



THE THERAPEUTIC PROPORTIONALITY STANDARD: A NEW CONTENT FOR THE BEST INTERESTS STANDARD

EL ESTÁNDAR DE PROPORCIONALIDAD TERAPÉUTICA: UN NUEVO CONTENIDO PARA EL MEJOR INTERES ESTÁNDAR

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ABSTRACT:

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The best interests standard, futility, ordinary, extraordinary, life-sustaining treatments.

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The standard of the patient's best interests is the main bioethical standard used in the decision-making process that involves incompetent patients (i.e. neonatology, pediatric patients and incompetent adults). This standard has been widely criticized as being self-destructive, individualistic, vague, unknown, dangerous and open to abuse. With the purpose of defending it, several reforms of this standard have been proposed, especially in the pediatric field. We propose a redefinition of the standard based on two concepts: 1) medical futility as a negative criterion, and 2) the principle of proportionality as a positive criterion. Our work includes a new relationship between concepts in classical moral theology (i.e. ordinary / extraordinary; proportionate / disproportionate) applied to the bioethics of life-sustaining treatments for incompetent patients.

RESUMEN:

Palabras clave:

Estándar del mejor interés, futilidad, ordinario, extraordinario, tratamientos de soporte vital.

El estándar del mejor interés del paciente es el único estándar bioético utilizado en los procesos de decisión de tratamientos en enfermos no competentes (neonatología, pediatría y adultos no competentes). Este estándar ha sido ampliamente criticado por autodestructivo, individualista, vago, desconocido, peligroso y abierto a abusos. Para defender el estándar se han propuesto varias reformulaciones especialmente en el ámbito pediátrico. Nosotros proponemos una redefinición del estándar basada en dos conceptos: 1) el de futilidad médica como criterio negativo, y 2) el principio de proporcionalidad como criterio positivo. Nuestro trabajo incluye una nueva relación entre los conceptos de la teología moral clásica (ordinario / extraordinario; proporcionado / desproporcionado) aplicados a la bioética de los tratamientos de soporte vital en pacientes no competentes.

1. Introduction

The inclusion of the concept of patient autonomy at the heart of medical ethics was the most striking innovation in bioethics field¹. From this moment, the development of bioethics had as its nuclear objective to defend individual autonomy through the informed consent of the patient to treatment². The informed consent determined the bioethical frame of reflection for the bioethical principles, established for a bioethics of adults and competent patients³. At that time it was thought that this framework could be extended to children and other incompetent patients⁴.

The doctrine of informed consent requires three elements: 1) that the decision is free, 2) informed and 3) that the person is competent⁵. The key concept of competence divided patients into competent individuals who can make autonomous decisions about a medical treatment, and incompetent individuals who can't make decisions for themselves⁶.

Problems arise when patients are not competent: who should decide for them? Buchanan and Brock raised the need for a *theory of surrogate decision making* that could extend respect for the autonomy of the competent autonomous patient to the incompetent patient⁷. Beauchamp and Childress proposed the application of certain standards that, from the judicial context, could be applied to the surrogated decision-making in the medical field⁸. *The bioethics of principles* pointed to four standards when making medical decisions⁹: 1) *The*

respect for the patient's autonomy applies to the voluntary decisions of legally competent and informed adult subjects who make their own choices about their well-being as long as it does not harm or violate the rights of others; 2) *Advance directives or vital wills*. Competent persons can draft advance directives on their treatments or verbally express what they would prefer in the case that they become incapacitated. This standard is also known as *pure autonomy* or *precedent autonomy*¹⁰; 3) *The third standard is that of the substituted or surrogated judgment standard*, which applies to an incompetent patient but who was once able to express preferences; the person making this substitute decision chooses the option that he/she believes the person would have chosen if he or she was able to do so; 4) *The standard of the patient's best interest* is to identify the highest net benefit among the various options available. This standard applies to pediatric neonatal patients, unqualified minors, and incompetent adult patients¹¹. Often, adults have provided in advance their decisions regarding their preferences in the form of an advanced directive or a living will. Even in situations where they have not done so, they often will have told the family what they would prefer then to do if they were to become incapacitated. In such cases, surrogate decision makers must apply the principle of substituted judgement. The best interest standard is the only guiding principle for medical decisions in pediatrics.

2. The standard of the patient's best interests

The patient's best interest standard is to identify the greatest net benefit among the different options available, assigning different weight to the interests that the patient has in each option and subtracting the risks or costs inherent in each of the options. Already in the first definition of the standard of the best interests ap-

1 Cfr. Jonsen, A.R., *A short history of medical ethics*, Oxford University Press, New York 2000.

2 Cfr. President's Commission for the Study of Ethical Problems in Medicine and Behavioral Research, *Making health care decisions*, Washington DC, U.S. Government Printing Office, 1982, 17-35.

3 Cfr. Beauchamp, T.L., Childress, J.F., *Principles of biomedical ethics*, New York, Oxford University Press, 2008⁶, 136.

4 Cfr. Buchanan, A.E., Brock, D.W., *Deciding for others: The ethics of surrogate decision-making*, New York, Cambridge University Press, 1989, 113.

5 Cfr. President's Commission for the Study of Ethical Problems in Medicine and Behavioral Research, *Making health care...*, *op. cit.*, 55.

6 Cfr. Buchanan, A.E., Brock, D.W., *Deciding for others...*, *op. cit.*, 27.

7 *Idem*, 87.

8 Cfr. Beauchamp, T.L., Childress, J.F., *Principles of biomedical ethics...*, *op. cit.*, 136.

9 Cfr. Kopelman, L.M., "Children: health care and research issues", in Post, S.G. (ed.), *Encyclopedia of Bioethics*, New York,

Macmillan, 1995³, 387-399, 389-390; Beauchamp, T.L., Childress, J.F., *Principles of biomedical ethics...*, *op. cit.* 135-140; Buchanan, A.E., Brock, D.W., *Deciding for others...*, *op. cit.*, 87-151.

10 Cfr. Davies, J.K., "The concept of precedent autonomy", *Bioethics*, 16 (2002) 114-133.

11 Cfr. Kopelman, L.M., "Children: health care and research...", *op. cit.*, 390. Usually adults may have enumerated how they want decisions made by completing

appears the factors that must be taken into account when assigning a treatment seeking the best interests of the patient: relief of suffering, preservation or restoration of functions, and quality and extension of life¹².

Buchanan and Brock's definition was paradigmatic in establishing the conditions of the best interest standard: "... Instructs us to determine the net benefit for the patient of each option, assigning different weights to the options to reflect the relative importance of the various interests the further or thwart, then subtracting costs or "disbenefits" from the benefits for each option. The course of action to be followed, then, is the one with the greatest net benefit to the patient"¹³. Buchanan and Brock, such as Beauchamp and Childress, insist on quality of life (QL) judgments as a fundamental part of the patient's best interests assessment. Beauchamp and Childress' definition is clear: "The best interests standard protects an incompetent person's well-being by requiring surrogates to assess the risks and benefits of various treatments and alternatives to treatment. It is therefore inescapably a quality-of-life criterion"¹⁴.

The best interests is a doctrine that appears first in jurisprudence to determine a wide range of issues related primarily to the well-being of children. The introduction of the best interests standard implied that in those divorce or dissolution processes, the family courts are called upon to assess the best interests of each child in these unions¹⁵. A trilogy of books published in the decade of the 70s and the end of the 80s had a great influence at the time of applying in the courts the standard of the best interests¹⁶. These books guided the application of the standard by judges in the cases of parents who refused medical treatment and who were reported by

doctors. Two characteristics marked this orientation: 1) the assessment of individual circumstances required in the application of the standard will be based solely on the assessment of the patient's QL in the present and in the future after treatment¹⁷, and 2) the application of the best interests, in cases in which the parents refuse medical treatment, was reduced to respect for the autonomy of parents' decision¹⁸.

The best interests standard comes into the medical and ethical fields through the neonatology units and, more specifically, in decision-making process on withholding and withdrawing life support treatments (LST). Two questions will establish this relationship: 1) Is it ethically justifiable to limit LST potentials in the treatment of neonates? And, 2) if it is, who has the authority to make such decisions?

Three stages can be established in the answers to these two questions that coincide with three stages in the birth and assumption of the best interests¹⁹: 1) (1971-1981) A first stage takes place before Baby Doe, in which these questions are introduced and several answers are given. One of the answers is the use of the best interests standard and its application taking into account QL judgments. This may be understood as the pre-history of the standard of the best interests in the medical field; b) (1982-1988) *The definition and assumption of the standard in the pediatric area* is marked by the "Baby Doe" case, and the legislation established as a response to this case. At this stage the best interest standard appears, for the first time, as a guide in the decision making process about children in medical associations and in declarations of bioethics Councils²⁰

12 Cfr. President's Commission for the Study of Ethical Problems in Medicine and Behavioral Research, *Making health care...*, *op. cit.*, 180.

13 Buchanan, A.E., Brock, D.W., *Deciding for others...*, *op. cit.*, 123.

14 Beauchamp, T.L., Childress, J.F., *Principles of biomedical ethics...*, *op. cit.*, 138.

15 Cfr. Kohm, L.M., "Tracing the foundations of the best interests of the child standard in american jurisprudence", *Journal of Law and Family Studies*, 10 (2008) 337-376.

16 The three books were gathered in a single book under the title "The best interests of the child". Cfr. Goldstein, J., Solnit, A.J., Goldstein, S., Freud A., *The best interests of the child. The least detrimental alternative*, New York, The Free Press, 1996.

17 Cfr. Beauchamp, T.L., Childress, J.F., *Principles of biomedical ethics...*, *op. cit.*, 138; Buchanan, A.E., Brock, D.W., *Deciding for others...*, *op. cit.*, 123; Cfr. Kopelman, L.M., "Children: health care and research...", *op. cit.*, 390-391.

18 Cfr. Moos, K., "The 'Baby Doe' legislation: it rise and fall", *Policy Studies Journal*, 15 (1987) 629-651.

19 Placencia, F.X., McCullough, L.B., "The history of ethical decision making in neonatal intensive care", *Journal of Intensive Care Medicine*, 26 (2011) 368-384, 368.

20 Cfr. President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *Deciding to forego life-sustaining treatment: a report on the ethical, medical, and legal issues in treatment decisions*, March 1983, Washington DC, U.S. Government Printing Office, 1983, 217; American Academy of Pediatrics Committee on Bioethics, "Treatment of critically ill newborns", *Pediatrics*, 72 (1983) 565-566.

while, at the same time, it was widely criticized by the Reagan administration for its link to the QL concept; c) *The consecration of the standard of the best interest*. The standard of the best interests of the child has been imposed, above all, from the United Nations Convention on the Rights of the Child (1989), which established it as the only standard applicable in pediatric bioethics and in all areas of life of the minor²¹, but not without criticism²². In 2013, the Committee on the Rights of Children presented a General Comment No. 14 regarding art. 3 para.1 in which they tried to explain how to assess and determine in each case, what the best interest may be. The Committee follows the interpretation of the best interests of the child standard as a threefold concept: a substantive right, an interpretative legal principle and a rule of procedure during the decision-making process²³.

3. Criticism and defense of the best interests standard

From the very beginning, many authors criticized the use of the best interests standard in the field of medical decisions. Some authors thought it was a *self-destructive* standard because, taken literally, no decision could be put into practice insofar as it would be extremely difficult to determine whether, in an absolute way, what is literally best for the patient²⁴. Others argued that it was too *individualistic* to consider only the interest of a person without regard for the rest of the family²⁵. Also

21 United Nations, Convention on the Rights of the Child (1989), art. 3. para.1 "In all actions concerning children, whether undertaken by public or private social welfare institutions, courts of law, administrative authorities or legislative bodies, the best interests of the child shall be a primary consideration".

22 A summary description of these three stages in González-Melado, F.J., Di Pietro M.L., "El estándar del mejor interés del niño en neonatología: ¿es lo mejor para el niño?", *Cuadernos de Bioética*, 26 (2015) 201-222.

23 Cf. Committee on the Rights of the Children, General Comment No 14 (2013) on the right of the child to have his or her best interests taken as a primary consideration (art. 3, para. 1)*. This interpretation has also many criticism. Cfr. Kilkelly, U. (2016). "The Best Interests of the Child: A Gateway to Children's Rights?", in Sutherland, E. - Barnes Macfarlane, L. (Eds.), *Implementing Article 3 of the United Nations Convention on the Rights of the Child: Best Interests, Welfare and Well-being*, Cambridge: Cambridge University Press, Cambridge, 2016, 51-66, [doi:10.1017/9781316662977.004]

24 Cfr. Veatch, R.M., "Abandoning informed consent", *The Hastings Center Report*, 25 (1995) 5-12.

25 Cfr. Downie, R.S., Randall, F., "Parenting and the best interests of minors", *The Journal of Medicine and Philosophy*, 22 (1997):

some authors insisted that it is an *unknown* standard, i.e. can we really know what are the best interests of people, especially a child or an incompetent adult?²⁶. In the same sense manifested those who believe that it is a *vague* standard, because often the values that people use to judge what is best are not clear, when measuring the benefits or when establishing what amount of net benefit is necessary to, for example, continue the LST²⁷. It has also been considered a *dangerous* standard which is *open to abuse*, especially when withholding or withdrawing improperly the treatment of disabled patients, mainly because relatives and physicians used criteria based on QL judgments²⁸. Other authors have proposed replacing the QL criterion in the case of children, who cannot express how they perceive their QL, by the criterion of "*social value*" that would claim to assess the social value that the child's existence has for their parents²⁹.

3.1 Attempts to defend and redefine the best interests standard

Some authors have tried to defend the best interests standard by clarifying its meaning and structure (Kopelman) or by trying to give it a clearer content (Malek and Wilkinson).

In 1997 L. Kopelman defended the best interests standard a) *as a threshold for intervention* in cases of child abuse and negligence on the part of parents; b) *as an ideal* to establish policies actions and to clarify our prima facie duties, and c) *as a standard of reasonableness* that guides us in the selection of that which maximizes the net benefits and minimizes the net damages of the child, taking into account the legitimate interests and

219-231, 230; Martin, W., Freyenhagen, F., Hall, E., O'Shea, T., Szerletics, A., Ashley, V., "An unblinkered view of best interests", *British Medical Journal*, 345 (2012) e8007.

26 Cfr. Brody, H., "In the best interests of", *The Hastings Center Report*, 18 (1988) 37-39, 38.

27 Cfr. Miller, R.B., *Children, ethics and modern medicine*, Bloomington, Indiana University Press, 2003, 120; Salter, E.K., "Deciding for a child: a comprehensive analysis of the best interest standard", *Theoretical Medicine and Bioethics*, 33 (2012) 179-198.

28 Cfr. Koop, C.E., "The Challenge of Definition", *The Hastings Center Report*, 19 (1989) 2-3.

29 Cfr. Engelhardt, H.T. Jr., "Medicine and the concept of person", in Beauchamp, T.L., Perlin, S., (eds.), *Ethical issues in death and dying*, Englewood Cliffs, Prentice-Hall, 1978, 227.

Table 1. Interests of children

1.- Life: To life and to anticipate a life of normal human length
2.- Health and healthcare: To have good health and protection from pain, injury, and illness. To have access to medical care.
3.- Basic needs: To have and adequate standard of living, especially to be adequately nourished and sheltered.
4.- Protection from neglect and abuse: To be protected from physical or mental abuse, neglect, exploitation, and exposure to dangerous environments. To be secure that they will be safe and cared for.
5.- Emotional development: To experience emotion and have appropriate emotional development.
6.- Play and pleasure: To play, rest, and enjoy recreational activities. To have pleasure experiences.
7.- Education and cognitive development: To have an education that includes information from diverse sources. To have the ability to learn, think, imagine, and reason.
8.- Expression and communication: To have the ability to express themselves and to communicate thoughts and feelings.
9.- Interaction: To interact and care for others and the world around them. To have secure, empathetic, intimate, and consistent relationships with others.
10.- Parental relationships: To know and interact with their parents.
11.- Identity: To have an identity and connection to their culture. To be protected from discrimination.
12.- Sense of self: To have a sense of self, self-worth, and self-respect.
13.- Autonomy: To have the ability to influence the course of their live. To act intentionally and with self-discipline. To reflect on the direction and meaning of their lives.

the rights of others, within the available options. This correction of the standard attempts assume the most important criticisms that referred to the absolute and individualistic character of the standard, trying to soften its interpretation so that it is reduced to a standard of reasonableness for medical decisions on incompetent minors³⁰.

In 2005, coinciding with the 20th anniversary of the amendments to the Child Abuse Prevention and Treatment Act, Kopelman wrote an extensive article in which she advocates a negative analysis of the standard of the best interests for decision making regarding incompetent individuals³¹. According to Kopelman the negative version of the best interests standard: a) *instructs those who are entrusted with decisions what action operates in favor of the immediate and long-term interests of the incompetent individual, and to maximize their net benefit and minimize their net burden, arguing that this action should be considered as prima facie duty;* b) it presupposes a *consensus among reasonable and*

informed people, of goodwill, about which choices are not acceptable, for the incompetent individual, considering all the elements, and c) determines the objective of the best interests in terms of established moral or legal rights for incompetent individuals.

Given the criticism that the best interest standard is vague and unknown, some authors have wanted to give it a more precise content. J. Malek proposes, after a comparative study of three sources, a list of thirteen basic interests of all children that can help to defend the best interests standard of subjectivity, individual preferences, beliefs or prejudices of physicians³². We reproduce in Table 1 the list of interests of Malek.

D. Wilkinson has recently tried to give a new content to the best interests standard answering two problems: The first is that protocols do not serve in critical decisions, and the second one is that the best interests standard limits the participation of parents in the decision-making process. Wilkinson proposes a reading of the best interests from two thresholds: a “upper threshold” where the child’s prognosis is good enough for treatment to be mandatory, and a “lower threshold”,

30 Cfr. Kopelman, L.M., “The best interests standard as threshold, ideal, an standard of reasonableness”, *The Journal of Medicine and Philosophy*, 22 (1997) 281-289.

31 Kopelman, L.M., “Rejecting the Baby Doe rules and defending a ‘negative’ analysis of the Best Interests Standard”, *The Journal of Medicine and Philosophy*, 30 (2005) 331-352.

32 Cfr. Malek, J., “What really is in a child’s best interest? Toward a more precise picture of the interests of children”, *The Journal of Clinical Ethics*, 20 (2009) 175-182, 180.

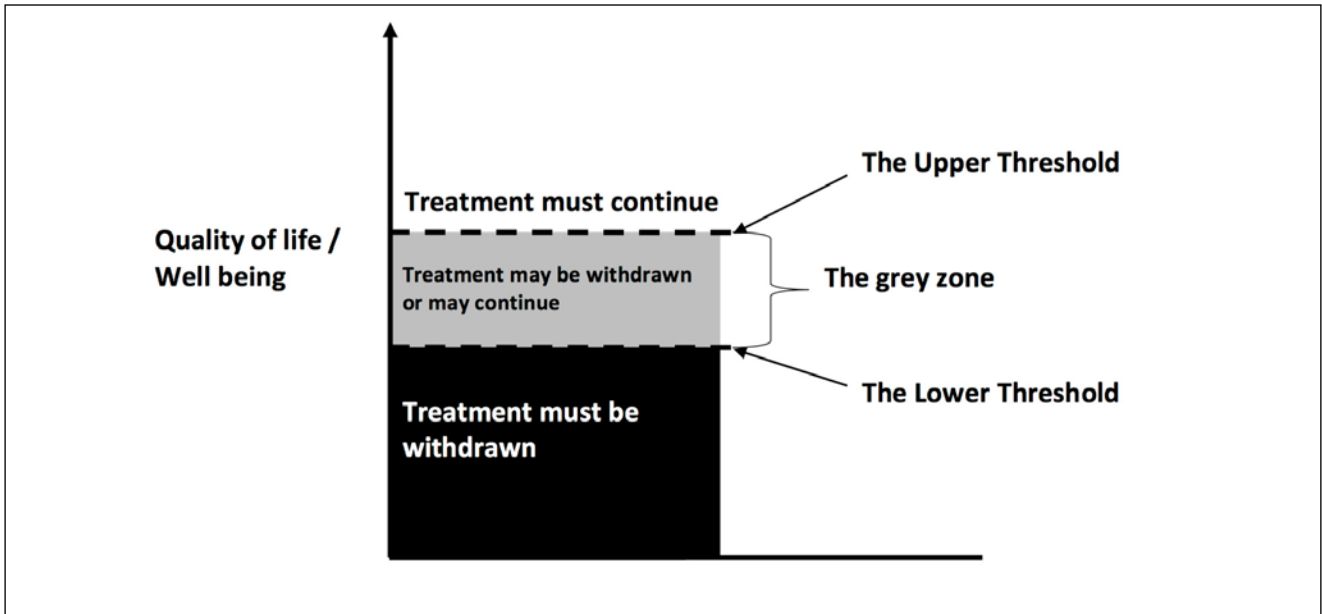


Figure 1. “The threshold framework” proposed by D. Wilkinson. (Figure drawing it by the authors of this paper).

below which the child’s prognosis is so poor that parents should not be allowed to decide on treatment, and that treatment should be discontinued by physicians regardless of parental opinion (Figure 1). Between these two thresholds, there is a grey area. This is the area where both morality and treatment uncertainties are located. This is the area where the family can participate in the decision making process. Wilkinson’s redefinition of the best interests is limited to the introduction of protocols that signal both the lower threshold and the upper threshold, leaving the decision to parents only within the grey zone of uncertainty³³.

33 Wilkinson, D., *Death or Disability? The “Carmentis Machine” and decision-making for critically ill children*, Oxford, Oxford University Press, 2013; A similar proposal to Wilkinson’s can be found in Rhodes, R., Holzman, I.R., “Is the best interest standard good for pediatrics?”, *Pediatrics* 134 (2014) S121-S129, where through several cases they present the weaknesses of the best interest standard and defend their three-box model: at one extreme is the box for the set of cases that are likely to have poor outcomes regardless of the interventions that are tried, and physicians should and do encourage surrogates to withhold or discontinue treatment; at the opposite extreme is the box for the set of cases in which treatment promises a likely and significant medical benefit, whereas refusal of treatment is very likely to result in significant harm and surrogates should not be allowed the authority to impose their own personal values, and when a surrogate’s choice would clearly subvert any universal treatment goal, the choice must be rejected; and a middle box, when nothing crucial turns on the decision or when reasonable people could accept or refuse the treatment option, medical should accept the decisions of surrogates.

Neither Kopelman nor Malek nor Wilkinson respond satisfactorily to criticism. On the one hand, Kopelman does not define who has to make the decisions and she establishes the formula of the consensus as criterion of the decisions on the treatments that should not be applied because they are not acceptable. This does not correct the danger of an abuse of the standard, by not establishing objective criteria, when defining what kind of decisions are *not acceptable*. As far as content is concerned, it is clear that Malek’s list of interests is as subjective as the beliefs, prejudices and preferences of doctors which want to be avoided. What Malek does is to replace the table of values that each doctor has, in particular, by the table of values of her consulted sources. Finally in Wilkinson, the main problem is the direct relation that is established between the QL and the decisions on LST. The prognosis used to establish the thresholds is a QL-based prognosis understood as personal autonomy, with the absence of suffering and intellectual values. It is this QL concept, when deciding whether or not to treat seriously ill newborns, which makes Wilkinson’s approach highly problematic from an ethical point of view³⁴.

34 Gonzalez-Melado, F.J., “Wilkinson D., *Death or Disability? The “Carmentis Machine” and decision-making for critically ill children*. Oxford: Oxford University Press; 2013”, *Theoretical Medicine*

3.2. The necessity of redefining the best interests standard

In recent years, in some cases there have been entrenched disagreements between parents and clinicians, and these have received a great deal of media and academic attention³⁵. One may recall the cases of Ashya King³⁶, Charlie Gard³⁷, Alphonse Evans³⁸, or more recently,

and *Bioethics*, 36 (2015) 363-368.

35 Adult cases, such as Vincent Lambert's one, have also attracted the mass media attention, but these cases are usually resolved using the substituted or surrogated judgment standard.

36 Ashya was diagnosed with an aggressive brain tumor known as medulloblastoma, and had to have brain surgery. Doctors recommended he also have chemotherapy and radiotherapy as part of his treatment, although Ashya's parents Brett and Nagemeh King rejected that treatment and wanted to try proton therapy – which wasn't available in the UK at the time – instead. Brett and Nagemeh – during one of the allocated times Ashya was allowed to be taken home – left Southampton General Hospital on 28 August 2014 with their son and boarded a ferry to France. When they didn't return, an international alert was set up to find the boy, and a manhunt began. The King family were eventually found in Malaga (Spain), Ashya was taken to a local hospital while his parents were detained in a jail. They were later released as the request to extradite them to the UK was denied. It was found that the threat to Ashya's life was not as serious as once thought. After this, Brett and Nagemeh took the case to the High Court, and on 5 September 2014 it was ruled that they could take Ashya to Prague for proton therapy, which they did shortly after. At November of 2019, Ashya shows no signs of cancer. Cfr. [<https://www.theguardian.com/uk-news/ashya-king>]

37 Charlie Gard was an 11-month-old British infant with infantile-onset mitochondrial DNA depletion syndrome. While his parents and medical team were pursuing options for investigational nucleoside therapy, Charlie's condition deteriorated. His medical team then determined further treatment was not in Charlie's best interests, and a judge agreed. His parents petitioned to transfer Charlie's care to the United States for experimental therapy, but the Court held that this transfer was not in Charlie's best interests and that life support should be stopped. After an expert consultation revealed it was too late for the experimental treatment, the parents sought to take Charlie home to die. The Court ordered Charlie be moved to hospice care instead, and he died shortly after treatment was withdrawn. Cfr. Shad, S.K., Rosenberg, A.R., Diekema, D.S., "Charlie Gard and the limits of Best Interests", *JAMA Pediatrics* 171(2017) 937-938; Cfr. High Court of Justice Family Division, *Great Ormond Street Hospital and Constance Yates, Christopher Gard, and Charlie Gard*, (2017) EWHC 972 (Fam.). No. FD17P00103. 11 April 2017, section 53. See also European Court of Human Rights, *Charles Gard and Others against the United Kingdom*. Application n°. 39793. 3 July 2017, p.2, point 4.

38 Alfie was born on 9 May 2016. He was first admitted to Alder Hey Children's Hospital in Liverpool in December 2016. Doctors diagnosed a degenerative neurological condition, which they have not been able to identify definitively. Alfie's parents and the hospital clashed over what should happen to Alfie, who had been in a semi-vegetative state for more than a year. His parents said they wanted to fly him to a hospital in Italy but this was blocked by Alder Hey Hospital, which said continuing treatment was "not in Alfie's best interests". The Alder Hey Children's Hospital NHS Foundation Trust went to the High Court to seek a declaration that "continued ventilator support is not in Alfie's best interests and, in these circumstances, it is not lawful that such treatment continue". Mr. Justice Hayden ruled in favor of hospital bosses, and doctors were set to withdraw ventilation on 23 February before his parents embarked on a lengthy legal battle. Alfie's parents refused to give

Tafida Raqeeb³⁹. These cases have returned the best interests standard to the center of the bioethical debate regarding its usefulness, its content and the possible alternatives to the use of the best interests standard⁴⁰. A brief analysis of the current proposals on the content of the standard of best interest, allows us to identify four different groups (Table 2):

1) The first group collects the proposals that consider the best interests standard as determined by patient's clinical needs. In this group, it can be found in the English Law, and the particular court that applies it such as the High Court of Justice Family Division of the United Kingdom, which understands the best interest standard only in an objective way⁴¹; Winters proposes a "thinking list" as a tool for making decisions in situations of uncertainty and complexity⁴²; a group of bioethics specialists that substitute the best interest standard for the "harm principle"⁴³, and Lynn Gillam who intended

up hope and took the case to the Court of Appeal on 6 March where judges upheld Mr. Justice Hayden's decision. On 20 March, the couple appealed to the Supreme Court where justices refused to give the couple permission to mount another appeal. Despite this, their lawyers went to the European Court of Human Rights after exhausting all legal avenues in the UK. But three judges ruled the submission "inadmissible", saying they were unable to find any violation of human rights. On 11 April, Mr. Justice Hayden then endorsed an end-of-life care plan for Alfie, setting a date to switch off life support. On 23 April, Alfie's life support was turned off at 21:00 after a High Court judge dismissed fresh submissions heard in private from lawyers. Alfie's father had said his son was continuing to breathe unassisted and his life support should be reinstated. Alfie died at 2:30 a.m. on 28 April 2018. Cfr. [<https://www.bbc.com/news/uk-england-merseyside-43754949>].

39 Tafida suffered a traumatic brain injury in February 2019 and clinicians at the Royal London Hospital in Whitechapel said there is no hope for her, and being allowed to die is in her best interests. Tafida's mother, Shelina Begum, and her father, Mohammed Raqeeb, wanted to seek treatment in Italy. Tafida's parents, took the case to the High Court. Mr. Justice MacDonald handed down his judgment in the High Court, holding that continuation of medical treatment was in Tafida Raqeeb's best interests. The effect of this decision being that she can be treated in Italy, in line with the wishes of her parents. Cfr. [<https://www.independent.co.uk/news/uk/home-news/tafida-raqeeb-court-result-life-support-italy-brain-injury-age-disability-latest-a9136031.html>].

40 In addition to countless articles published on the subject, recently two important bioethical journals have dedicated monographic to this issue: Cfr. *The American Journal of Bioethics*, 18 (2018); *The Journal of Clinical Ethics*, 30 (2019).

41 Cfr. The Children Act 1989 section 1 (3-4); High Court of Justice Family Division, "Great Ormond Street Hospital..." *cit*.

42 Cfr. Winters, J.P., "When parents refuse: resolving entrenched disagreements between parents and clinicians in situations of uncertainty and complexity", *The American Journal of Bioethics*, 18 (2018) 20-31.

43 In this movement it can be find Diekema, Salter, Shah, Ellinston and De Vos, and others. Cfr. Diekema, D.S., "Decision making on behalf of children understanding the role of the harm prin-

her Zone of Parental Discretion as a tool for putting the harm principle into practice⁴⁴. Birchley refers to all these authors, who support the “harm principle”, as a movement within bioethics that he refers to as the “harm consensus”⁴⁵.

2) The second group is made up of those specialists who understand that the best interest standard has to take into account a subjective evaluation of the patient’s wider social and welfare preferences, separately and subsequently to the doctor’s determination of the clinical interest. In this group, we can find Ross’s defense of the best interest standard, which implies the modification of the standard in what she calls “the constrained parental autonomy”, which consists in promoting and protecting the child’s primary goods or basic needs⁴⁶. Edmund Howe also can be put into this group by his intention to implant Ross’s theory in a practical way⁴⁷.

3) The third group understand the best interest standard as an objective evaluation of what the “reasonable” patient’s preferences would be, if the patient in question’s view are not known. In this group, it can be found: Kopelman⁴⁸; Bester and his defense of the best interests standard rejecting the harm principle⁴⁹; Hub-

berd and Greenblum that critic the weakness of Bester’s standard and replace it with three commonly held principles of bioethics – autonomy, beneficence, non-maleficence- and a standard of reasonableness⁵⁰; Baines who considered the best interests standard as a “reasonable” assessment of the individual child’s interests⁵¹; Millum and his proposition that parents should decide for their child as the child would if she were a moral agent trying to act prudently within the constraints of morality⁵², and Hester who proposes to substitute the best interest standard for a “reasonable interests standard”⁵³.

4) In the fourth group are those who understand the best interests standard as a conflation of both clinical and wider welfare issues. In this group can be situated Malek, Wilkinson, Coulson-Smith *et al.*⁵⁴, along with Rhodes and Holzman with their “three boxes theory”⁵⁵.

These four groups respond to two fundamental frameworks of current pediatric bioethics:

a) The first framework, which corresponds to the first group, wants to replace the best standard interest with the “harm principle”. The main criticism to this framework is that while defining the State intervention threshold well, it does not exhaust all the possibilities for the best decision, thus excluding parents from decision-making process and focusing only on the patient’s medical good. Using the “harm principle”, a decision could be made which assumes that continuing to live is a “harm” for the patient, and the best option is to leave the child to die.

principle cannot replace the best interest standard: problems with using the harm principle for medical decision making for children”, *The American Journal of Bioethics*, 18 (2018) 9-19.

50 Cfr. Hubbard, R, Greenblum, J., “Parental decision making: the best interests principle, child autonomy, and reasonableness”, HEC Forum, acces online [https://doi.org/10.1007/s10730-019-09373-9]

51 Cfr. Baines, P., “Family interest and medical decisions for children”, *Bioethics*, 31 (2017) 599-607.

52 Cfr. Millum, J., *The moral foundations of parenthood*, New York, Oxford University Press, 2018; Millum, J., “The ‘reasonable subject standard’ as an alternative to the ‘best interest standard’”, *The American Journal of Bioethics*, 18 (2018) 66-67.

53 Cfr. Hester, D.M., “Offering the ‘reasonable interests standard’ in response to Ross’s analysis of the best interests standard”, *The Journal of Clinical Ethics*, 30 (2019) 196-200;

54 Cfr. Coulson-Smith P., Fenwick, A., Lucassen, A., “In defense of best interests: When parents and clinicians disagree”, *The American Journal of Bioethics*, 18 (2018) 67-69.

55 Cfr. Rhodes, R., Holzman, I.R., “Is the best interest standard good...”, *cit.*, S121-S129.

44 Cfr. Gillam, L., “The zone of parental discretion: an ethical tool for dealing with disagreement between parents and doctors about medical treatment for a child”, *Clinical Ethics*, 11 (2016) 1-8.

45 Cfr. Birchley, G. “Harm is all you need? Best interests and disputes about parental decision-making”, *The Journal of Medical Ethics*, 42 (2016) 111-115.

46 Cfr. Ross, L.F., “Better than best (interest standard) in pediatric decision making”, *The Journal of Clinical Ethics*, 30 (2019) 183-195; Paquette, E.T., Ross, L.F., “Pediatric decision making requires both guidance and intervention principles”, *The American Journal of Bioethics*, 18 (2018) 44-46.

47 Cfr. Howe, E.G., “Treating children maximally: practical applications”, *The Journal of Clinical Ethics*, 30 (2019) 171-182.

48 Cfr. Kopelman, L.M., “Why the best interest standard is not self-defeating, too individualistic, unknowable, vague or subjective”, *The American Journal of Bioethics*, 18 (2018) 34-36

49 Cfr. Bester, J.C., “The best interest standard is the best we have: why the harm principle and constrained parental autonomy cannot replace the best interest standard in pediatric ethics”, *The Journal of Clinical Ethics*, 30 (2019) 223-231; Bester, J.C., “The harm

Table 2. Current theories for the best interest standard on pediatric field.

Group	Theory	Authors	Criticism
First group	The harm principle = clinicians should invoke the harm principle if and only if intervening is necessary to prevent a significant risk of serious harm to a child and is reasonably likely to prevent that harm compared with the alternatives.	High Court of Justice Family Division; Dikema, D.S; Shad, S.K; Elliston, S.; De Vos, M.A. <i>et al.</i> ; Winters, J.P.	Focus on the patient’s medical good. Do not exhausted all possibilities for the best option.
	Zone of Parental Discretion as a tool for putting the harm principle into practice.	Gillam, L.	Exclude parents from decision-making process.
Second group	Constrained parental autonomy = promoting and protecting the child’s primary goods or basic needs.	Ross, L.F.	Vague and unknown. Difficulties to establish a hierarchy on the primary goods or basic needs. Subjective preferences over what are children’s basic needs
	Supports Ross’s standard and offers some suggestions to putting into practice.	Howe, E.	
	A list of thirteen basics interests of children	Malek, J.	
Third group	The best interests standard as a threshold for intervention, as an ideal to stablish policies actions as a standard of reasonableness .	Kopelman, L.M.	Do not decided who has to make decisions.
	Defends the best interests standard as an option or range of options that protect the interest of the child better than any alternative.	Bester, J.C.	Do not established criteria in order to correct the danger of an abuse of the standard.
	Tree principles – autonomy, beneficence and non-maleficence – and a principle of reasonableness , properly weighed.	Hubberd, R. and Greenblum, J.	Do not defined what kind of decisions are not acceptable.
	As a “ reasonable ” assessment of the individual child’s interests	Baines, P.	
	The “ reasonable Subject Standard ” = parents should decide for their child as the child would if she were a moral agent trying to act prudently within the constrain of morality.	Millum, J.	
	“ Reasonable Interests standard ” = the analysis of the morality of decision making for children must account for three conditions: Threshold (interventional) condition, aspirational (guidance) condition, and pragmatic (reasonable) condition.	Hester, D.M., et al.	
Fourth group	The two thresholds: an “upper threshold” and a “lower threshold”. In the middle a grey area.	Wilkinson, D.	Relation between the QL and decisions on withhold or withdraw LST in disabled patients or children.
	To adopt the broadest view of the best interest , trying to understand the particular experiences, expectations, and nuances in each unique case.	Coulson-Smith, P. <i>et al</i>	
	The three-box model	Rhodes, R. and Holzman,	

b) The second framework, which corresponds to the other three groups, maintains the best interest of the child as the main standard but by redefining its content: some authors limit the parental decision-making autonomy (second group); others establish as a content the standard of reasonableness in their different versions (third group) and, finally, there are those who want to facilitate decision making with tools that assess

the child’s clinical situation, possible treatment options and parental values (fourth group). The main criticisms, from these three groups, is the difficulty to establishing some criteria to determine what the best reasonable option may be, and how different parents have different values and perceptions about what is the best for their children. In the face of these difficulties, physicians have found a shortcut in their application of QL judgments,

insofar as to be able to decide what the “best reasonable option” is for a patient, and the best interests standard has become an *utilitarian* standard that attempts to determine whether the patient’s life after treatment will be a “life worth living”, especially when deciding to withhold or withdraw the LST of a disabled patient or a child.

For all these reasons, we consider that it is necessary to redefine the best interest as a standard so that it can respond to the bioethical problems of minor and incompetent patients⁵⁶. This redefinition has to correct deviations from the best interest standard of the child:

1.- Promoting a correct ethical framework for the application of a bioethics that responds to the needs of minors and incompetent adults patients⁵⁷.

2.- Establishing the necessary clinical criteria for the application of the standard, that is to say, it tries to answer the question: when is it necessary to apply the best interests standard?

3.- To determine who is responsible for the application of the standard and the role of the family in the decision-making process.

4.- Finally, it will be necessary to provide a new content to the best interests, which allows us to answer the question: how to apply the best interests? This new content will serve to define what is the best treatment and justify why we consider it to be the best possible treatment.

4. Redefining the best interests of the child as an applicable standard

Daniel Callahan raised in 1991 what he called “the problem without a name”⁵⁸ to refer to a series of limiting situations that arise in medicine. The problem that

56 Cfr. González-Melado, F.J., Di Pietro, M.L., “El estándar del mejor interés del niño...”, *op. cit.*, 219; Salter, E.K., “Deciding for a child: a comprehensive analysis of the best interest standard”, *Theoretical Medicine and Bioethics* 33 (2012): 179-188.

57 Cfr. González-Melado, F.J., “Family Centered Bioethics: a new bioethical framework for decision-making in neonatal and pediatric units”, *Journal of Clinical Research and Bioethics*, 7 (2016) 1-5.

58 Cfr. Callahan, D., “Medical futility, medical necessity. The problem-without-a-name”, *The Hastings Center Report*, 21 (1991) 30-35.

always appears, in these limiting situations, is to know what technical treatments benefit the patient and can be instituted and which must be rejected because of the risks involved. The patient’s best interest standard would be the standard that would have to be used only in these limiting situations with incompetent patients.

Fortunately these limiting situations are not the only ones that are given in medicine. There are situations where treatment is clearly indicated and effective for incompetent patients. It is clear that in these situations, neither the physician nor the family has a need to apply the standard of the best interests, but simply to proceed with the administration of the treatment, with the consent of the family.

It is in situations in which there is *uncertainty* about the treatment or the prognosis of the disease, that is to say in those situations in which *proportionality judgments* must be elaborated⁵⁹, where the standard of the best interests would come into play. As currently defined, this standard is not sufficient to ensure a correct analysis of the problematic cases by its almost exclusive dependence on QL judgments.

We consider that only a correct interpretation and redefinition of the standard of the best interests, and its relationship with QL, will allow us to use this standard correctly. The redefinition that we propose of the standard of best interest is based on two concepts: the concept of medical futility and the principle of proportionality.

4.1. Futility as a bridge concept between clinic and medical ethics

E. Pellegrino proposed that the correct use of the term futility, as a prudential clinical judgment, could be used as a bridge between the ethical formulation of proportionality judgments and the decisions to withholding or withdrawal treatments at the end of life⁶⁰. In de-

59 Cfr. Taboada, P., “El principio de proporcionalidad terapéutica en las decisiones de limitar tratamientos”, *Boletín Escuela de Medicina*, 27(1998)17-23.

60 Cfr. Pellegrino, E.D., “Decision at the end of life: the use and abuse of the concept of futility”, in Vial Correa, J.D., Sgreccia, E. (eds.), *The dignity of the dying person. Proceedings of the fifth assembly of the Pontifical Academy for life*, Ciudad del Vaticano,

fining the concept of futility, Pellegrino distinguishes at least two meanings: 1) a general notion, in which futility means the inability to achieve the proposed goal, and 2) a clinical sense, where futility means that a disease has progressed to a point where the proposed medical intervention may not serve the good of the patient.

4.1.1. The general notion of futility

The Latin word *fut* [t] *ilis* means “to let out its content [referring to the vessel]. Fragile, brittle. Futile, vain, light, frivolous; without authority. Man without foundation. Useless, without effect”. The etymology of *futilitas* is related to the verb *fundo*, “to pour”, to try to carry a liquid in a container that drops its content⁶¹. The futile action is not simply useless, but involves an effort and a time that will not get any fruit. Therefore it would be a relative term; we say that something is futile not because it is useless in itself, but because it is incapable of reaching the goal for which that medium has been proposed.

4.1.2. Futility in the medical field

More than 3,500 years ago, medicine recognized the existence of futile treatments as a clinical fact with moral implications, although it is true that the concept as such was not coined. Hippocratic doctors also recognized the futile treatments and advised against treatment when the patient had been “dominated” by the disease. Therefore the concept as such was present in medicine as a clinical criterion, applied unilaterally by the physician in critical situations about the prolongation of life. The moral force of non-application of a useless treatment derives, in the Hippocratic tradition, from the principle of beneficence⁶².

It is in the last quarter of the 20th century when the moral problem of the futility of treatments and the invention of the term become an important topic of

debate within medical ethics⁶³. The debate about futility is not only a consequence of the medical advances in the LST, but is also a consequence of the change that occurs in the doctor’s authority when the principle of the patient’s autonomy is assumed in bioethics⁶⁴. We can verify this change when analyzing the most known judicial cases that demanded the suspension of the LST between the decades of the eighties and nineties of last century. The most famous cases of the eighties are cases in which patients, or relatives, ask for the suspension of a treatment against the opinion of doctors. However, in the most famous cases of the 1990s, there is an inversion of the terms: now the doctors are presented with complaints when they request that the treatments have to be withdrawn while the patients, or relatives, are the ones who ask to continue the treatments. Medical criteria are sought that seek the justification of denial, withdrawal, treatment and defense of the physicians so that they are not obliged to offer a treatment that they consider useless⁶⁵. The term “futility” arises, therefore, as a defensive response of the autonomy of the doctors against the autonomy of the patient⁶⁶.

The debate will focus on who should define futility (the doctor, patient, or family members who make surrogate decisions), how futility should be defined, and what to do when physician, patient, or family disagrees with its definition. All of this debate led to the elaboration of a series of operational definitions of futility, that is, definitions that could be applied to specific cases that appear in critical situations.

We are able to group the different definitions into four groups: a) futility in the physiological sense; b) quantitative and qualitative futility; c) social and economic futility, and d) integrative definitions of futility. It is necessary to add a fifth group in which would be all of

63 Cfr. Burns, J.P., Truog, R.D., “Futility: a concept in evolution”, *Chest*, 132 (2007) 1987-1993.

64 Cfr. Helft, P.R., Siegler, M., Lantos, J., “The rise and fall of the futility movement”, *The New England Journal of Medicine*, 343 (2000) 293-296.

65 Cfr. Pellegrino, E.D., “Patient autonomy and the physician’s ethics”, *Annals Royal College of Physicians and Surgeons of Canada*, 27 (1994)171-173.

66 Cfr. Hook, C.C., “Medical Futility”, in Kilner, J. et al., (eds.), *Dignity and dying: a christian appraisal*, Michigan, Paternoster Press, 1996, 84-95, 87.

Libreria Editrice Vaticana, 2000, 219-241.

61 Segura Munguía, S., *Diccionario Etimológico Latino-Español*, Madrid, Ediciones Generales Anaya, 1985.

62 Cfr. Pellegrino, E.D., “Decision at the end of life...”, *op. cit.*, 223-224.

those who are of the opinion that futility is not a useful concept, since the application of the treatments depends solely on the patient, or those who, although considered futility as a useful concept, do not believe that a definition which could be accepted by all is possible⁶⁷.

*Physiological futility*⁶⁸ defines that a treatment is futile when it does not achieve the desired physiological effect; the treatment does not offer benefits to the patient and, therefore, the doctor is not obliged to offer it. The main criticism of this definition is that it adds little to the usual practice and would only be useful in cases where the family insists on treatment against a physician's opinion. It does not avoid the problem of the therapeutic binge, and could even encourage it, having a vision centered on the organ and not on the "person as a whole"⁶⁹.

Quantitative and qualitative futility tries to evaluate two independent thresholds, one quantitative and the other qualitative, so that if the treatment does not exceed one of these two thresholds the physician should not offer the therapy⁷⁰. The quantitative threshold attempts to examine the objective aspects of treatment. For example, in an analysis of the last one-hundred cases collected in the literature, if from the experience, it would be concluded that the treatment has only been useful in one of the cases, the physicians should consider the treatment as futile. The qualitative threshold attempts to assess the subjective aspects of treatment. The qualitative threshold will be determined by the physician's evaluation of the patient's present and future QL. Both the quantitative threshold and the qualitative threshold are defined and evaluated by the physi-

cian. These thresholds have presented many critics but were however quickly accepted and incorporated into the guidelines of some medical associations. The quantitative dimension does not seem to take into account the problems of data interpretation, bias in the study of populations, statistics regarding the probability of survival, and ultimately the difficulty of determining if in one-hundred of the last cases the result has been unsatisfactory⁷¹. Regarding the qualitative threshold, the truth is that it wants to be objective, defined by the doctor, but at the end it falls into subjectivity when evaluating the patient's QL⁷².

c) *social or economic futility* integrates not only clinical data but also the economic costs⁷³. This kind of futility would try to establish a rationalization of resources through a definition of futility by social consensus. The main criticism that the authors make of the criterion of social or economic futility is that they confuse the plans of rationalization of resources (social plane) with that of futility (clinical problem)⁷⁴.

d) *Integrative definitions of futility*, integrate the different elements that appear as central in other definitions⁷⁵. It is about including both objective criteria, which belong to the physicians, and subjective criteria, which belong to the patient. The problem is that the futility thus understood loses its objective character. When integrating the physiological, quantitative and qualitative elements, when considering the costs and the economic expenses, are also incorporating all the negative considerations that these definitions present.

e) *The futility of the futility concept*⁷⁶. One group of authors consider that the concept of futility would be the new name of an old problem, namely that at a given

67 Cfr. Iceta, M., *Futilidad y toma de decisiones en medicina paliativa*, Córdoba, Caja Sur, 1997, 191.

68 Cfr. Council on Ethical and Judicial Affairs - American Medical Association, "Guidelines for the appropriate use of do-not-resuscitate orders", *JAMA*, 265 (1991) 1868-1871; The Hastings Center, *Guidelines on the termination of life-sustaining treatment and the care of the dying*, Bloomington, Indiana University Press, 1987; Truog, R.D., Brett, A.S., Frader, J., "The problem with futility", *The New England Journal of Medicine*, 326 (1992;) 1560-1564; American Academy of Pediatrics Committee on Fetus and Newborn, "The initiation or withdrawal of treatment for high-risk newborns", *Pediatrics*, 96 (1995) 362-363.

69 Cfr. Schneiderman, L.J., Jecker, N.S., "CPR-not-indicated and futility", *Annals of Internal Medicine*, 124 (1996) 75-77.

70 Cfr. Schneiderman, L.J., Jecker, N.S., Jonsen, A.R., "Medical futility: its meaning and ethical implications", *Annals of Internal Medicine*, 112 (1990;) 949-954.

71 Cfr. Nelson, S.N., "Do everything! Encountering 'futility' in medical practice", *Ethics & Medicine*, 19 (2003) 103-113, 106.

72 Cfr. Harper, W., "Judging who should live: Schneiderman and Jecker on the duty not to treat", *The Journal of Medicine and Philosophy*, 23 (1998) 500-515, 512.

73 Cfr. Murphy, D.J., Finucane, T.E., "New do-not-resuscitate policies. A first step in cost control", *Archives of Internal Medicine*, 153 (1993) 1641-1648, 1644.

74 Cfr. Jecker, N.S., "Medical futility: a paradigm analysis", *HEC forum, an Interdisciplinary Journal on Hospitals' Ethical and Legal Issues*, 19 (2007) 13-32, 23.

75 Cfr. Iceta, M., *Futilidad y toma de decisiones...*, op. cit., 191.

76 Cfr. Brody, B.A., Halevy, A., "Is futility a futile concept?", *The Journal of Medicine and Philosophy*, 20 (1995) 123-144.

time the physician cannot give a treatment that worsens the patient's condition, has no efficacy, or that its side effects are much more harmful than the benefits that are sought. Understood as such, the concept of futility would be a useless concept because it was already present in a practical way in medicine, and it should be replaced with other concepts that better respect the patient's participation in the decision as *risk-benefit balance*, *medically appropriate* or *the best interests of the patient*.

4.1.3. The only possible bridge: physiological futility

Given the various proposals of futility that we have presented, our question is: can these concepts of futility be bridges that connect medical ethics with decisions about to withhold or withdraw the LST? What concept of futility serves to configure the first element in the redefinition of the best interests standard? The application of different definitions, with different values and probabilities of success, has undermined the foundations of the concept of "futility"⁷⁷. The promise of objectivity, which was sought in the bioethical debate of the term futility, has not been achieved. Only physiological futility can serve as a bridging concept between bioethics and decisions about withholding or withdrawing the LST.

In presenting physiological futility as a bridge between medical ethics and decisions to withhold or withdraw the LST, we understand that defining the futility of treatment is only the first step in the decision process. It is the objective step, focused on the identification of treatments that should not be applied. The criticisms made about ignoring the whole person and not taking into account the preferences of the patient, will be overcome when we incorporate the second element in the redefinition of the best interests: the principle of proportionality.

4.2. The principle of proportionality

The *proportionality of treatments* is a solid term in

⁷⁷ Cfr. Truog, R.D., Brett, A.S., Frader, J., "The problem with futility...", *op. cit.* 1562.

the bioethical debate⁷⁸ and it is only the last crystallization of a long process of reflection that, within the Jewish-Christian tradition, has wanted to identify the ethical criteria that can guide us in the decisions about limiting or withdrawing treatments in a particular medical situation, and to establish the patient's moral obligation to care for and preserve his own life.

4.2.1 Historical and systematic roots of traditional moral teaching

From the origins of Christianity, the existence of a "positive" moral duty to care for health and life has been recognized⁷⁹. This reflection on the moral duties of preserving physical life had been welcomed by sixteenth-century moralists who, starting from the commentaries to Aquinas, developed the traditional distinction between ordinary and extraordinary measures of preserving life. Francisco de Vitoria [1486-1546], Domingo de Soto [1494-1570] and Cardinal Juan de Lugo [1583-1660], structured the formal application of these concepts to new medical therapies. Vitoria justifies the duty to use medical treatments on the moral certainty of possible benefits, preserving health or preventing an avoidable death. He even argues that when the use of medicine serves only to prolong life, the patient could be exempted from the moral duty to use such treatment if there are conditions that cause him moral impossibility, such as an excessive economic cost⁸⁰.

The writings of Vitoria recognize at least two requirements that tradition has accepted as a basis for the moral obligation of ordinary means of preservation of life: a) the hope of obtaining a reasonable profit (*spes salutis/vitae*)⁸¹; and b) the absence of a physical or moral impossibility for its use by the individual (*quaedam impossibilitas*)⁸². Tradition considers that the two condi-

⁷⁸ Cfr. Sacred Congregation for the Doctrine of Faith, Declaration on Euthanasia *Iura et bona* (05.05.1980), n. 27.

⁷⁹ Basilius Magnus, *Regulae Furius Tractae*, 398 ed. Migne, J.P., *Pratologiae Graecae* XXXI.

⁸⁰ De Vitoria, F., "Relecciones de la templanza", in Urdanoz, T. (ed.), *Obras completas*, Madrid, Biblioteca de Autores Cristianos, 1960, 995-1069, n.1, 1008.

⁸¹ Cfr. Cronin, D.A., *Ordinary and extraordinary means of conserving life*, Philadelphia, The National Catholic Bioethics Center, 2011, 122.

⁸² Idem, 139.

tions have to be given so that a medium can be defined as ordinary and, therefore, morally obligatory⁸³. In the Catholic tradition a series of expressions are used to define the characteristics of ordinary and extraordinary means which Cronin collects and fixes⁸⁴, in such a way that:

a) An ordinary treatment should have all of the following characteristics: *Spes salutis vitae*, that is, hope that the result is beneficial to the patient and that it should be worth it for its quality and duration. The greater the inconveniences they bear, the greater will have to be the hope. *Media communia*: the medium has to be in common use so that it can be considered mandatory. *Secundam proportionem status*: refers to the economic situation. Means that could be mandatory for a person with a lot of purchasing power, can be optional for an individual with normal resources. *Media non difficilia*: should not be too difficult to obtain or use, although moderate difficulty is admitted as the effort to obtain health is compensated. *Media facilia*: is easy to obtain and use.

Under these characteristics, Cronin proposes the following definition of ordinary means: "*Ordinary means of conserving life are those means commonly used in given circumstances, which this individual in his present physical, psychological, and economic condition can reasonably employ with definite hope of proportionate benefit*"⁸⁵.

b) An extraordinary treatment must meet the following characteristics. *Quaedam impossibilitas*, following the principle according to which *ad impossibilia nemo tenetur*, if for any reason a means is impossible to obtain, it is no longer mandatory. *Summus labor or media nimis dura*: the means used involves an effort or difficulty that goes beyond what is reasonable. *Quidam cruciatus or ingens dolor*: unbearably strong pain. *Sumptus extraordinarius, media pretiosa or media exquisitae*: excessive expenditure, not reasonable according to the economic situation itself. *Vehemens horror*: unconscious fear or re-

pugnance that constitutes a moral impossibility.

Once the characteristics are established, Cronin proposes the following definition of extraordinary means: "Extraordinary means of conserving life are those means not commonly used in given circumstances, or those means in common use which this individual in his present physical, psychological, and economic condition cannot reasonably employ or, if he can, will not give him definite hope of proportionate benefit"⁸⁶.

According to tradition, the distinction between ordinary and extraordinary means does not refer first to the type of medium in general, but to the moral character that the use of this medium has for a particular person. The distinction focuses on the person of the patient and the obligation he has to care for and protect his own life⁸⁷. It is what is called the relative norm. The relative norm allows one to be excused from the fulfillment of certain positive duties linked to the conservation of life, but it does not allow one to be exempted from the negative duties of the conservation of life⁸⁸. It is within the scope of positive duties that the relative norm can be adopted to define the ordinary (obligatory) or extraordinary (non-mandatory) nature of a life-preserving medium⁸⁹. The teaching of the moral theologians of the 16th Century has been transmitted without great variations to the magisterium of the Catholic Church throughout the 20th Century in diverse magisterial documents (Table 3).

We summarize below some of the characteristics of the doctrine on ordinary and extraordinary means by the Magisterium:

- It is a doctrine consolidated from the discourse of Pius XII in 1957.
- There is no uniformity in the use of the terms or in the meaning given to the terms used, sometimes being almost equivalent, while in other cases, when they are

⁸⁶ Idem, 112-113.

⁸⁷ Cfr. Taboada, P., "El principio de proporcionalidad terapéutica...", *op. cit.*, 124

⁸⁸ Cfr. Calipari, M., "The principle of proportionality in therapy: foundations and applications criteria", *NeuroRehabilitation*, 19 (2004) 391-397, 393.

⁸⁹ Cfr. Kelly, G., "The duty to preserve life", *Theological Studies*, 12 (1951) 550-556, 555.

⁸³ Cfr. Wildes, K.W., "Ordinary and extraordinary means and the quality of life", *Theological Studies*, 57 (1996) 500-512, 506.

⁸⁴ Cfr. Cronin, D.A., *Ordinary and extraordinary means...*, *op. cit.*, 112-139.

⁸⁵ Idem, 160.

Table 3. Documents of the Catholic Church Magisterium.

Year	Documents	Fundamental content	Input
1957	Pío XII, <i>En réponse à trois questions de morale médicale sur la réanimation</i> (24.11.1957)	It picks up the distinction between ordinary and extraordinary means. Ordinary means compel to the patient, the family and the doctor. Extraordinary means do not bind the patient, the family, or the doctor. Extraordinary means can be used but are not morally obligatory.	First appearance in the magisterium of distinction between ordinary and extraordinary means.
1980	Congregation for the Doctrine of Faith <i>Declaration on euthanasia – Iura et bona</i> (05.05.1980)	It tries to overcome ordinary / extraordinary distinction by introducing the principle of therapeutic proportionality. It gives a series of criteria: - illicit use of disproportionate means - is licit to discontinuation of disproportionate treatment - is licit be content with ordinary means - regardless of the means used, it is lawful in conscience to make the decision to renounce treatments that would seek a precarious and painful prolongation of life.	Definition of euthanasia It introduces the concept of therapeutic proportionality. It places the ordinary / extraordinary reflection in the context of the reflection on the end of life.
1981	Pontifical Council <i>Cor Unum</i>, Question of ethics regarding the fatally ill and the dying (27.06.1981)	Chapter 2.4 It collects the nomenclature of proportionality but uses in the text the ordinary / extraordinary distinction. It introduces the distinction between objective and subjective criteria. The fundamental criterion will be to establish a ratio between the means and the ends pursued. It defines the obligatory minimum means as “those which are normally and customarily used for the maintenance of life”. Chapter 7.2 - 7.3 Doctor's position. Avoid the therapeutic obstinacy. Evaluate the particular situations of the light of the principle of distributive justice.	It introduces the criterion of “quality of life to be saved or kept living by the therapy” as a criterion of proportionality to which to give a special relief. It includes “what effect will be had upon the family” as an element of the possible decision.
1992	Catechism of the Catholic Church n. 2278 y 2279	n.2278 Discontinuing medical procedures that are burdensome, dangerous, extraordinary, or disproportionate to the expected outcome can be legitimate; it is the refusal of “over-zealous” treatment. n. 2279 Encourages palliative care.	Encourages palliative care.
1995	The Pontifical Council for Pastoral Assistance to Health Care Workers <i>Charter for Health Care Workers</i>	n.119 The problem of dying with dignity and therapeutic obstinacy. n. 120 The proportionality of the treatments. It also insists on nutrition and hydration as normal treatments. n.121 The role of the doctor is not to decide on life or death, but the care of living and dying of the patient.	The ordinary / extraordinary distinction must be applied not only in the fine-vitae context but also in any situation in which the moral obligation to use medical therapy is called into question.
1995	John Paul II, Encyclical letter <i>Evangelium Vitae</i> (25.03.1995)	n. 65 Definition of euthanasia. It places euthanasia at both the level of intentions and the methods used. n. 65 Definition of aggressive medical treatment. Medical interventions not adequate to the actual situation of the patient, because they are disproportionate or because they are too burdensome for the patient or his family. n. 65 The methods of palliative care, as a condition to assure the patient adequate human accompaniment.	Definition of aggressive medical treatment

used, they have different nuances.

- The terms ordinary / extraordinary are the most used-

- The terms proportionate / disproportionate have not been fully assumed in the subsequent documents to *lura et bona*. The principle of proportionality has been used as a criterion for distinguishing between ordinary treatments and extraordinary treatments.

Applying the principle of proportionality, both objective factors (quantitative) and subjective factors (qualitative) are considered, not only in relation to the patient, but also to the family.

4.2.2. The principle of ethical adequacy

From the analysis of classical theology and the assumption of the Magisterium about the concepts of ordinary and extraordinary treatment, M. Calipari has emphasized the difficulty that supposes the existence of several ordinary / extraordinary and proportionate / disproportionate terms, and the necessity to consider objective and subjective aspects when evaluating treatments that should be mandatory or optional. Therefore, he proposes a decision making process in two phases⁹⁰:

a) Firstly, an objective phase, based on the evaluation of the medical efficacy of the treatment. This stage is called *the evaluation of the proportionality* of the medium and tries to evaluate "the technical-medical adequacy or inadequacy of its use, in relation to the achievement of a specific health objective or vital maintenance for the patient"⁹¹. At this stage, the most objective aspects of treatment should be taken into account, such as its reasonable availability, the technical possibility of using it properly, a reasonable expectation of medical efficacy, possible harmful side effects for the patient, possible risks to health and life of the patient, the possibility of appealing to other therapies, and the quantification of health resources.

b) A second phase, subjective stage, is based on the

evaluation of the global effectiveness of the treatment. It is about evaluating the most significant health effects that therapy produces for the life of the patient, according to the personal assessment of the patient, in the context of his/her personal history and according to a scale of values. Calipari puts this second phase in relation to the concept of ordinary / extraordinary treatment considering that this phase is the one that better reflects the subjective dimension of the patient, who is responsible for evaluating this phase. Based on the physical or moral *quaedam impossibilitas* that Cronin proposed, Calipari considers that it would have to be evaluated, in this second phase, if excessive effort is demanded for the patient, or an enormous or unbearable pain is provoked which cannot be sufficiently relieved; if the economic costs are very burdensome for both the patient and his / her relatives, or if there is an invincible fear or a strong disgust with regard to the treatment: to evaluate the reasonably high probability of a serious risk to the life or to the health of the patient, evaluated by the patient itself in relation to his or her current condition; the low overall efficiency of treatment in relation to the expected benefits and the possible permanence, due to the use of the medium, of clinical conditions such as to prevent the patient from fulfilling their more serious and pressing moral duties, which cannot be deferred without negative consequences for the patient or for other people.

Calipari considers that these two phases are not independent nor successive but they are crossed and overlap. He then carries out a synthesis process, obtaining three possible results that Calipari values morally:

- a proportionate and ordinary means is compulsory.

- a proportionate and extraordinary means is not obligatory (only if it is necessary for the spiritual good of the patient or in situations of special obligation of justice would it be obligatory)

- a disproportionate means is morally illicit (treatment could only be considered if it was the only way for the patient to perform serious and pressing moral duties).

The main criticism that can be made to Calipari, and which the author himself acknowledges, is that this ap-

⁹⁰ Cfr. Calipari, M., *Curarsi e farsi curare: tra abbandono del paziente e accanimento terapeutico*, Torino, San Paolo, 2006, 147-168.

⁹¹ Idem, 152.

proach, although it includes the elements indicated in the magisterial documents, cannot be considered as a conclusion that is contained in them. What it does is to propose a uniform use of terminology (proportional / disproportional = objective level, ordinary/extraordinary = subjective level) and a procedure, when assessing treatments in the later stages of life, which is presented as very practical to analyze the most complex cases.

5. The best interests standard as the therapeutic proportionality standard

Following Sullivan, we believe that the proposal presented by Calipari on ordinary and extraordinary means could be developed through the distinction between: *judgments that refer to futility* and *judgments that refer to proportionality*, or to the ordinary / extraordinary treatments⁹². The best interests standard would be safeguarded whenever a two-step decision process would be followed: the first step, using a negative criterion, in which the protagonist is the physician, and the second step, using a positive criterion, in which the protagonists are the physician, the incompetent patient and their relatives or guardians. At the end of these two steps a moment of synthesis would come in which the moral assessment of the treatment would be carried out. The whole of this process is what we call the principle of therapeutic proportionality, and we propose it as the new content for the standard of the best interests of the patient.

5.1. Physiological futility as a negative criterion

We believe that making a judgment on the physiological futility of treatments, understood in this rigorous sense, is based on facts and values that fall within the normal competencies of physician and other health agents and that, therefore, it would be ethically justified to not propose these measures to patients and, in

the case of incompetent patients, to their relatives or guardians.

This first step focuses on the technical-medical efficacy of treatment and would correspond to the first step in the principle of ethical adequacy of Calipari⁹³. However, we believe that the concept of futility reflects more clearly this first step, which corresponds to a negative criterion (the identification of treatments that should not be applied), whose agent is always the medical team and which amounts to a morally illicit treatment. This is what Calipari would call "disproportionate". In this sense we prefer the distinction between futile treatment and proportionate treatment (which in turn is distinguished in ordinary and extraordinary treatment). The criterion of physiological futility thus becomes the first step of the decisional process, as a negative criterion, and is the "useful bridge"⁹⁴, to arrive at the ethical formulation of ordinary and extraordinary treatments, in the specific cases about the end of life.

5.2. The principle of proportionality as a positive criterion

When we talk about making proportionality judgments, we have to keep in mind that it is a separate category of other judgments. These judgments would be necessary when medical information on the efficacy of possible treatments, in relation to the global target of the chosen treatment, is uncertain, probable or incomplete. That is, proportionality has to do with uncertainty about the effects of treatment and uncertainty about the prognosis of the disease. In this second moment the subjective aspects are taken into account.

Contrary to the judgments about futile treatments, judgments regarding the proportionality of treatments, in relation to the overall objective, should be discussed with the patient and, for incompetent patients, with their relatives or guardians⁹⁵. They are the ones who

92 Cfr. Sullivan, S.M., "The development and nature of the ordinary/extraordinary means distinction in the Roman Catholic tradition", *Bioethics*, 21 (2007) 386-397; You can also see, Requena, P., "Il principio di prudenza terapeutica. Oltre le distinzioni ordinario-strarordinario e proporzionato-sproporzionato", *Medicina e morale*, (2019) 125-139, where he arrives at the same conclusion but with a different analysis.

93 Cfr. Calipari, M., *Curarsi e farsi curare...*, *op. cit.*, 152.

94 Cfr. Pellegrino, E.D., "Decision at the end of life...", *op. cit.* 220.

95 Cfr. Sullivan, W., "Diferenza tra limitazione dell'impegno terapeutico ed eutanasia omissiva: il ruolo dell'indicazione medica", in Sgreccia, E., Laffitte, J., (eds.), *Accanto al malato inguaribile e al morente: orientamenti etici ed operativi. Atti della quattordi-*

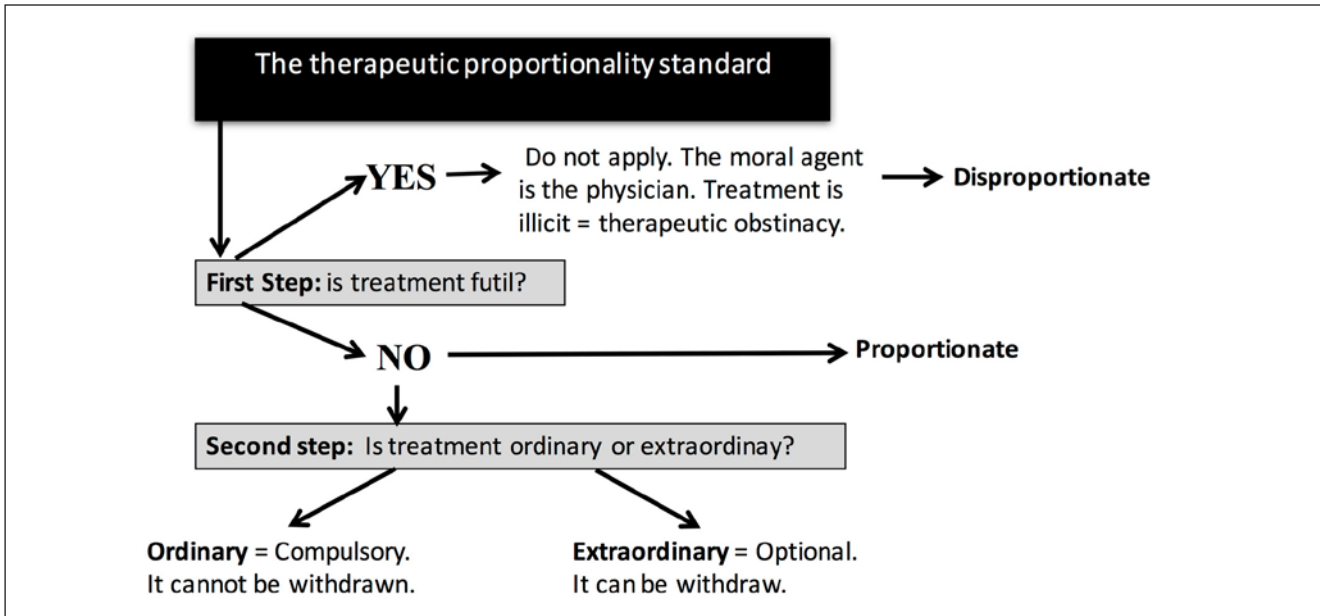


Figure 2. The application of the therapeutic proportionality standard

have to evaluate, together with the doctors, if at this moment and in this specific situation, they have a certain impossibility (*quaedam impossibilitas*), physical or moral, for the use of this particular treatment. The following must be evaluated:

- If the effort is excessive when disposing or using the treatment not only by the patient but by the family.
- Whether the physical pain will be heavy or unbearable or cannot be sufficiently relieved.
- If the economic costs to use the treatment are burdensome for the family of the patient.
- If the patient or his / her relatives, caregivers, experience a tremendous fear or a strong repugnance regarding the use of the means.
- A reasonably high probability of serious risk to the life or health of the patient that is linked to the use of the medium that is valued by the family in relation to the severity of the patient’s current situation.
- A low “global efficacy” rate, in relation to the benefits reasonably expected for the patient, according to the

axiological and values scale adopted by their relatives.

- The permanence, after the use of the treatment, of clinical conditions that prevent the patient from fulfilling the most serious and pressing duties.

5.3. Two moments that overlap

We believe that these two moments are not successive phases but they overlap in the dialogue of the medical team and the relatives when deciding which treatments can be applied to incompetent patients. The meaning of the therapeutic proportionality standard is not tied to the state of technological progress nor to the naturalness or artificiality of the treatment, but taking into account the specific situation of the patient and his / her family, examines the efficacy (objective / futility) and the global efficacy (subjective / the principle of proportionality) having as protagonists and moral agents in the decision both physicians and relatives. This is the only way to safeguard the patient’s best interest standard.

5.4. The ethical assessment of treatment

The evaluation of treatment would be defined ac-

cesima assemblea generale della Pontifica Accademia per la Vita, Ciudad del Vaticano, Libreria Editrice Vaticana, 2009, 173-195; González-Melado, F.J., “Family Centered Bioethics: a new bioethical framework for decision-making in neonatal and pediatric units”, *Journal of Clinical Research and Bioethics*, 7 (2016) 1-5.

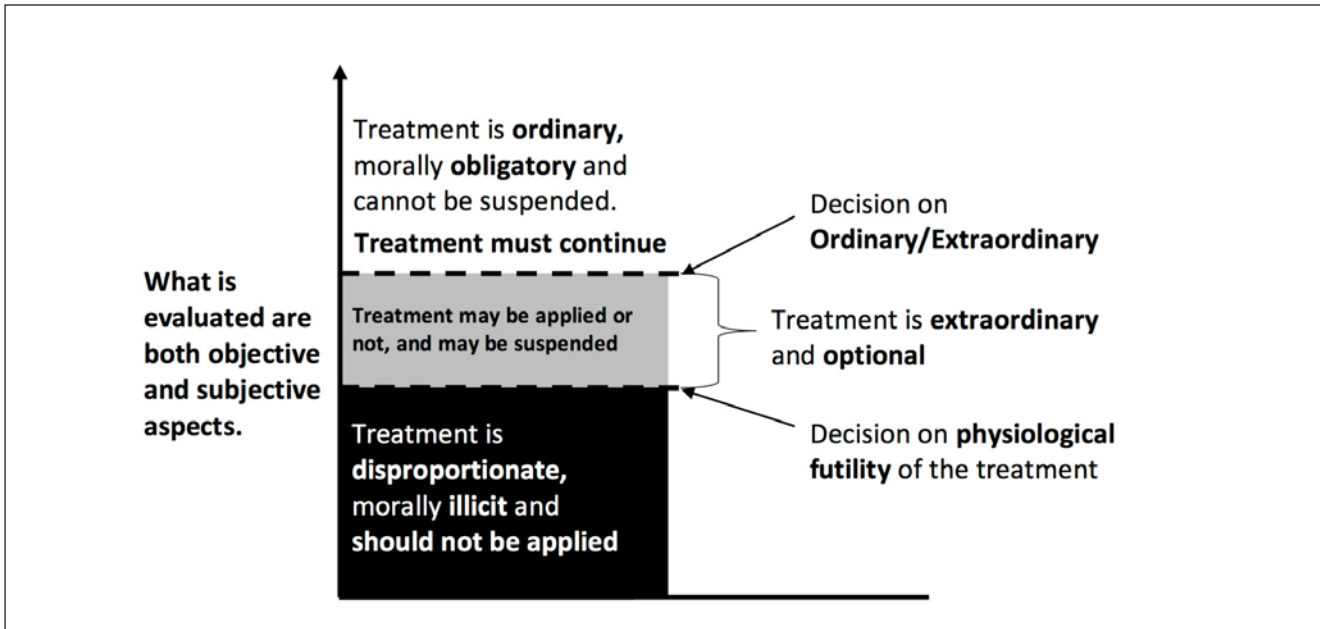


Figure 3. Modification of the figure proposed by Wilkinson according to the standard of therapeutic proportionality. We eliminate the criteria based on QL prognosis and replacing them with the objective criteria of treatment efficacy (physiological futility as a “lower threshold”), and the assessment of treatment by the medical team with the patient’s family (ordinary treatment = “upper threshold”, extraordinary treatment = “gray zone”). The process, as a whole, is the therapeutic proportionality standard as the new content for the patient’s best interest standard.

According to the results obtained in the two steps of our decision process (Figure 2):

- If the doctor considers that a particular treatment is futile, given the patient’s clinical situation, it is ethically justified not to offer this treatment to his relatives, although it would be advisable to explain to his parents the reasons that lead him to consider it futile. Following Wilkinson’s scheme, physiological futility would be the “lower threshold” below which doctors would not be allowed to offer treatment to the patient’s family members (Figure 3).

- If the doctor considers that the treatment is not futile, given the patient’s clinical situation, he/she should offer it to the parents, initiating a dialogue in which, together with the family members, he/she must evaluate whether the treatment is ordinary or extraordinary. If the assessment they make is that the treatment is ordinary, it means that the treatment is mandatory and cannot be withdrawn. It would equate to what Wilkinson considers “upper threshold”, above which treatment is

mandatory and physicians cannot allow family members to stop treatment (Figure 3). If the assessment they make is that the treatment is extraordinary, it means that the treatment is not mandatory, it is optional, and that if you choose to start treatment it can be suspended at a certain time. This is what Wilkinson called the “grey zone”.

In developing the two steps of the patient’s best interest standard, understood as the therapeutic proportionality standard, we obtain the following classification of treatments destined to the conservation of life:

- A) futile (disproportionate)
- B) non-futile and ordinary treatment (proportionate & ordinary)
- C) non-futile and extraordinary treatment (proportionate & extraordinary)

In critical clinical situations, where the patient’s best interest standard is required, physicians and their families can make a moral assessment of treatments by assigning them to one of these three categories. The moral

value of each category is defined by the moral duty of the use of this means to preserve the life of the patient and which is defined, in turn, by three moral categories: *illicit, compulsory and optional*.

The possible treatments would be morally valued as follows:

A) A futile treatment would be morally illicit, could be considered excessive and would amount to a therapeutic obstinacy.

B) A non-futile and ordinary treatment would be morally compulsory and cannot be suspended without committing euthanasia.

C) A non-futile and extraordinary treatment would be morally optional or facultative, and the patient, or his/her relatives in the case of an incompetent patient, can decide whether to use it or not.

6. Conclusion. Answering three questions

In redefining the patient's best interest standard, we asked ourselves three questions that we have attempted to answer by redefining the content of the best interests as the therapeutic proportionality standard.

The answer to the first question, when to apply the standard of the best interests?, is given by the *clinical situation of the patient*. In cases where treatment is clearly indicated and effective, although the process of ethical deliberation would not be strictly necessary, it is convenient to carry out a deliberative communication process prior to the decision-making process, where doctors can propose to the relatives of the incompetent patient the elected treatment. The application of the best interests standard would be reserved for those critical situations, where proportionality judgments come into play, that is, where there is an uncertainty both in the effectiveness of the treatment and in the prognosis, or when it is the same, in the global objective of treatment.

The second question refers to the application procedure: "How should it be applied?" We propose an application of the standard in two phases, not successive but overlapping, and which correspond to a dialogical process between physician and family. In a first step, and as a negative criterion, would be the analysis by

the medical team of the physiological futility of possible treatments. It is a technical-medical decision that includes the objective level of the moral qualification of treatment. At another given time, it would try to establish the best interests of the patient through the content that gives us the principle of proportionality. It is a moment of evaluating the subjective aspects, which refer to the patient and his / her relatives when facing the disease and the proposed treatments.

The sum of these two elements (futility + principle of proportionality) is what we consider to be the content of the standard of best interest of the patient and which we call the standard of therapeutic proportionality.

The third question referred to the moral agent, the protagonist in the decision making process: "Who should decide?" In the first step, the technical-medical analysis of the futility of the treatments, pertains to the medical team. It is very important that in this part of the process, the medical team's decision is marked by scientific-medical data and is not influenced by subjective assessments, such as the patient's future QL, which could condition the approach to a particular treatment. In the second step, the decision belongs to the medical team and family members. Through a process of decision-making in dialogue, it is the medical team who must present to the relatives the different possibilities of treatment, showing the difficulties, risks and complications of each treatment. The relatives are those who, based on the offer of possible treatments, must make an analysis of the proportionality (ordinary / extraordinary) of the treatments, taking into account the specific circumstances of both the patient and his/her family. The decisions are taken by the medical team and the family members. They are the moral agents responsible for the decision making process in this second phase.

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