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# Futile therapy protocols: A 3-year review of the implementation of Polish guidelines on ineffective organ function maintenance in pediatric intensive care unit—A pilot study

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## Abstract

**Background and objectives** This study aimed to evaluate the implementation and impact of futile therapy (FT) protocols in pediatric intensive care units (PICUs) in Poland.

**Methods** A retrospective analysis 48 futile therapy protocols signed at three academic pediatric intensive care units (PICUs) in southern Poland. A designated individual at each of the hospitals gathered detailed data from the protocols.

**Results** The children's ages ranged from 1 month to 18 years, the primary diagnoses were neurological conditions ($n=22$, 45.83%), oncological conditions ($n=11$, 22.92%), and prematurity ($n=9$, 19.75%). The most common concomitant complications included severe birth asphyxia ($n=21$, 43.75%), chronic respiratory failure ($n=18$, 37.50%), circulatory failure ($n=10$, 20.85%), and acute respiratory failure ($n=10$, 20.85%). More than one-third of the patients were discharged ($n=17$, 35.42%), while the remaining patients continued treatment in their primary wards ($n=31$, 64.58%). Information on the 37 patients treated at these two centers shows that most ($n=25$, 67.57%) died in the ward where they were hospitalized. The survival time after the protocol was signed ranged from 2 to 705 days, with a median of 42 days.

**Conclusions** The guidelines implemented in the study centers facilitated decision-making regarding the discontinuation of FT. The protocol was most frequently applied to newborns and children under 1 year of age. A median of survival time after implement FTP affirming the positive role of palliative care.

**Keywords** Pediatric intensive care, Futile therapy, Life-sustaining treatment, Pilot study

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## Introduction

The admission and treatment of a child in the pediatric intensive care unit (PICU), regardless of the underlying cause, is always a stressful experience for the parents. This stress intensifies when doctors inform them that their child will not recover. Such situations are challenging for both families and medical teams. To prevent the continuation of therapies that are deemed futile, pediatric intensivists may decide to implement a futile therapy protocol (FTP). Futile therapy (FT) refers to therapy that maintains organ function without bringing any benefits to the patient and without supporting the assumed therapeutic goals. FT, which prolongs the dying process, is associated with the suffering of patients and their families and the violation of human dignity. FT is therefore similar to "low-value care," defined as care that is unlikely to benefit patients and can even unintentionally harm them [1, 2]. In 2021, the Pediatric Section of the Polish Association of Anesthesiology and Intensive Therapy (PAAIT) developed and published special guidelines [3]. The aim of this protocol is to formally discontinue advanced treatments when they no longer provide benefit, marking the transition to palliative care. Prior to implementing the protocol, specialist consultations related to the underlying condition, as well as multidisciplinary consultations, must be carried out. FTP is a protocol for the withdrawal or withholding of certain forms of treatment owing to their futility, with the only motivation being the good of the patient, considered individually for each patient. The FTP is a separate and formal medical document. Although parental consent is not required to sign the FTP report, parents should be invited to participate in the consultation forum so that they have the opportunity to ask questions and to express their doubts and concerns. In Poland, in controversial situations or if the parents do not agree with the treatment, we usually refrain from withdrawing therapy, to avoid negative media campaigns and misleading publicity. In Poland, this issue remains controversial, particularly in non-medical circles, and is often mistakenly equated with euthanasia. Many doctors are reluctant to make decisions regarding the limitation of life-sustaining treatment (LLST) owing to concerns about media attention. The decision-making process is a crucial aspect of patient care planning. The guidelines introduced in Poland in 2021 are designed to standardize and unify the process of LLST decision-making.

Our study aimed to analyze the futile therapy protocols implemented over the past 3 years, based on documentation from three major clinical centers. Specifically, we sought to identify the age and disease groups in which futile therapies were applied, determine which treatments were discontinued, and assess patient survival outcomes.

**Table 1** Patients'age ($n=48$)

| Age | Number | Percentage |
|---|---|---|
| < 1 year | 20 | 41.67 |
| 1–6 years | 8 | 16.67 |
| 7–18 years | 20 | 41.67 |

## Materials and methods

We conducted a retrospective analysis of 48 futile therapy protocols signed at three academic pediatric intensive care units (PICUs) in southern Poland. We analyzed clinical cases for which FTPs were prepared. A designated individual at each of the hospitals gathered detailed data from the protocols, including demographic information, medical history, and the patient's clinical status at the time the protocol was signed. The data also included details of subsequent palliative care provided and the patient's survival or death. To assist in categorizing patients based on their clinical situation and other characteristics, we utilized the concept of "normal life." Although what constitutes a "normal life" is subjective, varying greatly depending on cultural, social, and individual perspectives, we define it here as the absence of chronic illness prior to hospitalization and lack of hospitalization due to serious diseases (more generally, it refers to the routines and experiences that most people encounter in their daily lives). Data were collected using an Excel spreadsheet and analyzed statistically. The study group was characterized using descriptive statistics. In order to examine the relationship between two qualitative variables, the Chi2 test was used. The significance level of $p<0.05$ was assumed. Statistical analysis was performed in Statistica 13.3 (TIBCO Software Inc., 2017). The study design was approved by the Ethics Committee of the Medical University of Lublin (KE/651/07/2024).

## Results

A total of 48 futile therapy protocols from three pediatric university hospitals were analyzed. The children's ages ranged from 1 month to 18 years (minimum 0.1 years, maximum 18 years), with a median age of 3.5 years. The protocols were most commonly signed for newborns and infants under 1 year of age ($n=20$, 41.67%), followed by school-aged children between 7 and 18 years ($n=20$, 41.67%) and less frequently for children aged 1–6 years ($n=8$, 16.67%). Detailed data are shown in Table 1.

The futile therapy protocols were applied to 29 boys and 19 girls. The primary diagnoses were neurological conditions ($n=22$, 45.83%), oncological conditions ($n=11$, 22.92%), and complications related to premature birth ($n=9$, 19.75%). Detailed data are presented in Table 2.

The most common concomitant complications included severe birth asphyxia ($n=21$, 43.75%), chronic respiratory failure ($n=18$, 37.50%), circulatory failure

**Table 2** Primary disease ($n=48$)

| Cause | Number | Percentage |
|---|---|---|
| Neurological | 22 | 45.83 |
| Oncological | 11 | 22.92 |
| Prematurity | 9 | 18.75 |
| Congenital heart disease | 2 | 4.17 |
| Genetic | 2 | 4.17 |
| Non-traumatic intracranial haemorrhage | 1 | 2.08 |
| Others | 1 | 2.08 |

**Table 3** Concomitant problems ($n=48$)

| | Number | Percentage |
|---|---|---|
| Severe birth asphyxia | 21 | 43.75 |
| Chronic respiratory failure | 18 | 37.50 |
| Circulatory failure | 10 | 20.85 |
| Acute respiratory failure | 10 | 20.85 |
| History of cardiac arrest | 5 | 10.42 |
| Renal failure | 4 | 8.33 |

**Table 4** Department-wise number of hospitalized patients ($n=48$)

| Department | Number | Percentage |
|---|---|---|
| Paediatric intensive care unit | 35 | 72.92 |
| Pulmonology | 1 | 2.08 |
| Cardiology | 2 | 4.16 |
| Oncology | 2 | 6.16 |
| Neonatology | 7 | 14.58 |
| Gastroenterology | 1 | 2.08 |

($n=10$, 20.85%), and acute respiratory failure ($n=10$, 20.85%). Detailed data are shown in Table 3.

In nearly three-quarters of the children, the primary health issue was present from birth ($n=35$, 72.92%), and for the remaining children, the condition had been present for at least 6 months. Most children did not experience what might be considered a "normal life" after birth owing to their health challenges ($n=36$, 75%), although a quarter of them had such experiences ($n=12$, 25%). The futile therapy protocol was most frequently signed by ICUs ($n=35$, 72.92%) and less often by the neonatology department ($n=7$, 14.58%). Detailed data are presented in Table 4.

More than one-third of the patients were discharged ($n=17$, 35.42%), while the remaining patients continued treatment in their primary wards ($n=31$, 64.58%). Information on the 37 patients treated at these two centers shows that most ($n=25$, 67.57%) died in the ward where they were hospitalized. The survival time after the protocol was signed ranged from 2 to 705 days, with a median of 42 days. This means that among the children who died in the ward, one-quarter survived for no longer than 30 days, half survived for 42 days, and another quarter survived for at least 88 days. Only one child survived for more than a year under the futile therapy protocol, living for nearly 2 years (705 days). These data reflect the outcomes of the most critically ill children who were neither discharged nor sent home.

**Table 5** Patient's age and having tracheostomy/peg ($n=48$)

| Age | Tracheostomy ($n=20$) | No tracheostomy ($n=28$) | *p* |
|---|---|---|---|
| < 1 year | 6 (30.00%) | 14 (70.00%) | 0.383 |
| 1–6 years | 4 (50.00%) | 4 (50.00%) | |
| 7–18 years | 10 (50.00%) | 10 (50.00%) | |
| **Age** | **PEG ($n=16$)** | **No PEG ($n=32$)** | ***p*** |
| < 1 year | 3 (15.00%) | 17 (85.00%) | **0.038** |
| 1–6 years | 5 (62.50%) | 3 (37.50%) | |
| 7–18 years | 8 (42.00%) | 12 (60.00%) | |

Bold values represent statistically significant

Children in the youngest age group (under 1 year) underwent PEG insertion less frequently (15%) than preschoolers (62.5%) and school-aged children (40%), $p=0.038$. These younger children also had fewer tracheostomies (30%) than preschool (50%) and early school-aged children (50%), $p=0.383$. Detailed data are presented in Table 5.

School-aged children (55%) were more likely to have experienced a "normal life" than preschool children (12.5%) and infants under 1 year (0%), $p=0.004$. School-aged children were also more likely to be discharged (50%) than infants (25%) and preschool children (25%), $p=0.203$. Infants were more likely to die in their department (76%) than preschool (60%) and school-aged children (60%), $p=0.566$.

## Discussion

Maintaining organ functions that do not benefit the patient or contribute to the achievement of therapeutic goals is referred to as futile therapy. This approach prolongs the dying process and is associated with increased suffering for both patients and their families, as well as a violation of human dignity. In Poland, pediatricians, often in collaboration with pediatric anesthesiologists, were the first to address the withdrawal of LLST in children, followed by adult anesthesiologists, neonatologists, pediatric section of PAAIT, and internal medicine specialists [3–6]. Pediatricians were the first to highlight prolonged therapies that failed to benefit patients, particularly in children with genetically determined complex congenital defects. Our study revealed that most analyzed protocols were related to neonates. Decisions made during this early clinical stage are critical for planning ongoing care ( pediatric advance care plans). Discontinuing futile therapy in infancy, while providing continued palliative or peri palliative care, helps prevent unnecessary suffering for both young patients and their families [7]. Perinatal palliative care (PPC) is an increasingly important option for pregnant women carrying fetuses with life-limiting

conditions who choose to continue their pregnancies [8]. As an interprofessional, holistic approach, PPC aims to reduce suffering and enhance quality of life, respecting the family's values and preferences [9]. As an interprofessional, holistic approach to care, PPC aims to minimize suffering and maximize quality of life in accordance with the family's values and preferences [9]. Children with chronic critical illness (CCI) are high-risk patients with persistent multiple-organ dysfunction and functional morbidities requiring recurrent or prolonged critical care. Nonetheless, the formal definition of CCI remains unclear. The current definitions of pediatric CCI, while variable and often subjective, form the basis for a more precise definition of this patient population, based on examination of factors related to complexity (including the patient's medical complexity and technology dependence) and chronicity (including prolonged PICU length-of-stay and hospital readmission) [10].

In Poland, discussions on quality of life are often contentious. The World Health Organization defines quality of life as an individual's perception of their position in life, considering the culture, value systems, goals, expectations, standards, and concerns that shape their perspective [11]. Most ethicists agree that we should not decide what constitutes a life worth living. However, this question becomes more complex for children, who may lack the self-awareness to understand their condition or communicate their thoughts. In Japan, discussions on discontinuing therapy in children with chronic respiratory and circulatory failure generally begin only when their condition deteriorates. According to experts, intensive care should be reconsidered when a chronically ill child experiences a sudden deterioration in their clinical status. Everyday questions arise, such as: Can a child with severe cerebral palsy die from pneumonia? Can they refuse antibiotics? Can a child with end-stage renal failure be denied a blood transfusion? Can a child with congenital hydrocephalus and minimal consciousness be denied reimplantation of a shunt system? When most medical issues can be addressed, should we still attempt to sustain life if the child's quality of life remains poor [12]?. Medical interventions are intended to achieve specific therapeutic goals, and it is crucial to consider the relativity of these goals. This means that while a patient may survive a critical condition or surgery, they may remain dependent on life-supporting treatments and unable to live outside the ICU [13].

This issue is not unique to Poland. In Spain, nearly half of pediatric ICU deaths occur after the withdrawal of LLST [14]. In 2008, the Italian Society of Neonatal and Pediatric Anesthesia and Intensive Care issued recommendations, acknowledging that end-of-life decisions are among the most challenging in pediatric intensive care [15]. A Taiwanese study found that the integration of a palliative care consultation service, following a national revision of the "Palliative Care Act," led to greater acceptance of treatment withdrawal and a reduction in ICU care intensity at the end of life [7]. Similarly, Chilean pediatric ICUs and the American Academy of Pediatrics have provided recommendations on forgoing LLST [16, 17]. In 2021, a team of experts appointed by the Patient Ombudsman developed the "Standards of Conduct in Medical Therapies Used at the End of Life." That document addresses an extremely important issue related to FT, which is that it should be avoided because it is detrimental to the patient. The solutions proposed in the 2021 standards, such as a consulting the patient's proxy or living will, are appropriate for use in the care of adult patients [18].

Another group of patients requiring futile therapy protocols are those who suddenly fall ill owing to trauma or oncological disease, and whose condition deteriorates despite treatment. In these cases, the ethical dilemma is less about discontinuing treatment and more about avoiding the prolongation of death. During the initial phase of treatment, everything possible is done to save the patient, but the eventual outcome is often uncertain. As prognosis worsens, time-limited trials are used to allow the patient a chance to survive a potentially fatal situation [19]. However, when death is inevitable, continued intensive care becomes futile. In Poland, we do not perform extubation or disconnect mechanical ventilation (except when death has been pronounced) and do not stop feeding the patient prior to death. Withdrawing catecholamines, blood transfusions, and renal replacement therapy or withholding intubation and mechanical ventilation help to avoid prolonging dying. In such cases, a palliative care approach can offer more benefit, allowing the patient to spend their remaining time with family, away from hospital equipment. One-third of the patients in our study were discharged to home hospice care, significantly improving their quality of life. Hospice care is a model of compassionate care for those with life-limiting conditions, focusing on pain and symptom management, emotional support, and meeting the patient's and family's needs [20, 21]. While some children remained in the hospital, discontinuing burdensome therapies also improved their quality of life, with the median survival time after initiating futile therapy being 42 days, reflecting the positive impact of palliative care. The patients who survived and were discharged from the hospital (usually into hospice care) were those who were able to function outside the ICU despite being chronically ill. These were patients who were breathing independently or had a tracheostomy, but due to their chronic clinical condition, had not undergone invasive life-saving procedures. Surprisingly, discharge from ICU turned out to be the most beneficial action for such patients, minimizing the risk of

complications arising from invasive methods involving aggressive treatment.

Here, the association between chronic respiratory failure and the need for tracheostomy was not related to the patient's age, whereas the need for PEG or invasive feeding was significantly greater in the older patient group. The results of a meta-analysis [22] suggest that tracheostomy performed within 14 days of ventilation can reduce the time spent on ventilation and the length of hospital stay, with no effect on mortality. Further, the indications for PEG can be individualized and decisions regarding PEG insertion made by a multidisciplinary team, considering all of the relevant circumstances [23].

Effective communication with parents and fostering mutual trust are crucial for ensuring decisions that align with the best interests of the child. In practice, if both parents oppose the FTP, we do not continue preparing the protocol. Therefore, although the guidelines for FTP do not required parental consent, our data set excludes cases where the parents did not agree with the medical decision. In most cases, efforts were made to provide the family with ample time, psychological support, and reassurance regarding the appropriateness of the decision. However, it is important to note that the decision to implement a futile therapy protocol is a medical one and does not require parental consent. This can sometimes lead to conflicts, as we have observed in recent months in Poland.

A limitation of our study is its reliance on data from only three centers. This pilot study is ongoing, and we are expanding our database by inviting additional pediatric hospitals in Poland to participate. Another limitation is the lack of data regarding the patients' clinical condition after discharge into palliative care. Such data should be examined in future studies.

## Conclusion

The guidelines implemented in these study centers facilitated decision-making regarding the discontinuation of FT. In these centers, FTP was most frequently applied for newborns and children under 1 year of age. A median of survival time after implement FTP affirming the positive role of palliative care.

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**Author contributions**
M.D., B.R., A.Ś-B. designed the study and drafted the manuscript. M.D., B.R., A.Ś-B. collected the data. A.A. conducted the data analysis. M.D. and B.R. prepared the final version of the manuscript. A.Ś-B. and A.A. critically reviewed and edited the manuscript. All the authors read and agreed to the published version of the manuscript.

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**Data availability**
The datasets used and analysed during the current study are available on: https://uniwersytetmedyczny-my.sharepoint.com/:x:/g/personal/annaaftyka_365_uml_edu_pl/EeJp-AVUfJVKmaInkpcwr-sBBjrAGEbThnlYtygZ8Yzlxw?rtime=L2RrsBZ23Ug%26;nav=MTVfezAwMDAwMDAwLTAwMDEtMDAwMC0wMDAwLTAwMDAwMDAwMDAwMH0.

## Declarations

**Ethics approval and consent to participate**
The study design was approved by the Ethics Committee of the Medical University of Lublin (KE/651/07/2024). It wasn't experiment on humans. There was no need to obtain consent to participate. We used available medical documentation with the consent of the Ethics Committee. The study was conducted in accordance with the Declaration of Helsinki.

**Consent for publication**
Not applicable.

**Competing interests**
The authors declare no competing interests.

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## Publisher's note