

Limitation of therapeutic effort in person with severe brain injury

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Abstract

Discussions about the limitation of therapeutic effort are common in intensive care units and oncology and are also important in long stay hospitals for victims of major trauma and injuries that require long-term health care and social reintegration. In clinical practice, the decision making for limitation of therapeutic effort is complex and multifactorial and should involve the individual, the family and the multidisciplinary team. The purpose of this article is to discuss about limitation of therapeutic effort as a comprehensive process of “adjustment of measures” for consensual aggregation of person-centered factors, marked by intensification of palliative care.

Key words: Right to die. Bioethics. Palliative care. Decision making. Brain injury, chronic. Persistent vegetative state.

Resumo

Limitação de esforço terapêutico na pessoa com lesão encefálica grave

As discussões a respeito das condutas de limitação de esforço terapêutico (LET) são frequentes nas unidades de terapia intensiva e na especialidade médica oncológica e são também importantes em contextos hospitalares de internação de longa permanência para vítimas de grandes traumas e agravos que necessitam de cuidados prolongados à saúde e de reinserção social. Na prática clínica, a tomada de decisão para LET é complexa e deve envolver o indivíduo, a família e a equipe multiprofissional. O objetivo deste artigo é discorrer a respeito da LET como um abrangente processo de “adequação de medidas” por agregação consensual de fatores centrado na pessoa, pautado por intensificação dos cuidados paliativos.

Palavras-chave: Direito a morrer. Bioética. Cuidados paliativos. Tomada de decisões. Traumatismo encefálico crônico. Estado vegetativo persistente.

Resumen

La limitación del esfuerzo terapéutico en persona con lesión cerebral grave

Las discusiones acerca de las conductas de limitación del esfuerzo terapéutico (LET) son comunes en las unidades de cuidados intensivos y oncología y también son importantes en hospitales de larga estancia para las personas víctimas de traumatismos graves y lesiones que requieren atención de salud a largo plazo y la reintegración social. En la práctica clínica, la toma de decisiones para la LET es compleja y debe abordar al individuo, la familia y el equipo multiprofesional. El propósito de este artículo es discutir sobre LET como un proceso integral de “adecuación de medidas” mediante la agregación consensual de factores centrados en la persona, marcado por la intensificación de los cuidados paliativos.

Palabras-clave: Derecho a morir. Bioética. Cuidados paliativos. Toma de decisiones. Traumatismo encefálico crónico. Estado vegetativo persistente.

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The progressive technological development and the adoption of effective measures of life support have enabled an increase in the number of major trauma survivors in intensive care units (ICU) ^{1,2}. Consequently, there has been a growing demand of patients for long-stay hospitalization with serious neurological sequelae and totally dependent in their activities of daily living. This is the case of comatose patients, unresponsive or minimally responsive post-coma.

The keynote of human dignity in dying and the ethical and legal dilemmas in relation to the politics of resource allocation, the appropriate treatment to be provided to patients in clinical and functional decline and the complex process to identify clear therapeutic limits, especially in victims of severe brain injury, raise ongoing discussions on the limitation of therapeutic effort (LTE). Discussions about the LTE behaviors are common in ICU and in oncology medical specialty. Reflections on the decision making process in LTE are also needed in hospital contexts of long-stay for neurological cases. For example, the multidisciplinary team may come across a scenario of a patient in clinical decline, with loss of autonomy for severe neurological injury for months or years, and a psychological and socially dysfunctional family, when present, or even when not identifying relatives.

The expression "limitation of therapeutic effort" (LTE) has been questioned by some authors ³. Herreros et al., for example, argue that "limitation" is not restricted to therapy, covering also diagnostic procedures. In addition to this consideration, the expression can bring the negative connotation of "limitation of effort" of a professional or team, with the relativization of "effort." Finally, being "out of therapeutic possibilities" may refer to the "nothing to do" in a circumstance that, paradoxically, intensify palliative care in a measure that they become exclusive. Thus, Herreros et al. (2012) have proposed the term adaptation measures (AM) in the debates on LTE ³.

The adoption of the expression AM in this article reflects the proposal of reaffirming ethical and human values in assisting the person with severe brain injury, terminally ill or not. Therefore, the main objective is to discuss about the decision making of AM as consensual process of aggregation

factors centered in the person, seeking to stimulate and broaden reflections on the ethical, normative and clinical perspectives.

Adequacy of measures

The AM is established in patients whose clinical condition is serious, irreversible or terminal and may be defined as restrictive medical procedures, in which the use of certain therapeutic resources is limited ². The orthothanasia or the "art of dying well" approaches to this definition, human, from point of view of the management of care of patients and their families in the dying process, distinguishing from disthanasia and euthanasia, in which the intention is to merely to prolong dying or accelerate this natural process, respectively ^{2,4}. Despite the theoretical distinction of these definitions, the conceptual boundaries in the clinical practice for the long stay patients with severe brain injury may sometimes not be as clear, considering the hospitalized person, the family and the multidisciplinary team. Thus, the clinical decision making on the use or suspension of therapeutic measures in this clinical profile requires constant reflections on the relationship between life prognosis and future quality of life throughout the hospitalization period.

A humanized perspective arised from the palliative philosophy that has been transformed into reality refers to the understanding that the curative model does not linearly precedes the palliative, but they both act together, by superimposition, in the pursuit of collateral relief of symptoms that cause discomfort since the diagnosis of the life threatening disease ^{5,6}. Particularly in the hospital context, it is recommended this concomitant action since the admission in the ICU, and then the hospitalization, extending to the post-death with psychological support to family ^{5,6}. Thus, the AM could also be understood as the process of overlapping the curative model for the palliative care, firming the individualized and humanized palliative care as the therapy to be enhanced or exclusive. Recommendations for AM, as proposed by the Spanish Society of Intensive Care Medicine, can currently be seen as indicators of quality in health care ⁷.

AM as “as consensual process of aggregation factors centered in the person”

Key elements of the decision-making process of AM

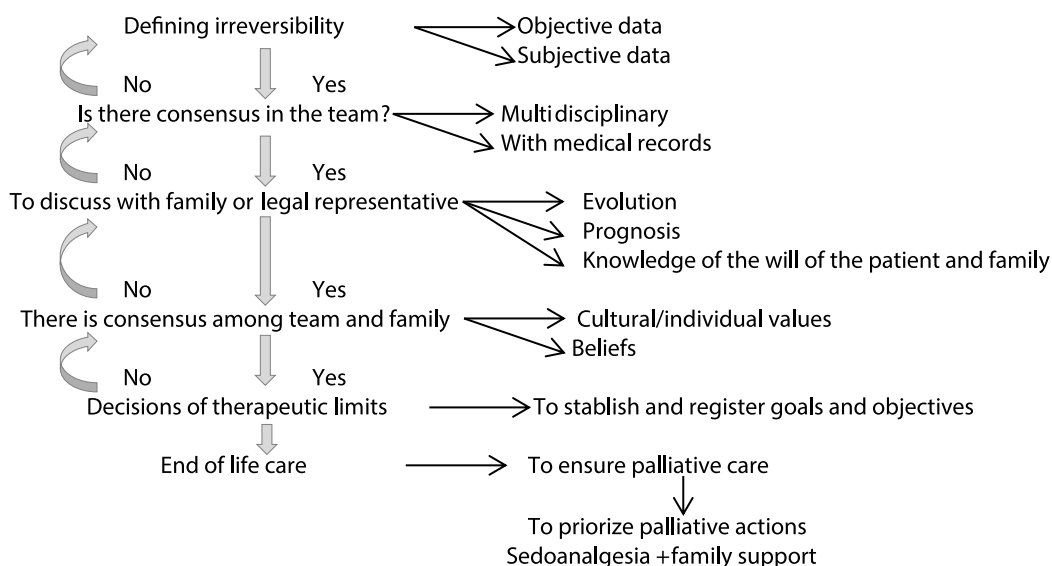
The Australian Government, through the National Health and Medical Research Council, recommends the use of the word “person” instead of “patient” in order to emphasize the autonomy, values, and personal, family and spiritual beliefs, as well as the socioeconomic context of the individual⁸. It suggests to refer to a person by the following expressions “non-responsive post-coma” or “minimally responsive”, and not a “vegetative state” for ethical purposes in order to avoid such potentially pejorative expressions⁸. And according to that, this article proposes the use of the word “person” and the expressions “non-responsive post-coma” or “minimally responsive” in the reflections on AM.

The decision making is permeated by the subjectivity of those involved. Herreros et al. highlight the complexity of the AM thematic when stating that rational arguments can serve as criteria for decision making, but do not completely eliminate the uncertainty of the process³. Moritz et al. highlight that objective and subjective criteria should be considered in this broad decision-making process that is certainly individual².

Flowcharts for AM have been proposed in the literature (Pictures 1 and 2)^{6,9}. The analysis of these graphic representations of AM allows highlighting some important points. The person, the family (legal representative) and the multidisciplinary team are intrinsic fundamental elements that need to be considered as participatory parts in the decision-making process. The autonomy of the person (preferences) in the decision making, or of the family (legal representative) when it applies, is the main guiding the process, both from ethical and legal perspective.

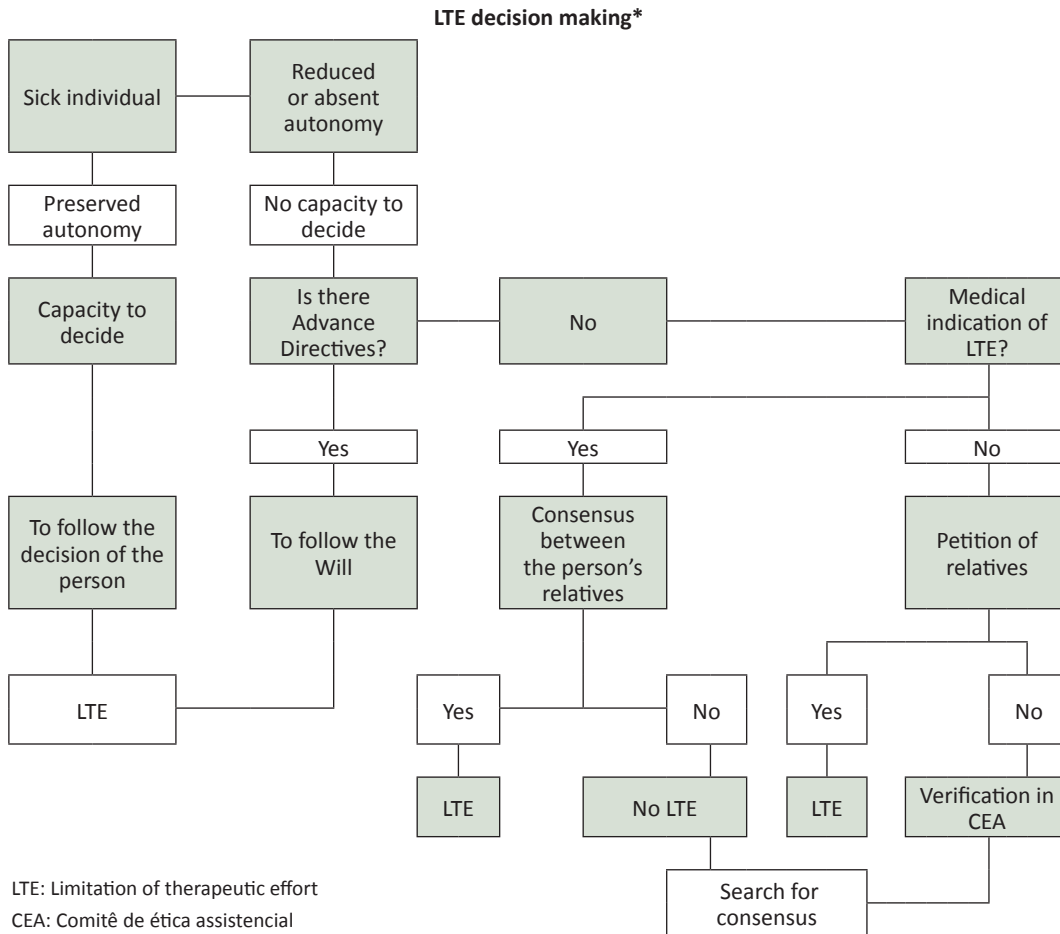
The decision is consensual, multifaceted and shared from questionings to be discussed at relevant levels and times to each of the intrinsic elements of AM: diagnostic accuracy, the chances of success of available therapies, the prostration of therapeutic means, the probability of cure and life expectancy for the current evolutionary stage in which this “this” person is, in other words, the prognosis of life - one of the biggest challenges in medicine, taking into consideration the quality of life (previous and future), the age and the cognitive impairment^{3,6,9} of each case. For this, the time of the person and their family should be respected regarding the comprehension of the process, during which it must ensure palliative care and support for each of the three participatory elements. Moreover, any decision should be reviewed at any time⁶.

Figure 1. Flowchart for AM decision making proposed by Moritz et al. (2011)



We emphasize → The support to patient, family and the multidisciplinary team must be guaranteed throughout the process.
 → Any decision can be reviewed at any time.
 → The time of the patient and family regarding the understanding of the process must be respected.

Figure 2 Flowchart for AM decision making proposed by Ortega and Cabré (2008)



Fundamental ethical principles for the AM decision making process

Bioethics is guided primarily by four principles: autonomy, beneficence, non-maleficence and justice ². These principles can be understood as guidance to justify the medical precepts and human actions in the area of sciences of life and health care ¹⁰.

The principle of autonomy refers to self-determination, to self-government, to the power of deciding by your own. This ability to making the own choices entails responsibilities and represents an inalienable right. In general, the respect for autonomy makes the decision-making authority to reside in the person and, being this person unable to do so, it is made by his legal representative, usually a close relative ^{2,10}.

The principle of beneficence constitutes the duty to promote benefits to others, regardless of desiring it. Also assumes the primary ethical obligation to provide such benefits by suppressing the malefaction. The physician must commit to the pursuit of

meeting the goals of medicine, which can be summarized in treating the person with the best possible, restoring to health, preserving life and relieving suffering ^{2,10}.

The principle of non-maleficence requires not harming another and is violated when in a person a not indicated treatment is applied, which causes complications, damage or injury of any kind. The professional compromises on assessing and preventing foreseeable harm ^{2,10}. In general, the principles of beneficence and non-maleficence should be analyzed together in order that decisions are more useful than harmful. The phrase from Hippocrates reflects that: *Practice two things in dealing with diseases: assist and do not harm the patient* ².

The principle of justice as *prima facie* duty involves ethical-cultural and temporal issues and is based on the possibility that the distribution of social goods does not occur according to the merits of the persons affected ^{2,10}. The principle of justice that governs the distribution of health resources, duties

and social benefits is consistent and appropriate. It is in agreement with the formal justice proposed by Aristotle stating the impartial provision for the recognition of everyone's right and the provision of an equal treatment^{2,10}.

Despite the conceptual clarity of each of the four bioethical principles of medical practice, unceasing questionings of the application of collective clinical practice in AM. Moritz et al. claim that *therapeutic decisions are certainly individuals, based on a broad context that involves the evaluation of clinical and social aspects based on objective and subjective criteria. However, with no doubt, there is the ethical basis of the promotion of orthothanasia and in the implementation of palliative care to critical patients*². For these authors, the referred orthothanasia approaches its conceptual reference to LTE, *restrictive medical procedures that limit the use of certain inappropriate or useless resources, as opposed to the practice of any therapy that will only prolong the dying and increase the suffering of the person and the family*².

Relevant normative aspects of the AM decision making process

Relevant to the theme of AM, Torres affirms that *the extension of dying, that is, the therapeutic obstinacy, brought specially by the technology of this modern world is stimulated by the practice of a "defensive medicine", consistent in the adoption of all available resources and procedures, even known as useless and unnecessary, with the sole purpose of providing evidence of a good professional practice. In the treatment of patients with terminal illnesses, the fear of the possibility of ethical, civil and criminal liability for death has led physicians to promote dysthanasia*¹¹.

From a normative point of view, in November 2006, the Federal Council of Medicine (FCM) published the Resolution FCM 1805/06, describing in his 1st article that: *in the terminal stage of serious and incurable illnesses the physician is permitted to limit or suspend procedures and treatments prolonging the life of the patient, assuring him/her the necessary care to alleviate the symptoms that lead to suffering, in the perspective of a full assistance, by respecting the wish of the patient or of his/her legal representative*. In paragraph 4, describes: *When it comes to unable patient, if absent the legal representative, shall the physician to decide on the measures mentioned in the caput of this article*. Moreover, describes in paragraph 2: *The patient will continue to receive all necessary care to alleviate symptoms that lead to suffering, assured the full*

*assistance, physical, psychological, social, spiritual comfort, including the right of discharge from the hospital*¹².

It is emphasized in these articles and paragraphs of the resolution the delimitations within the principle of autonomy in the decision making process of therapeutic limitation: first the person, second the legal representative, and finally the physician. Also, the continuous palliative care is ensured. In 2007, this resolution was suspended and, in December of 2010, repealing the injunction suspended after debates of federal prosecutors, representatives of CFM, health professionals and representatives of society regarding orthothanasia as a morally and legally legitimate medical practice¹¹.

In accordance with this resolution, the Code of Medical Ethics (CME) of 2010, in section XXII of Chapter I, Fundamental Principles, provides that *in the irreversible and terminal medical conditions, the physician will avoid performing unnecessary diagnostic and therapeutic procedures, and will give all appropriate palliative care to patients under his responsibility*¹³.

Besides, the Article 41 of the Code of Medical Ethics claims that *the physician is prohibited to shorten the patient's life, even if requested by him or his legal representative*. This article considers in its sole paragraph that *in cases of incurable and terminal disease, the physician must provide palliative care available, and all actions must be taken without being unnecessarily diagnostic or therapeutic or stubborn, always taking into consideration the wishes of the patient or, in their absence, of their legal representative*¹³. It is once again emphasized the autonomy of the person or legal representative, ensuring palliative actions in the terminality.

As for the autonomy of the person, the Resolution 1995/12 of FCM¹⁴ provides for the advance directives of *patients will, defining in its article 1st as set of desires, previously and expressly manifested by the patient, the care and treatments you want or not receive at the time is unable to express freely and autonomously, will*. In Article 2, the norm refers to the decisions on care and treatment of patients who are unable to communicate or to freely and independently express their will, indicating that the physician should take into account the patient's advance directives, emphasizing in the following paragraphs that:

§ 1 If the patient has designated a representative for this purpose, your information will be taken into consideration by the physician. § 2 The doctor will

take into account the will of advance directives from the patient or representative who, in his analysis, are at variance with the precepts dictated by the Code of Medical Ethics. § The third patient's advance directives shall prevail over any other non-medical opinion, including on the wishes of the family. § 4 The medical record, the medical records, advance directives will directly communicated to them by not being known patient. § 5th the advance directives of the patient's will, or designated representative there, available family or lack of consensus among these, the doctor will use the Bioethics Committee of the institution, if any, or in his absence, the medical Ethics Committee of the hospital or the Federal Regional Council of Medicine and base your decision on ethical conflicts, when deemed necessary, but this should be ¹⁴.

This resolution reinforces the autonomy of the person about the care and treatment provided since in accordance with the Code of Medical Ethics. Also supports the medical decision making in situations of AM in comatose people, post-coma unresponsive or mentally incapable, without family reference or legal representative, socially disadvantaged - a hospital reality that should not be neglected. From the reflection on the normative medical practice in the context of terminal illness and palliative care, it can be observed the principles and ethical and regulatory aspects intrinsic to AM. In this sense, Moritz et al. affirm that one can see *that in Brazil there is ethical support to palliative care, covering the treatment limitation considered futile or useless* ².

Historical factors

The socioeconomic background, the previous quality of life and comorbidities of the person are some of the factors that make part of the process of consensual aggregation for the AM decision making ³. For example, elitism, smoking and drug use can negatively impact or even worsen the clinical course of a person with significant brain injury. Comorbidity is considered as the leading predictive indicators of mortality and morbidity ¹⁵.

Prognostic factors

In 2000, the Brain Trauma Foundation (BTF) has published a document with the aim of identifying early indicators of prognosis in severe traumatic brain injury based on the 'Glasgow Outcome Score' (GOS) ¹⁶. Originally, the GOS is a five-item scale: 1) death; 2) persistent vegetative state; 3) severe disability; 4) moderate disability; 5) good recovery. In-

dicators endorsed by The American Association of Neurological Surgeons and the World Health Organization's Committee on Neurotrauma and that have a positive predictive value (PPV) of at least 70% are initial score of the Glasgow Coma Score (GCS), age, pupillar reflection, hypotension, and specific findings on the computed tomography (CT) exam ¹⁶.

The GCS measures the level of consciousness in acute neurological conditions and is based on three criteria: eye opening, motor response, and verbal response. The lower the initial score, the higher the commitment level of consciousness and a growing likelihood of an unfavorable outcome in GOS. The GCS should be measured in a standardized manner through the interaction with the person by a trained staff (for example, application of a painful stimulus in people unable to follow commands). For prognostic purposes, the measurement should be made only after pulmonary and hemodynamics resuscitation, and after pharmacological sedation or the metabolizing of paralyzing agents. If the initial GCS is reliably obtained, not being influenced by pre-hospital medication or intubation, nearly 20% of patients with lower initial scores survive and 8% to 10% will present GOS 4 or 5 ¹⁶.

Regarding age, there is an increased likelihood of an unfavorable outcome with aging. This variable is not subject to variability as measured by the observer and should be obtained on admission, preferably with supporting documentation. Age is considered a strong independent predictor of mortality and morbidity, particularly in those over 60 years old ¹⁶.

The pupillar diameter and pupiloconstrictor reflex to light are two important parameters associated with the prognosis. The absence of the pupillary reflex to bilaterally light is an important predictor of a favorable outcome. This parameter should be evaluated after pulmonary and hemodynamic resuscitation by the trained staff. Upon examination, it is noteworthy registering the evidence of direct orbital trauma, asymmetric response to light, asymmetry at rest, fixed pupil (one or both), dilated pupil (one or both). Recommendations for the measurement of this parameter are described by BTF ¹⁶.

Less than 90 mmHg systolic blood pressure reaches 67% of PPV for unfavorable outcome and, when combined with hypoxia, a value of 79% of VPP. Systolic and diastolic blood pressures should be measured frequently by trained staff using the most accurate system available, preferably one that measures the average blood pressure. A single hypotensive episode is usually associated with a double increase in mortality ¹⁶.

The presence of abnormalities on initial CT consistent with TBI evaluated by a medical expert in the first 12 hours of injury, of compressed or absent basal cisterns, of traumatic subarachnoid hemorrhage (Hsat) are considered important prognostic factors for unfavorable outcome. The cisterns compressed or its absence should be measured in the middle cerebral line; Hsat should be observed in the basal cisterns or over the convexity; the midline shift should be measured in the septum pellucidum. CT findings may generate significant prognostic information for being mainly routinely analyzed in patients with severe TBI¹⁶.

Although any analysis of prognostic factors of life and disability should be made with careful considerations, clinical parameters described above with prognostic significance in patients with severe TBI could be considered in the aggregation of factors process for the AM. Analyzed together, these parameters can provide information that will impact on future quality of life of persons with TBI, contributing for discussions on AM.

Factors of clinical and/or functional decline

In 2011, the Royal College of General Practitioners (RCGP) has published the gold standard framework prognostic indicator guidance (GSF) to support physicians as to the early recognition of patients at end of life¹⁵. The end of life care was defined as intended for people who are approaching the end of life, probably in the next 12 months, including those in imminent death (hours or days)¹⁵. The framework proposed by the RCGP is based on three “triggers” for the completion of which raise the need for reflections on AM.

Two of these “triggers” are general indicators of clinical and/or functional decline (deterioration, increasing dependency or choose not to take active care) and specific clinical indicators related to certain health conditions such as cancer, chronic obstructive pulmonary disease, congestive heart failure, kidney disease, Alzheimer’s disease, Parkinson’s disease, motor neuron disease, multiple sclerosis, fragile, cerebrovascular (stroke) and coma, and amyotrophic lateral sclerosis¹⁵. Interestingly, the literature contains eligibility criteria for hospice approach or for palliative care, which are in agreement with the general and specific criteria proposed by the RCGP^{17,18}.

The general criteria for clinical and functional decline are described recurrent or intractable infections (pneumonia, sepsis or infection of the upper uri-

nary tract); unintentional progressive loss of weight and not associated to depression or diuretics (greater than 10% in the last six months; greater than 7.5% in the last three months); serum albumin less than 2.5 dg/l; Dysphagia leading to recurrent aspiration and/or inadequate oral intake; frequent hospitalizations; decline in functional performance (limitation of self-care and restriction to bed rest) and increased dependence in most activities of daily living; comorbidities; general physical decline and increased need for support; advanced disease; decreased response to treatment, reversibility decreases; the choice for not to receiving further active treatment; sentinel event (severe fall, mourning)^{15,17,18}. The decline should be established and documented from objective information of the records of each person.

The specific criteria described for neurological health conditions are abnormal brainstem response; lack of verbal response; absence of withdrawal response to pain; palliative performance scale of less than or equal to 40%, that is, maximally, the patient remains in bed most of the time, unable for most activity, depends on a nearly complete support, and has generally low intake and level of consciousness characterized by drowsiness and/or confusion; serum creatinine greater than 1.5 mg/dl; aspiration pneumonia; upper urinary tract infection (pyelonephritis); refractory decubitus ulcers of stage 3 or 4; recurrent fever after antibiotic therapy; progressive deterioration in physical function and/or cognitive with optimized therapy; dysphagia; sepsis; dyspnea, respiratory failure; current history of pulmonary aspiration without effective response to phonological interventions^{15,17,18}. Such specific criteria should be used in conjunction with the general and analyzed with respect to time and the other factors in the aggregation process.

The not expected question

In the gold standard framework prognostic indicator guidance, published by the RCGP, there is the unexpected question: *would you be surprised if this person died in the following months, weeks or days?*¹⁵. The positive answer to this question, although subjective, is also considered a trigger for deepening discussions about AM, beyond the general and specific criteria presented.

Reflections

Considering the relevant ethical and normative aspects to AM and the palliative care, the history of

the person, the prognostic indicators post-neurological injury, and the criteria for clinical and/or functional decline as aggregation factors centered on the person, the reflections throughout this process are related to the diagnosis, to the proposal of diagnostic and therapeutic measures, to the prognosis and to spirituality. Is there a precision in clinical and neurological medical diagnosis? By being proposed, whether diagnostic, therapeutic, is it able to provide greater life prognosis with a better quality of future life? Is this measure able to provide comfort to the person? And how about the spirituality of the person and the family? Are there considerations that influence the decision making? Person-centered, the process for decision making in AM must be prior and concomitantly accompanied by the palliative approach based on comfort measures, which will ultimately become exclusive.

Final considerations

The aim of this article was discoursing about the AM as a comprehensive process of consensual aggregation of person-centered factors. It is not

intended to systematically exhaust the theme of AM in the person with brain injury, particularly the victim of major trauma and injuries that require extended health care and social reintegration. The authors sought to further discuss the *limitation of therapeutic effort* with the prospect of a complex, multifaceted decision making and accompanied by the intensification of palliative care, avoiding unilateral, linear and simplistic decisions.

The authors hope that with the ethical and technical proposal described in this article, other perspectives can be magnified: the limitation of therapeutic effort for maximum effort of care; obscure criteria of LTE for the discussed eligibility, consensual and shared of the AM person-centered; the participation of the person, the family and the multidisciplinary team in the AM; the linearity of the curative/palliative models; of the multidisciplinary team for disciplinary team of humanized "look" for the person with severe brain injury, in terminallity or not. Still expect that the presented proposal may stimulate further discussion of AM in institutions that provide assistance to those individuals and families, revealing the unconditional respect to the person.

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