediatric patients to create a balance against efforts to protect patient autonomy when the patient has no competence. Reconstruction of regulations governing the qualifications that must be met before the family can be involved in making these decisions and the regulation regarding the limitation of family or guardian authority on pediatric patients based on two important principles namely positively health care must respect the best interests of patients, and negatively health services must avoid situations that endanger the safety (harm principles) of pediatric patients as an effort to fulfill human rights to health services guaranteed by the Indonesian Constitution.

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