

Adequacy of therapeutic effort: Challenges in pediatrics

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ABSTRACT

The term “therapeutic limitation” has been replaced by “adequacy of therapeutic effort” and is defined as the decision to withhold or withdraw diagnostic and therapeutic measures in response to the patient’s condition, avoiding potentially inappropriate behaviors and redirecting treatment goals towards comfort and well-being. In the pediatric population, this decision is even more challenging given the nature of the physician-patient-family relationship and the paucity of guidelines to address treatment goals.

The adequacy of therapeutic effort is framed by ethical and legal principles, but, in practice, there are several challenges. Each adequacy process is unique and dynamic, and should be addressed by taking into account with what measures, how, when, and in whom it should be implemented.

Keywords: *pediatrics; palliative care; medical futility; withholding treatment; advance care planning.*

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INTRODUCTION

Technological advances in health care have led to a significant increase in pediatric patients' survival and, consequently, in the prevalence of life-limiting and life-threatening diseases. Life-prolonging technology is not exempt from harm and often has an impact on function and quality of life; therefore, health care providers must consider whether anything technically possible is ethically adequate.¹ In recent years, it has been proposed to have the concept of "therapeutic limitation" replaced by "adequacy of therapeutic effort" reflecting that care changes response to the course of disease and that it is neither limited nor discontinued, but redirected towards comfort and well-being.^{2,3}

The adequacy of therapeutic effort in pediatrics is especially complex because of the unique nature of the physician-patient-family relationship.^{4,5} The assumption that pediatric patients are in good health and do not suffer from catastrophic illness turns a difficult decision into a moral and emotional challenge. Other barriers include the absence of universal standards for these practices and the paucity of guidelines to address treatment goals. Understanding the importance of respect for life and the prevention of suffering resulting from extreme treatments, we propose an updated review of the adequacy of therapeutic effort, exploring its challenges and suggesting a practical plan for its implementation based on questions.

LIMITATION OR ADEQUACY OF THERAPEUTIC EFFORT?

The population candidate for palliative care and possibly for an adequacy of therapeutic effort is broad and heterogeneous, but is characterized by presenting life-limiting or -threatening conditions. In the former, there is no reasonable hope of cure, while the latter includes life-threatening conditions for which curative treatment may be feasible, but could fail.⁶

The term "therapeutic limitation" describes the withholding or withdrawal of life-prolonging treatment.³ Recently, it has been proposed to have it replaced by *adequacy or redirection of therapeutic effort*, defined as the adjustment of treatment to the patient's clinical situation, based on the assumption that care changes and is redirected towards comfort and well-being.^{2,3} The two main strategies—withdrawal and withholding of measures—seek to avoid potentially inappropriate procedures that do not offer a reasonable chance

of survival or quality of life or that are not in the best interests of the child.^{7,8} The implementation of this novel term allows its use in a broader clinical context and could facilitate communication with the child and family, avoiding misconceptions about neglect, as assistance and care is often intensified.^{3,9,10}

ETHICAL AND LEGAL FOUNDATIONS

The adequacy of therapeutic effort is framed in the 1996 Hastings Center Goals of Medicine, emphasizing the cure of the diseased, the care of those who cannot be cured, and the relief of pain and suffering.¹¹ From Beauchamp and Childress' principlism, beneficence is respected with attention to needs and comfort; nonmaleficence, by avoiding disproportionality; autonomy, by promoting participation in decision making about their health; and justice, by promoting a reasonable use of resources.^{3,12}

In pediatrics, where the unique nature of the physician-patient-family relationship is emphasized, making difficult decisions is part of the daily practice. Children become involved to the extent that their cognitive and psychosocial development allows them to understand the disease and, in most cases, the decisions are left to the parents, based on their desire for the best interest of the child. Physicians should always favor the best interests of patients, encouraging their evolving autonomy through an informed consent or assent according to the age and national laws.^{4,5,13} Participation may not be possible and will require consensus between parents and physicians, respecting parental autonomy and having, as a common goal, the best interests of the child and respect for their fundamental rights.¹⁴

In Colombia, Resolution no. 229 of 2020 defines the adequacy of therapeutic effort as the "adjustment of treatments and care goals to the individual's clinical situation if they suffer from an advanced incurable, degenerative, irreversible, or terminal disease and when these do not comply with the principles of proportionality in therapy or do not serve their best interest." The resolution further describes that the adequacy of therapeutic effort involves the "withdrawal or non-initiation of activities, surgeries, supplies, drugs, devices, services, procedures or treatments, where the continuation of these could result in harm and suffering, or be disproportionate."¹⁵

The cre team must be advocate for the child's best interests and be prepared to discuss

differences with parents from such perspective. The Nuffield Council on Bioethics recommends assessing certain aspects to determine whether a course of conduct is in the best interest of the child: the degree of suffering, pain or mental distress it may cause; the expected benefits; the possibility of living without advanced support measures and interacting with the environment; how long it will effectively prolong life; the health care support the child will receive; and the wishes and feelings of the patient and their family.¹⁶

ANSWERING PRACTICAL QUESTIONS

The decision to implement the adequacy of therapeutic effort is challenging for the care team, not only at a moral, but also at a practical level. It is generally accepted that the decision should be based on scientific evidence and consensus and recorded in detail in the medical record.^{2,17} Regarding treatment, measures most commonly recommended include non-resuscitation, withdrawal of mechanical ventilation, and pain management optimization, while measures such as nutrition and diagnostic studies are less clear.^{18,19}

Although several articles have focused on the ethical and legal aspects of the adequacy of therapeutic effort, only a few have described its practical aspects and provided guidance on its implementation. Literature search is hindered by the absence of standardized terms that group these measures; multiple recent publications still use the expression therapeutic limitation despite its obsolescence.

In whom?

In 2015, the Royal College of Pediatrics and Child Health proposed 3 situations in which the adequacy of therapeutic effort is ethically approved: when life is limited in quantity and treatment is not capable of significantly prolonging life; when life is limited in quality and treatment could prolong life, but not alleviate the burden of the disease and its treatment; and in cases of treatment refusal.²⁰ These replace the 5 scenarios proposed by the same institution in 2004: brain death, persistent vegetative state, no chance situations, no purpose situations, or unbearable situations.²¹

Other authors propose initiating the discussion on adequacy of therapeutic effort in 2 scenarios: in patients with an acute onset of an irreversible critical condition and for chronic patients with life-threatening or -limiting diseases.¹⁸ In the

latter scenario, it would be ideal to discuss it progressively throughout the course of the disease, although it is usually done when the patient is beyond the inflection point, when more aggressive procedures and longer hospital stays are frequently required, while the quality of life decreases.¹⁰

When?

There is no specific timing; the adequacy of therapeutic effort involves a complex and dynamic process determined by the needs and the course of the disease of each patient. After this, there are two scenarios: premature death or the patient overcoming the event. In the latter, treatment goals should be re-assessed, continuing with measures proportional to the patient's baseline condition.²⁰

Taking into account the severity of the consequences, when uncertainty prevails, measures should be continued while the necessary information is collected to make a decision. In each case, it is necessary to consider the patient's condition, the course of the disease, scientific evidence, keeping in mind a reasonable period of time.²⁰ It is advised to make an analysis based on facts (diagnoses, prognosis, indications, and adverse events) and individual values (wishes, understanding and acceptance of the disease by the patient and their family), weighing the benefit and proportionality of each measure.²²

How?

The discussion on adequacy of therapeutic effort can be started by the patient, their caregivers, or any health care provider, even without experience in pediatric palliative care.²² López-Sánchez *et al.*, described that almost 40% of pediatric intensive care unit providers in Madrid do not feel qualified to make this decision, so it may be beneficial to train medical staff, especially in pediatric tertiary care centers.²³

The Andalusian Palliative Care Plan suggests that, when a patient is considered to possibly benefit from the adequacy of therapeutic effort, the care team should be informed and, if consensus is met, this should be recorded in the medical record.¹⁹ The team should be made up of all specialists with significant participation in the patient's care, including nurses and psychosocial care providers.²² The importance of including the parents in the conversation and agreeing on a decision should be emphasized, always basing it on the degree of participation they wish to have

and with the understanding that decision-making responsibility lies in the medical team.^{20,22} The support of external agents, such as the Ethics Committee, religious or spiritual leaders, and even legal advisors, may be necessary and should be considered in each case.

A useful ethical concept to reconcile the wishes of parents and health care staff when consensus cannot be reached is the zone of parental discretion, which protects the parental autonomy and their right to decide in the best interest of their child. By adhering to the harm principle and recognizing the wide gap between what is considered optimal for the patient and what could result in harm, this tool allows suboptimal decisions to be tolerated as long as they do not cause any harm to the patient.^{24,25}

Recording the decisions in the medical record acts as a road map and ensures continuity of care. This reduces uncertainty in the care of complex patients, especially for casual health care staff, community-based teams, and in emergency situations.²⁶ A summary of the patient's condition, healthcare professionals involved in the decision, and a comprehensive plan including the measures to maintain, implement, and avoid should be provided, noting routes of administration and preferred site of care.²²

What?

The adequacy of therapeutic effort implies defining the goals to be achieved with an individual care plan. These goals include curing a disease, prolongation of life, quality of life and comfort, or avoidance of future hospitalizations, among others.²² It is recommended to assess the indication of each measure within the plan to define its actual benefit, considering whether the interventions could be potentially inappropriate, if they are unlikely to offer reasonable hope of recovery, if the patient would not benefit from a therapy that would only postpone inevitable death or increase survival in conditions that are not acceptable to the patient and their family.^{3,12,22,27}

The American Academy of Pediatrics recommends that, with the adequacy of therapeutic effort, life support measures, understood as those that may prolong the patient's life, should be withheld. This includes resuscitation, mechanical ventilation, vasoactive drugs, dialysis, and organ transplantation, but also less demanding measures, such as antibiotic therapy, chemotherapy, nutrition, and hydration.¹⁰ Cardiopulmonary resuscitation is not indicated as

part of the adequacy of therapeutic effort due to its low success rate, adverse events, and high probability of functional sequelae. However, this decision should always be made according to medical criteria and tailored for each patient.²⁰

Due to their social and cultural significance, nutrition and hydration are very controversial measures. Even critically ill patients need to meet nutritional requirements, but withholding these measures in those at high risk of mortality in the short term may be beneficial to ameliorate discomfort secondary to secretions, vomiting, coughing, and bronchial aspiration. Ensuring nutrition and hydration may be seen as a basic care measure or as a medical treatment that may be withheld in a morally acceptable manner. To make the decision, the recommendation is to weigh the pros and cons and to consider whether withdrawal would result in death as part of the natural course of the patient's condition or as a consequence of dehydration and starvation.^{19,20,28}

In all cases, pain relief should be warranted by optimizing analgesia and providing comfort measures, including ongoing companionship and spiritual and/or psychological support during bereavement.¹² The use of drugs and non-pharmacological treatments to control physical, emotional, and psychosocial symptoms is recommended, and palliative sedation should be considered in case of refractory symptoms.¹⁹

In patients with severe neurological conditions, varying degrees of life support, including mechanical ventilation, may be required. The recommendation is to implement the adequacy of therapeutic effort in a progressive manner, avoiding cardiopulmonary resuscitation, dialysis, central catheters, and empiric broad-spectrum antibiotic therapy. Mechanical ventilation may be continued considering its withdrawal, defining stable ventilatory parameters, and avoiding increasing or adjusting ventilation modes, except in the presence of hypercapnia. Comfort and pain management measures, as well as anticonvulsants, should be provided in all cases. Episodes of clinical deterioration, such as respiratory exacerbations, should be an invitation to reconsider the therapeutic goals.²⁹

In the case of newborn infants, it is necessary to consider situations in which an early adequacy of therapeutic effort might be appropriate, including preterm infants at the limit of viability or with malformations with a short life expectancy, such as trisomies 18, 13, and 9, severe cardiac anomalies (such as

severe forms of Ebstein's anomaly and left heart hypoplasia), severe diaphragmatic hernia, or severe structural alterations of the central nervous system. Antenatal communication with the family is recommended, proposing a birth plan to ensure support and comfort.¹⁹

Throughout the process of adequacy of therapeutic effort, the care team should strive to maintain communication with the patient and their family in an open, clear, and honest manner, paying attention to location, time, and availability.¹² Conversations with chronically ill patients and their families usually take place on a regular basis over time, which is not possible in the case of acute and unexpected clinical circumstances, in which a progressive communication is recommended.²² The child's involvement will vary according to age and maturity, taking into account their developing autonomy, which reflects that the capacities of understanding and decision making develop progressively during childhood.¹³

CONCLUSION

The adequacy of therapeutic effort has ethical, moral, and legal bases that support its implementation in the pediatric population with life-threatening and -limiting conditions. Recently, some articles have attempted to shed light on the practical aspects that this entails, although there are still many unanswered questions.

It is clear that this process must be thoroughly performed, with an individualized analysis in which each of the measures of the treatment plan is considered not only in terms of technical aspects, but also in relation to the values and wishes of the patients and their family. ■

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