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Original article

The troubling trichotomy in clinical nutrition and its application to human rights

La tricotomía preocupante en la nutrición clínica y su aplicación a los derechos humanos

A preocupante tricotomia na nutrição clínica e sua aplicação aos direitos humanos

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Abstract

Introduction: Nutrition support is a major advance in medicine which has made possible to feed all sick people unable to be orally fed. During the development of technologies such as this, the lack of anticipation of ethical and legal issues can be problematic. This conundrum has be dubbed "The Troubling Trichotomy" by the lead author (T3).

Objective: The aim of this evidence-based theoretically informed essay is to provide an overview of the three components of T3 and its relation to human rights, and an analysis of the ethical and legal challenges imposed by innovation in the field of clinical nutrition through selected leaders' opinions.

Methods: The analysis of the three components of the T3 was based on academic literature, and numerous data sources to illustrate the relevance of its interaction when applied to the field of clinical nutrition. An email survey was addressed to clinical nutrition leaders asking on the challenges ethically or legally of future technological developments.

Results: The challenges generated by advances in nutritional support must be addressed from the T3 approach which considers that the ethical and legal aspects cannot be separated from the technological advances. The ethical approach in the field of clinical nutrition can be considered as a systematic normative reflection based a framework of interdependent principles (i.e., principlism), moral values (i.e., attentiveness, responsibility) and actions that

Resumen

Introducción: el soporte nutricional es un gran avance de la medicina que ha permitido alimentar a todos los enfermos que no pueden ser alimentados por vía oral. Durante el desarrollo de tecnologías como esta, la falta de previsión de las cuestiones éticas y legales puede resultar problemática. El autor principal (T3) ha bautizado este enigma como "la tricotomía problemática".

Objetivo: el objetivo de este ensayo con base teórica es proporcionar una visión general de los tres componentes de la T3 y su relación con los derechos humanos, así como un análisis de los retos éticos y legales que impone la innovación en el campo de la nutrición clínica a través de las opiniones de líderes seleccionados.

Métodos: el análisis de los tres componentes de la T3 se basó en la literatura académica y en numerosas fuentes de datos para ilustrar la relevancia de su interacción cuando se aplica al campo de la nutrición clínica. Se dirigió una encuesta por correo electrónico a líderes de la nutrición clínica en la que se preguntaba sobre los retos éticos o legales de los futuros desarrollos tecnológicos.

Resultados: los retos generados por los avances en el soporte nutricional deben ser abordados desde el enfoque T3, que considera que los aspectos éticos y legales no pueden separarse de los avances tecnológicos. El enfoque ético en el campo de la nutrición clínica puede considerarse como una reflexión normativa sistemática basada en un marco de principios interdependientes (principialismo), valores mora-

Resumo

Introdução: O suporte nutricional é um grande avanço na medicina que tem permitido alimentar todos os pacientes que não podem ser alimentados por via oral. Durante o desenvolvimento de tecnologias como esta, a falta de previsão das questões éticas e legais pode ser problemática. O autor principal (T3) batizou esse enigma de "Tricotomia Problemática".

Objetivo: O objetivo deste ensaio teórico é fornecer uma visão geral dos três componentes da T3 e sua relação com os direitos humanos, bem como uma análise dos desafios éticos e legais que implica a inovação no campo da nutrição clínica através das opiniões de líderes selecionados.

Métodos: A análise dos três componentes da T3 foi baseada na literatura acadêmica e em inúmeras fontes de dados para ilustrar a relevância de sua interação quando aplicada ao campo da nutrição clínica. Uma pesquisa por e-mail foi conduzida com líderes de nutrição clínica perguntando sobre os desafios éticos ou legais de futuros desenvolvimentos tecnológicos.

Resultados: Os desafios gerados pelos avanços no suporte nutricional devem ser enfrentados a partir da abordagem T3, que considera que os aspectos éticos e legais não podem ser separados dos avanços tecnológicos. A abordagem ética no campo da nutrição clínica pode ser considerada como uma reflexão normativa sistemática baseada em um quadro de princípios interdependentes (principia-

can guide health care professionals and researchers in view of the future development of technologies. The legal aspects should consider the national differences to frame the ethical challenges and the practice of the discipline.

Conclusion: The Troubling Trichotomy should be considered as a comprehensive approach that may be at the core of clinical nutrition. With the hopeful global embrace of nutritional care as a human right the T3 should be less problematic.

Keywords: Bioethics; Principlism; Technology; Nutrition support.

les (atención, responsabilidad) y acciones que pueden guiar a los profesionales de la salud y a los investigadores ante el futuro desarrollo de las tecnologías. Los aspectos jurídicos deben tener en cuenta las diferencias nacionales para enmarcar los retos éticos y la práctica de la disciplina.

Conclusión: la tricotomía problemática debe ser considerada como un enfoque integral que puede estar en el centro de la nutrición clínica. Con la esperanzadora aceptación mundial del cuidado nutricional como derecho humano, la T3 debería ser menos problemática.

Palabras clave: bioética, principialismo, tecnología, soporte nutricional.

lismo), valores morais (atenção, responsabilidade) e ações que podem orientar aos profissionais de saúde e aos pesquisadores diante o futuro desenvolvimento de tecnologias. Os aspectos legais devem levar em consideração as diferenças nacionais para enquadrar os desafios éticos e a prática da disciplina.

Conclusão: A tricotomia problemática deve ser considerada como uma abordagem integral que pode estar no centro da nutrição clínica. Com a esperançosa aceitação global do cuidado nutricional como um direito humano, a T3 deveria ser menos problemática.

Palavras-chave: Bioética, principialismo, tecnologia, suporte nutricional.

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BACKGROUND

For many years healthcare professionals and other stake holders faced situations where technology (what can be done) prompted ethical considerations (what should be done) which ultimately had to be applied in the context of law (what must be done)[1]. This conundrum has been dubbed "The Troubling Trichotomy" (T3) by Barrocas[2, 3] (Figure 1).

This article will review the three components of T3 and focus on its application in clinical nutrition specifically nutrition support (i.e., enteral [gastrointestinal] and parenteral [intravenous] nutrition) and its relation to human rights. Clinical nutrition is "a basic interdisciplinary and applied science, concerned with the caring of those in need of nutrition care (i.e., undernutrition, inadequate diet intake, overweight and obese patients). Its aim is to apply the principles of nutritional care in order to ensure a balance in nutritional status, and modulate other biological functions to positively influence the individual's homeostasis, any healthcare treatment and outcomes"[4,5]. The practice of clinical nutrition is based on the application of nutrition support through the use of oral, enteral or parenteral nutrients.

The "troubling" aspect of T3 is based on its presentation/challenge "after the fact". During the development of technology little, if any, attention is given to the impact new discoveries have on the ethical and legal ramifications of their application. The lack of anticipation of these two components of the trichotomy is often problematic or "troubling". Some medical developments over the years which demonstrate this concept are:

- No issues regarding definition of death prior to development of ventilators, cardiac and resuscitative meds, etc.
- No issues regarding "rationing" of hemodialysis until development of hemodialysis machines.
- No issues regarding selection of individuals to receive organ transplants prior to development of surgical/immunological techniques.
- No issues regarding end-of life, vegetative states prior to the development of techniques leading to survival of patients experiencing severe neurological injuries.
- No issues regarding mortality from malnutrition in individuals unable to orally ingest foods until development of total parenteral nutrition (PN), enteral nutrition (EN).

The lack of anticipation is problematic because technological developments are being made without questioning the necessary boundaries to assure a responsible use of technology and the respect of fundamental principles such as autonomy or the respect of human dignity. Particularly to clinical nutrition, the

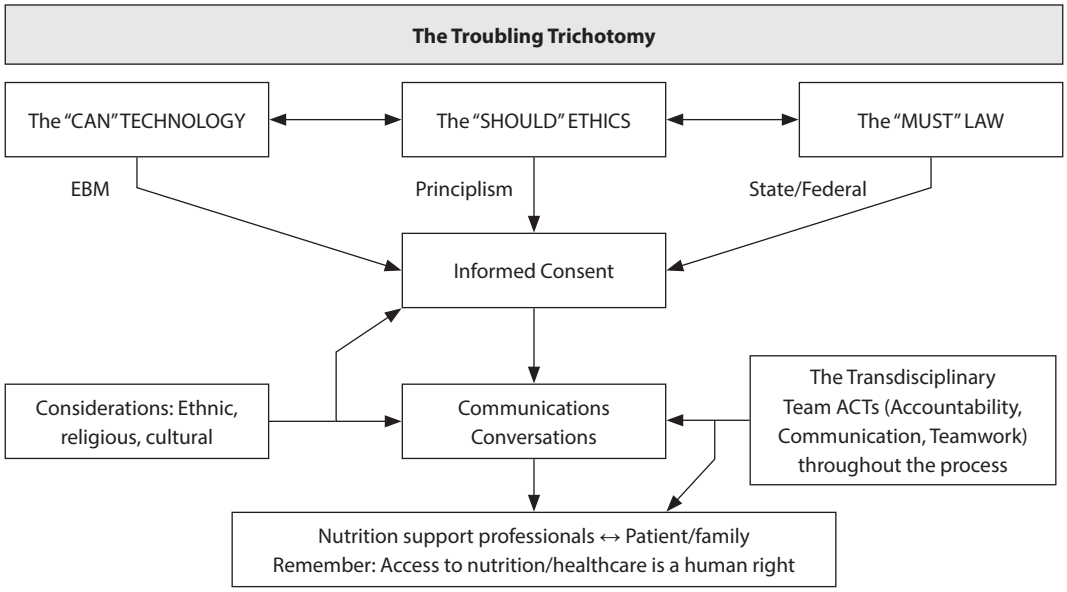

Figure 1. The Troubling Trichotomy. EBM: Evidence-based medicine; ACTs: Accountability, Communication, Teamwork. By: A. Barrocas, 2021.

lack of anticipation of the ethical and legal issues and the lack of an ethical approach to the application of the technology of artificially administered nutrition and hydration (AANH) ignores the principle of proportionality in nutritional care among others. The moral principle of proportionality states that "responses should be proportional to the good that can be achieved and the harm that may be caused"[6]. This moral principle becomes relevant in the context of ethical issues related to the allocation of resources during critical situations of scarcity such as pandemics. Moreover, as it relates to medical ethics, this means that "medical interventions and risks should be proportionate to the possible lives saved"[7], e.g., benefits v burdens/risks analysis.

TECHNOLOGY

Technology from Greek, τέχνη (tékhnē, "art") + λογία (logía, "study") refers to the "science of craft"[8]. The first idea of the concept of technology is found in ancient Greece, where philosophers as Aristotle argue a fundamental ontological distinction between "natural things" and "artifacts"[9]. Since then, the fundamental difference between man-made products and natural substances have influenced the philosophical reflection of technology until today, including the ethical approach. According to the Cambridge dictionary, technology is nowadays defined as "the study and knowledge of the practical, especially industrial, use of scientific discoveries"[10].

Legal and ethical considerations are often required in the development of technology. Among these are the issues of informed consent, ethical treatment of persons and animals, respect and dignity, truth telling regarding the research and outcomes, benefits vs. burden/risk analysis, etc. One sad example in United States history regarding results of uninformed experiences was the Tuskegee Study of Untreated Syphilis Experiment, a.k.a., Tuskegee Syphilis Experiment[11,12].

The study was conducted between 1932 and 1972 by the United States Public Health Services. Its goal was to observe the natural history of untreated syphilis. The subjects were told that they would receive free healthcare from the federal government, but they did not receive the promised care. They were never informed of their diagnosis or ineffective methods, diagnostic procedures, and disguised placebos as treatment. In 1947 Penicillin, which was widely available, became the standard treatment for syphilis. None of the infected men were ever treated with the antibiotic. Following the termination of the "ethically abusive" project, after a leak to the press in 1972, regulations and guidelines were developed including the Belmont Report in 1979[13] (because of the National Research Act of 1974), the

establishment of the Office for Human Research Protection, and Institutional Review Boards[14].

Internationally, the impetus for ethical/legal behavior in the conduct of experiments and research were the findings of the atrocities of the Holocaust regarding Nazi medical abuses. The Nuremberg code was established to protect the rights of research subjects[15]. The concept of informed consent was established by the World Health Organization (WHO) Declaration of Helsinki in 1964[15]. The recently adopted Cartagena Declaration[16-18] and the Position Paper "Clinical nutrition and human rights. An international position paper" are an extension of the latter document[4].

Looking towards the future and focusing on clinical nutrition the authors reached out to a group of thought leaders in the clinical nutrition/nutrition support arena and requested their input in two areas:

1. What technology/research did they foresee in the field in the field of nutrition support?
2. What ethical and or legal considerations would be prompted by the implementation of the research?

The results of the survey are summarized in Table 1.

The leaders' opinion shows opportunities of technological development in the field of nutrition support/clinical nutrition and the ethical and legal challenges. Most of them agree on the need of technological developments in terms of nutrition products and devices. The claim of such need for development is based on the fact that nutritional products have evolved little in the last two decades. New products and devises would respond to the need to supply nutrients to patients with particular needs due to metabolic adaptation to the disease. This implies consideration of the metabolic response to the disease as "adaptive" and that nutrition support is not the merely supply of nutrients (as can be considered the feeding of a healthy person), but instead, it should be considered as a medical treatment. This means that nutrients, calories and protein supply are responding to an adaptatively response to the disease, and not to the lack of nutrients due to simple starvation. It should be recognized that this adaptive response may sometimes become "pathological"[19]. Development of scientific knowledge on metabolism should help to identify where the limit between a normal and a pathological response is. Metabolomics and artificial intelligence (AI) could support the developments of these fields, particularly in the decision-making process. The ethical and legal approaches would be central to these developments[19].

Two leaders opinions mentioned the potential ethical impact of pharmaceutical industry on medical decision. The development and innovation of nutritional therapy products should be carried out considering the principles of beneficence and non-maleficence, and medical decisions independent of any marketing or commercial influence.

One of the leader' opinion considers that it is not the development of nutrition products *per se* that could have legal or ethical implications but what is done with them. This can be applied to all the technological developments. In fact, it is not the development per se, but what humans make of it. The ethical challenge would be to produce cost-effectiveness nutrition products that are capable of providing the best benefits/risks-burdens ratio according to the emergent knowledge. Metabolomics and AI can potentially jeopardize confidential handling of patient data. AI developments can be applied through the four-principles approach to which a four principle should be added, explicability, which should be understood as the sum of intelligibility (i.e., "how does it work?") and accountability (i.e., "who is responsible for the way it works?")[20].

ETHICS

Ethics, the second component of T3, is a pivotal one since it encompasses not only the expected behavior but also individual values which have the potential for conflict. The term ethics derives from the Greek word *ethos* and the term morals derives from Latin word *mores* both of which refer to "common customs or behavior"[21]. Because they originally had the same meaning, both terms are frequently used interchangeably, even if they do not mean the same thing. Morals refers to a group of rules and principles common to a social group. Morals are deeply influenced by several cultural factors, such as religion, history, tradition, education, beliefs, etc. Ethics is a branch of philosophy that aims to conduct an intellectual analysis of the moral human dimension in all of its complexity. Ethics is concerned with principles that allow us to make decisions about what is right and wrong. In other words, ethics is the study of what is morally right and what it is not. It refers to a judgment of behaviors, good or bad.

Ethics when applied to biomedical sciences faces an ambiguity since it covers medical ethics, bioethics indifferently, to which it is possible to add techno ethics (Table 2).

Table 1. Survey Responses of Selected Nutrition Support Thought Leader

Thought Leaders	Predicted technology/research in nutrition support?	Ethical/Legal Considerations

Bruce R. Bistrian, MD, PhD
Boston, MA, USA
	During early phase (10 Days)-Injury-Inflammation-Infection
	- Determination of what, how, how much and when to feed critically ill patients with inadequate intake.
	  - Trophic feedings beyond fluid and electrolytes only
	  - Permissive underfeeding of standard composition
	  - Hypocaloric feeding higher in protein
	  - Full feedings
	- Determination of:
	- Absence or presence of Protein Energy Malnutrition (PEM) i.e., Normal, Moderate, Severe
	- Absence or presence of systemic inflammation:
	- None>Moderate>Severe
	- Basic intent of future studies. >Abbreviated duration of first phase in those with pre-existing PEM and/or severe intensity of inflammatory response.
		- Determination of feeding for control group in each category.
		- Clinical equipoise would need to be provided.

	During second phase >10 Days, if still requiring invasive feedings - Control group fed based on guidelines/recommendations of critically ill patients established by national organizations, e.g., European Society for Clinical Nutrition and Metabolism (ESPEN), American Society of Parenteral and Enteral Nutrition (ASPEN). - Experimental group >Outcome variables would incorporate differences in amounts and types of energy intakes, amino acids, etc. and pharmacologic manipulations.	- No ethical challenge
	Lipid emulsions active ingredients eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) of fish oil - Current formulations demonstrate extremely variable concentrations of EPA and DHA. - Above of concern when pharmacologic doses of up to 4-8 g/d of EPA and DHA are provided with their putative ability to attenuate the systemic inflammatory response. - Such therapy would have potential benefits in certain hyperinflammatory conditions such as severe cases of Covid-19 or bacterial sepsis as a component of TPN. - Additional pharmacologic intent would require fish oil enriched in EPA or EPA + DHA with defined stable composition and qualify as a drug rather than a pure nutrient use.	- Legally, formal drug approval process. Studied as both stand alone therapy or when combined with TPN. - Effectiveness may be influenced by underlying nutritional state

Medical ethics, bioethics and techno ethics, conceived as sub-fields of ethics have close scopes of application but also share some principles and approaches that can be applied in the analysis of certain disciplines as for clinical nutrition.

When it comes to analyze the practice of clinical nutrition through the ethical approach it should be emphasized that nutrition as an ethical subject is able to present itself as a legitimate form of care in medical practice[19]. Feeding the patients becomes a form of care but also of treatment, raising new ethical issues when applied to specific situations. The relevant question here is to know which ethical characteristics are fundamental to the technological development of AANH, and its application in the clinical practice.

ETHICAL FRAMEWORK IN THE FIELD OF NUTRITIONAL CARE

The principle of respect for human vulnerability and personal integrity of the malnourished patient

The principle of respect for human vulnerability expresses a concern for the fragility of human beings.

Table 1. Survey Responses of Selected Nutrition Support Thought Leader
(continued)

Thought Leaders	Predicted technology/research in nutrition support?	Ethical/Legal Considerations

Kathy Gura PharmD, BCNSP, FASHP, FPPA, FASPEN, FMSHP Boston, MA, USA	- Improved intravenous lipid emulsions addressing the limitations of currently available products.
	  - Lower phytosterol content
	  - Improved omega 3-omega 6 ratio
	  - Improved alpha-tocopherol content
	  - Improved emulsifiers – need an egg-free alternative.
	- Need a way to provide essential fatty acids not as an emulsion – as a solution – would improve limitations associated with total nutrient admixtures.
	- Are there better oil sources besides soybean, fish, olive, or coconut?
	- Better parenteral multivitamins
	- Current products developed over 30 years ago.
	- Still no suitable multivitamin or premature infants
	- Need separate forms of ergocalciferol, alpha-tocopherol – only available as a multivitamin infusion.
	- Safer forms of parenteral iron – current products all have incidence of anaphylactic reactions.
	- Revisit amino acid formulations
	- Pediatric amino acid products developed 35 years ago and do not reflect needs of a preterm infant.
	- Current products cannot be concentrated – prone to precipitation – there are no 15% or 20% versions of TrophAmine for example.
	- Current conventional products may not be suitable for critically ill adults.
	  - glutamine
	  - arginine
	  - cysteine
	- Are there other micronutrients that need to be part of parenteral nutrition?
	  - Choline
	  - Molybdenum
	  - Fluoride
	  - Iodine
	- Alternative to dextrose solutions – current products made from corn – can another source be used?
	- Is there a role for parenteral fructose?
	- Improve software used to compound Parenteral Nutrition (PN) solutions.
	- Better decision-making support.
	- Improved compatibility information
	- Not just calcium and phosphorus
	- Consider magnesium/calcium/phosphorus.
	- Predict Total Nutrient Admixture (TNA)stability.
	- Ensure it is totally integrated in Electronic Healthcare Record (HER) to reduce transcription errors.
	- Improve quality of additives used to compound PN.
	- Low aluminum/no aluminum contamination
	- No other forms of metal contamination (chromium/manganese)
	- Use of more organic phosphate salts to decrease compatibility/ precipitation issues.
		- None of these ideas are new but because nutritionals are not blockbuster drugs no one has moved the field forward to launch new products – need to make these products not just nutrition focused but they must also demonstrate a therapeutic effect.
		- Difficult to move these products through Food and Drug Administration (FDA) and other regulatory agencies.
		  - Trial design difficult – too many confounders, often too short in duration
		  - Easier to do nutrition indications (bar very low) in comparison to trying to prove therapeutic benefit (involves more invasive testing in many instances)
		  - Attempting to determine meaningful outcomes given that a lot of nutrition related complications happen over time.
		  - A lot of nutritionals fall under Dietary Supplement Health and Education act of 1994(DSHEA) instead of FDA's Center for Drug Evaluation and Research (CDER) so they only must prove safety not efficacy.
		  - There are very few practitioners coming up the ranks to do these studies (not financially lucrative)
		  - Ethical issue – often financial benefits triumph over bringing newer, safer products to market because the return on investment is too low.

Dan Waitzberg MD, PhD São Paulo, Brazil	- Friendly apps of nutritional assessment, indications, and prescriptions of nutritional therapy available independent of industry sponsorship - Artificial intelligence applied to determination of which patients would benefit re: timing, calorie and protein, outcomes (morbidity, mortality Length of Stay (LOS), Intensive Care Unit (ICU)/Hospital) - Tracking and assessing nutritional therapy via large data banks	- Anonymity. - Agreement among different hospitals in development of central data repository to process Artificial Intelligence

Table 1. Survey Responses of Selected Nutrition Support Thought Leader
(continued)

Thought Leaders	Predicted technology/research in nutrition support?	Ethical/Legal Considerations

Gil Hardy PhD, FRSC, FASPEN Auckland, New Zealand	- Handheld device (mobile phone app?) that uses MRI, laser and/or a technology still to be invented, that will produce an immediate assessment of a patient's nutritional status.
	- A complementary app to the above that will automatically produce options, with a score for the likely most practical and efficacious nutritional therapy, for the attending clinician to make the best evidence-based decision.
	- Improved technology for ambulatory PN and EN patients, utilizing:
	  - Long term stability of truly All-in-One (AIO)PN admixtures, containing all micronutrients and other currently unstable nutrients.
	  - High tech mini ambulatory pumps, for PN, like the insulin pumps used by Type 1 diabetics.
	  - Revolutionary ways of delivering nutrients, for example using nanotechnology, skin patches etc. to avoid contamination from connecting EN feeding tubes, PN catheters to administration sets and the patient.
	- New Improved technology for harvesting and reinfusing chyme for intestinal failure
	- Patient-specific designer 3D Printing of artificial guts and other organs to correct intestinal failure.
		- None

Sonia Echeverri RN, MSc, FASPEN Bogota, Colombia& Portugal	- Enteral formulas and individualized parenteral mixtures (with much more specificity towards the pathology, including nutritional status and body composition, metabolic moment, microbiota, etc.) - Safer and more patient-friendly medical devices (probes, feeding tubes, equipment, infusion pumps).	- I believe that these developments *per se* do not have ethical or legal challenges. - What will represent challenges is how and who can access these technological advances (distributive justice) - All individuals who require them will have the right to them? starting with the right to artificially administered nutritional therapy (beneficence) - Will they be used with due medical judgment and the autonomy of the patient? (autonomy) - Medical criteria prevail, or is its use influenced or manipulated by the pharmaceutical industry? (non-maleficence)
Denise Baird Schwartz, MS, RD, FADA, FAND, FASPEN Studio City, CA USA	- Addressing any option of the substrate and administration of improving the benefit vs adverse/risk ratio of delivering artificially administered nutrition and hydration. - Designing and publishing research studies to substantiate that the individual's quality of life can be improved with these substrate and administration equipment and delivery improvements. - Clinicians made aware of the results of the research and using the information in the discussion with the patient and or surrogate decision maker with shared decision making in the clinical setting with all patients. - Incorporating the above items would then address the four ethical principles of respect for autonomy, beneficence, non-maleficence, and justice.	- The ethical aspects would be addressed for each item when designing the research study. - Legal aspects would vary between various states, regions, countries, etc.

Table 2. Sub-fields of ethics

Subfields	Definition	Approaches and moral theories
Medical Ethics	Is concerned with the ethical issues related to medical practice. Since Antiquity, the medical profession has subscribed to a body of ethical principles and statements developed primarily for the benefit of the patient. Those principles, integrated to deontological codes, are not laws but standards of conduct that define the essentials of honorable behavior for the physician[22].	- Principlism approach: autonomy, beneficence, nonmaleficence, justice - Human rights-based approach - Theories of distributive justice (Utilitarianism) - Deontological moral theory - Virtue ethics
Bioethics	Is specifically concerned with the ethical issues that have emerged in the field of living organisms with medical and scientific progress. The term "Bio-Ethic" from two Greek words, bios, and ethos, was used for the first time in 1927 by the Protestant theologian Fritz Jahr. But it was not until 1970 that the term began to be developed by Van Rensselaer Potter in the book Bioethics a Bridge to the Future[23]. He drew attention to the fact that the rapid advances in science had proceeded without due attention being paid to values. Potter conceived this new discipline, as a 'bridge' between 'facts' and 'values'.	
Technoethics	Also known as ethics of technology Is considered as "an interdisciplinary research area that draws on theories and methods from multiple knowledge domains (such as communications, social sciences information studies, technology studies, applied ethics, and philosophy) to provide insights on ethical dimensions of technological systems and practices for advancing a technological society"[24]. It focuses on the reflection of the ethical uses for technology, and the protection against the misuse of technology[24,25].	- Cultural and political approaches - Responsibility - According to Hans Jonas technology requires an ethics in which responsibility is the central imperative because "for the first time in history we are able to destroy the earth and humanity"[26].

The word vulnerable comes from the Latin *vulnerabilis*, formed from *vulnus* (wound) and suffix *abilis* (able indicating possibility). Hence, a vulnerable person is a person who can easily be injured and cannot easily defend themselves. Vulnerability is an inescapable dimension of the life of individuals and the shaping of human relationships[27]. In this way the law considers the vulnerable people who are to be protected from being the inappropriate object of investigation or subject to any coercion. The question of respect for and accompaniment of the vulnerable person goes beyond the protection of a category of individuals and the problem of informed consent. This issue does not concern the legal dimension exclusively or even essentially, but also an ethical dimension.

In ethics the notion of vulnerability is not just a neutral description of the human condition but also a normative prescription to take care of vulnerability. In the field of clinical nutrition, the malnourished or at-risk for malnutrition (ARFM) patient is considered as having a "special vulnerability". This means that the person is fragile and needs other people in order to meet basic material needs[19,27]. A malnourished or ARFM patient is vulnerable because their physical and psychological integrity is compromised as well as their quality of life. The person is fragile because of his/her situation of dependence. This can be explained because they are weakened and need know-how of others, especially healthcare professionals to help them get better. This vulnerability is compounded by the fact that disease-related malnutrition and/or malnutrition-related diseases and conditions lack recognition and awareness by healthcare professionals in a more general way. This can be partly explained by the lack of nutrition education, at undergraduate and postgraduate levels[28,29]. Thus, malnutrition implies a "double vulnerability" for the patient: one being that of physical and/or mental detriment, and another being the high unawareness and lack of education about clinical nutrition among healthcare professionals[19].

The recognition of this special vulnerability of the malnourished or ARFM patient entails the acknowledgment of the responsibility of the healthcare professional, and for public policy-making the need to make

more resources available. In this sense, commitment to respect of human vulnerability and for personal integrity is a mandatory constituent of politicians', legislators', regulators', administrators', and healthcare professionals' responsibilities.

Healthcare professional responsibility for the malnourished patient

The deepest ethical sense of vulnerability implies a commitment of responsibility towards others[30]. Responsibility must not be conceived in its narrow legal dimension, as an obligation to care for others and consequently to become subject to penalties if that care is not ensured. In contrast, according (for example) to Emanuel Levinas, the ethical relation begins with the response to the "other". Thus, the relationship to others is the starting point of ethics. To be responsible for the other is essentially to be a "substitution" for the other[31]. Being a substitution means, according to this French philosopher, to put myself in the other's place, not to subordinate him or her according to my wishes, but to offer what he or she needs, starting with basic material needs. Moreover, substitution means that the healthcare professionals should transmit the patient's will[31].

Particular to nutritional care is the fact that malnutrition may lead to the need for AANH, and this must be considered as a medical intervention requiring an indication for achieving a treatment goal and the informed consent of the patient[32]. It means first, that in addition to considering the patient through their capacity for autonomy (to take decisions about nutritional therapy) it is necessary to take their double vulnerability into account. Secondly, this also means that it should not be the fear of punishment that guides healthcare professionals in their practice of nutritional care but the ethical responsibility to treat and to give basic nutritional needs[19].

The responsibility to provide individual and specific nutrient requirements to each patient rests with the healthcare professionals. The challenge for the latter is, first of all, to ensure an appropriate assessment and diagnosis of malnutrition and then to ensure this treatment and to fulfill this vital need. Conflict may emerge when patients or families disagree about withholding or withdrawing (forgoing) nutritional therapy in some particular situations. Medical nutritional therapy is in constant tension between "care" and "cure". The origin of the problem is in the way the medical nutritional therapy is conceived: as part of a medical treatment or as a care (food and water). To understand better this duality, it is necessary to understand what an "artificial nutrient" is beyond its biochemical dimension, and how the technological development of AANH has made it possible to feed any patient today[5].

The relevant question here is to know how healthcare professionals should act when feeding the sick patient. What is the best way to care for one specific patient at a specific time? Joan Tronto's ethics of care theory[33] is a tool that can help to answer these questions.

THE ETHICS OF CARE

Nutritional care process and the phases of care

The ethics of care is a normative theory that places the phenomenon of care at the center of ethical reflection. It is developed based on the understanding of the human being as a vulnerable and interdependent relational being. While traditional moral theories (i.e., utilitarianism, deontology, theory of justice, virtue ethics) are based on the primacy of autonomy, the ethics of care, which is more context-based and concrete, emphasizes the notion of vulnerability, which it considers to be one of the essential characteristics of the human condition. The ethics of care emphasizes the importance of response, thus, the ethical question is «how to respond?»[33].

The ethics of care defined by Tronto as a "practice and a disposition" is an on-going process consisting of five phases of caring and four moral characteristics of care[33]. Those moral elements are specific attitudes and skills necessary for effective caring. This normative theory is useful to define some ethical characteristics necessary for good nutritional care. Thus, the phases of care can correspond to the seven steps of the nutritional care process as proposed in Figure 2.

According to the ESPEN guidelines on definitions and terminology of clinical nutrition, nutritional care should be provided in a systematic sequence that involves seven distinct interrelated steps, and this systematic sequence is called the nutritional care process[34].

The first and second steps are the malnutrition risk screening and the nutritional assessment, which can be conceived as the "caring about" phase of care ethics. This first phase requires an ethical element, that of attentiveness, namely a "just and affectionate regard to an individual reality"[33]. In a practical way, this means that the healthcare professionals identifies the need for nutritional care by identifying subjects malnourished

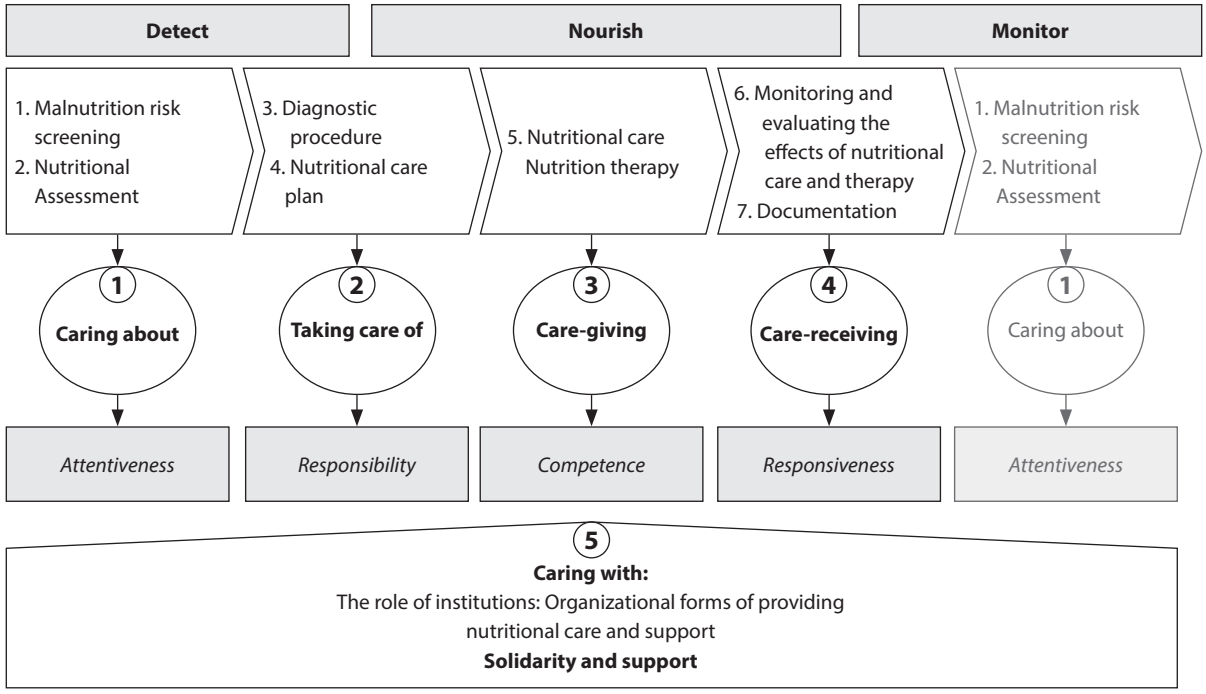

Figure 2. The five phases of ethics of care and their four ethical elements (or characteristics) integrated to the nutritional care process. The bold type in the circles represent the phases of care and the italics are the ethical elements required in each phase. The steps of nutritional care –detect, nourish and monitor– have been defined in the Declaration of Cartagena.

or ARFM by using an appropriate validated tool in all subjects that come in contact with healthcare services, and by assessing the patient's nutritional status[19]. In this sense, the need for a consensus in the scientific community on the diagnostic criteria[35] and on the nature of malnutrition associated with the disease[36] are fundamental to ensure adequate nutritional care.

Caring about malnutrition leads to the establishment of an appropriate response which is consolidated in the "taking care of" phase. In this phase, the healthcare professionals recognize their responsibility to respond to a patient's risk of malnutrition or to any degree of malnutrition and arrives at a diagnosis. This responsibility is shared and concerns all actors involved in care. The healthcare professional, by making a nutritional plan, will ensure that there are all the necessary conditions to meet the nutritional needs of the patient. In this phase, actions have mainly two specific purposes: to combat malnutrition or limit loss of quality of life through nutritional support. It is worth noting that responsibility is ethics-based and must not be conceived as an obligation(duty)-based responsibility[19].

The third phase of the ethics of care is the "care giving", which implies the direct activity of contact with the patient. The healthcare professionals should be able to respond in the best way to the nutritional needs of the patient, by providing nutrients orally, via enteral tube-feeding or parenteral nutrition, to prevent or treat malnutrition in an individualized way. In this phase, competence is considered as an ethical element. One cannot simply acknowledge the need to care, and accept the responsibility, but follow through without enough competence or adequate skill. Such a lack of competence would result in the needs of care not being met or in an increase in the risk of complications. Thus, healthcare professionals must commit to life-long learning to ensure competence in nutritional care practice[19].

Finally, in phase four "care receiving", the healthcare professionals assess the success of the nutritional therapy with the patient and documents this process. This phase is essential to preserve the relationship between patient and healthcare professional. The ethical element in this phase is responsiveness, which refers to the care receiver's responsiveness to the care. This means the way the patient or the family perceive the care[19]. According to the ethics of care, the realization of a complete nutritional care process by the healthcare professional means they are responding to the vulnerability of the patient.

The ethics of care highlights two key considerations. First, the *care* concerns a being who is suffering from a pathological condition that we are able to treat or prevent. Second, when we take care of someone, a being, this means that we care about the emotional, social and psychological dimensions. Consequently, *care* is not only a matter of supplying a treatment in order to alleviate or to *cure* but is also a matter of humanity. In that sense, nutritional therapy, as a medical therapy, is capable to cure or prevent malnutrition and help recovery from disease but it is also supporting basic nutrient feeding.

LEGAL

Notwithstanding what can and should be done, ultimately our behavior is governed by what must be done or what we are allowed to do according to laws. The practice of healthcare professionals is regulated by laws and norms found in different normative documents (constitution, laws, norms, rules, regulations, codes). Bioethics or medical ethics presupposes a normative system that does not initially belong to law but to morality or ethics[37]. Particularly, bioethics emerge as an approach to analyze and reflect the societal and ethical challenges imposed by the medical and technology development, as is AANH. Through the bioethical reflection the thoughts and legislations can evolve. Thus, bioethics is considered as a way to influence legislations concerning these progresses. The bioethical reflection "trends towards its legal consecration"[37]. The process of generating the norm begins in an ethical framework, and only becomes a rule of law through its consecration with the adoption of the law. The law is the first legal source to which must be added other sources such as extralegal (i.e., constitutional, international law and regulatory sources), as well as others specific to bioethics (i.e., those emanating from the bioethics committees)[35].

The legal normative frame of the practice of nutrition support varies from one country to another. For example, in France, the first bioethics law was enacted in 1994 and has been evolving into the current by Claeys-Léonetti in 2016 (is currently being revised). The status of AANH has been evolving through the legislation to finally recognize that to feed the patients by any means (enteral or parenteral nutrition) is a medical treatment. This led to consider that the questions of the introduction or withholding/withdrawing (forgoing) of AANH follows the same approach as for other life support treatments.

In Latin America, bioethics-based laws are scarce. Some countries have laws and regulation on palliative care as Argentina, Colombia, Uruguay and Chile. For example, in Colombia, the Law 1733 of 2014 and Resolution 1216 of 2015 recognizes the patient's right to refuse extraordinary treatments, including AANH. Moreover, according to a study by Cardenas et al.[38] there is a high heterogeneity in nutritional care regulations. Table 3 shows the National legislations and regulations in nutritional care in 17 Latin-American countries. In consequence, in Latin-America there is an important ambiguity on the status of nutrition products for nutritional therapy and a scarcity of bioethics-based laws that could lead to ethical dilemmas in the practice of nutrition support.

The US Legal System is summarized in Figure 3.

A more detailed discussion is provided elsewhere[39,40]. While there are no specific laws governing clinical nutrition per se, the provision of appropriate healthcare is expected. Inappropriate care can lead to criminal and most commonly civil litigation. Under the auspices of negligence, an individual not receiving adequate nutrition resulting in an untoward outcome can bring legal charges based on the ABCD rule which encompasses: Accept (established relation between patient and healthcare professionals); Breach (the duty to provide the standard of care); Cause (the etiology of the adverse event; and Damage (resulting from the adverse event)[40].

In another realm, as is the case in other countries, AANH is considered a medical treatment as ventilators and hemodialysis which can be withheld or withdrawn (forgo) under certain circumstances, respecting the autonomy and dignity of the patient or surrogate decision-maker. However, following the Terri Schiavo case[41] several states have established a more rigid requirement as it deals with AANH. Unless specifically stated in an advance directive AANH cannot be forgone without "clear and convincing evidence".

In addition to federal and state laws, regulatory bodies and insurers, e.g., The Joint Commission, Medicare, Medicaid, require specific nutrition interventions that include screening, assessment, diagnosis, treatment not only in the hospital, but also in alternate health care settings such as home, nursing homes, long-term acute care hospitals, etc. Rather than legal recourse, those violating these regulations face potential denial or reduction in reimbursement.

The summary of the ethical foundations of nutrition support practice and examples of legal and deontological sources for technology development and innovation in clinical nutrition is shown in Table 4.

Table 3. Latin-American national legislations and regulations in nutritional care

Country	Clinical nutrition categories								
	PN	EN	ONS	DFSMP	NST	CAPS	MDevs	HAAN	NCP
Argentina	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No
Bolivia	No	No	Yes	No	Yes	No	Yes	No	No
Brazil	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No
Chile	Yes	No	Yes	No	No	No	Yes	Yes	No
Colombia	No	No	Yes	Yes	No	Yes	No	No	No
Costa Rica	No	No	Yes	No	No	No	Yes	No	No
Ecuador	No	No	Yes	No	No	No	Yes	No	No
El Salvador	No	No	Yes	No	No	No	Yes	No	No
Guatemala	No	No	Yes	Yes	No	No	No	No	No
Mexico	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	No
Panama	No	No	Yes	No	Yes	No	Yes	Yes	No
Paraguay	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No
Peru	Yes	Yes	Yes	No	Yes	No	Yes	No	No
Dominican Republic	Yes	No	Yes	No	No	No	No	No	No
Uruguay	No	No	Yes	No	No	No	Yes	No	No
Venezuela	No	No	Yes	No	Yes	Yes	No	Yes	No

CAPS: Central Admixtures Pharmacy Services; DFSMP: Dietary foods for special medical purposes; EN: Enteral Nutrition; HAAN: Home Artificially Administered Nutrition; MDevs: Medical Devices; NCP: Nutritional Care Process (Screening, Diagnosis Nutritional Therapy and Monitoring); NST: Nutrition Support Teams; ONS: Oral Nutritional Supplements; PN: Parenteral Nutrition. Adapted from [35].

APPLICATION OF T3 TO HUMAN RIGHTS

Under the leadership and stimulus of Latin-American Society for Clinical Nutrition, Nutrition Therapy and Metabolism (FELANPE), a global (international) effort has been achieved in establishing nutrition access as a human right[4]. Technology exists to provide nutrition to all individuals including those unable to ingest any or sufficient nutrients through the oral route. Legal concerns would focus on developing statutes that would dictate how to achieve the goal of universal nutritional care access despite limited financial and other logistic resources.

Nutritional care should be considered as a fundamental human right intrinsically linked to the right to food and nutritional therapy as well as the right to health. The right to health includes access to timely, acceptable, quality, and affordable healthcare. This analysis could contribute to the construction of a moral, political and legal perspective globally, to the concept of nutritional care. Moreover, it can be the cornerstone of the rationale of political and legal instruments in the field of clinical nutrition.

By recognizing that nutritional care is a human right, this does not imply there is the obligation to feed all patients at any stage of life and at any cost. On the contrary, this right implies, from an ethical point of view, that the best decision for the patient must be taken and this may include under some circumstances the decision not to feed.

Human rights and healthcare ethics are intricately linked as they support and complement each other when applied together. Human rights concepts, according to E. Hirsch, "characterize and illuminate the

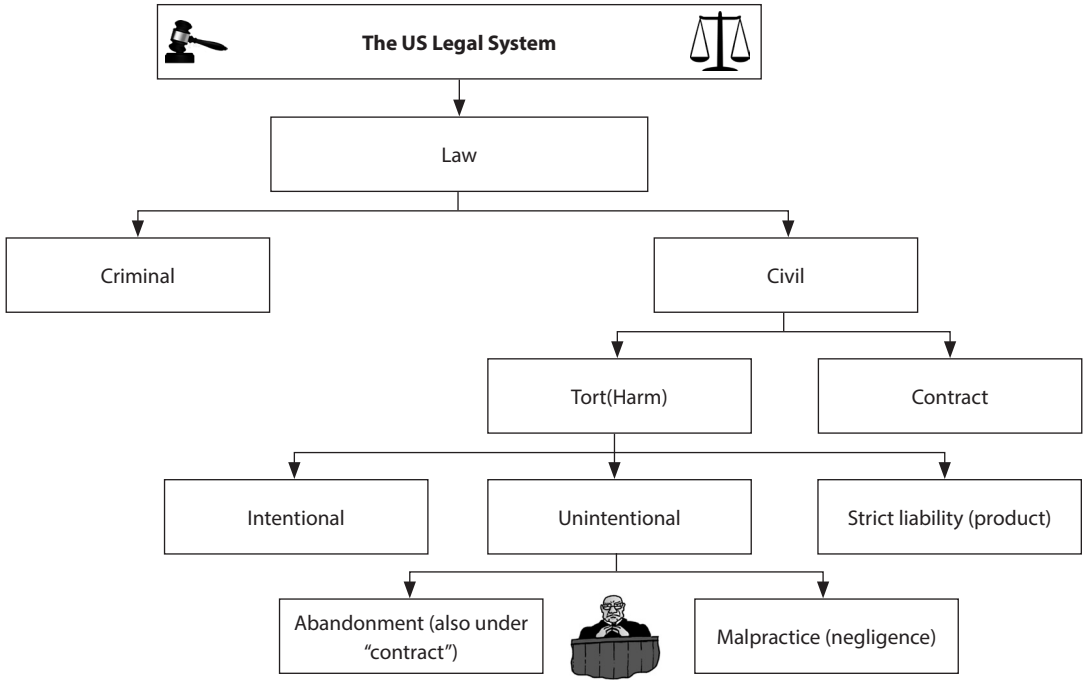

Figure 3. US Legal system. By: A. Barrocas, 2021.

Table 4. Summary of the ethical foundations of nutrition support practice and examples of legal and deontological sources for technology development and innovation in clinical nutrition

Technology	Ethical principles and moral values	Legal and deontological sources
Clinical nutrition practice	- Competent medical care - Compassion and respect for human dignity and rights - Principle of autonomy, beneficence, nonmaleficence and justice - Dignity, integrity, and vulnerability - Ethical responsibility - Moral values: Responsiveness competence attentiveness, responsibility	- Code of ethics - Hippocratic oath - Cartagena Declaration - National/Federal laws and regulations concerning AANH
Innovation in clinical nutrition and artificially administered nutrition developments	- Responsibility - Principle of autonomy, beneficence, nonmaleficence and justice - Principle of explicability - Cost-effectiveness, best benefits/risks-burdens ratio and based-evidence developments - Respect of patient's confidentiality	- Declaration of Helsinki - UNESCO recommendation on the Ethics of Artificial Intelligence

issues of an ethical requirement in the fields of care and research."[42]. In the context of nutritional care respect for human rights and dignity are not abstract values but take on a practical dimension "which define a social order and place us in mutual obligations towards each other"[42]. Moreover, ethics and human rights are guiding values for clinical nutrition practitioners, ensuring a patient-centered approach, where the needs and rights of the patients are of the greatest importance.

Recognizing the right to nutritional care as a human right, establishes a commitment to a very important ethical responsibility that must be based on the respect

of the four ethical principles (autonomy, beneficence, nonmaleficence, and justice)[43] as well as other principles as vulnerability, equality, justice and equity[44].

Likewise, following the concept of distributive justice, nutritional care should be fairly provided to all malnourished or ARFM individuals, but not equal in the sense that, depending on a variety of factors, e.g., regional, cultural, etc., may vary, albeit achieving similar goals. Another aspect that encompasses distributive justice human rights and T3 deals with the provision of nutritional care when resources are limited. Two areas of concern are raised here. First, the concept of autonomy can, in some instances, be considered subservient to the needs of the state or population at large. Thus, the principle of the greatest good for the greatest number supersedes the individual's interest. Secondly, it behooves healthcare institutions to develop the framework and protocols that govern allocation of resources long before shortages appear[45-48].

With the hopeful global embrace of nutritional care as a human right by governments, legislators, regulators and other stakeholders, T3 should be less problematic. All healthcare professionals should be aware of T3 and its specific components. They should be ambassadors who carry the message of T3 and nutritional care as a human right to constituencies outside the healthcare arena To do so requires time, commitment, and remembering to "seek first to understand, then to be understood"[49].

CONCLUSION

The Troubling Trichotomy, defined as the conundrum (enigma) arising to a great extent, from lack of anticipation in the ethical and legal aspects of the application of technology, can be considered as a comprehensive approach that should be at the core of clinical nutrition. With the hopeful global embrace of nutritional care as a human right T3 should be less problematic.

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Authorship statement

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Conflict of interest

None.

References

1. Barrocas A, Yarbrough G, Becnel PA 3rd, Nelson JE. Ethical and legal issues in nutrition support of the geriatric patient: the can, should, and must of nutrition support. Nutr Clin Pract. 2003;18(1):37-47. doi: 10.1177/011542650301800137
2. Barrocas A. Nutrition support and the troubling trichotomy: a call to action. Nutr Clin Pract. 2006;21(2):109-12. doi: 10.1177/0115426506021002109
3. Barrocas A. The Troubling Trichotomy 10 Years Later: Where Are We Now? Nutr Clin Pract. 2016;31(3):295-304. doi: 10.1177/0884533616629631
4. Cardenas D, Correia MITD, Ochoa JB, Hardy G, Rodriguez-Ventimilla D, Bermúdez CE, et al. Clinical nutrition and human rights. An international position paper. Nutr Clin Pract. 2021;36(3):534-44. doi: 10.1002/ncp.10667
5. Cardenas D. What is clinical nutrition? Understanding the epistemological foundations of a new discipline. Clin Nutr ESPEN. 2016;11:e63-e66. doi: 10.1016/j.clnesp.2015.10.001
6. Gewirth A. Reason and Morality. University of Chicago Press; 1981.
7. Jackson-Meyer K. The Principle of Proportionality: An Ethical Approach to Resource Allocation During the COVID-19 Pandemic [Internet]. Bioethics.net; 2020. [Cited: June 11, 2021]. Available from: https://www.bioethics.net/2020/04/the-principle-of-proportionality-an-ethical-approach-to-resource-allocation-during-the-covid-19-pandemic/
8. Liddell HG, Scott R. A Greek-English Lexicon. Seventh edition. New York: Oxford University Press; 1982.
9. Franssen M, Lokhorst G-J, de Poel IV. Philosophy of Technology [Internet]. The Stanford Encyclopedia of Philosophy. Fall 2018 Edition; 2018. [Cited: June 7, 2021]. Available: https://plato.stanford.edu/archives/fall2018/entries/technology
10. Cambridge Dictionary. Technology [Internet]. [Cited: June 7, 2021]. Available from:https://dictionary.cambridge.org/es-LA/dictionary/english/technology

11. Corbie-Smith G. The continuing legacy of the Tuskegee Syphilis Study: considerations for clinical investigation. Am J Med Sci. 1999; 317(1):5-8. doi: 10.1097/00000441-199901000-00002
12. Brandt AM. Racism and research: the case of the Tuskegee Syphilis Study. Hastings Cent Rep. 1978;8(6):21-9.
13. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report. Ethical Principles and Guidelines for the protection of human subjects of research [Internet]. Department of Health, Education and Welfare. [Cited: June 10, 2021]. Available from: https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html
14. Rice TW. The historical, ethical, and legal background of human-subjects research. Respir Care. 2008; 53(10):1325-9.
15. Grodin MA. Historical origins of the Nuremberg Code. In: Annas GJ, Grodin MA. The Nazi Doctors and the Nuremberg Code: Human Rights in Human Experimentation. Oxford: Oxford University Press; 1992. p. 121-144
16. World Medical Association. WMA Declaration of Helsinki-Ethical principles for medical research involving human subjects [Internet]; 9th july 2018. [Cited: June 14, 2021]. Available from: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/
17. Cárdenas D, Bermúdez CE, Echeverri S, Pérez A, Puentes M, López L, et al. Declaración de Cartagena. Declaración Internacional sobre el Derecho al cuidado Nutricional y la Lucha contra la Malnutrición. Nutr Hosp. 2019;36(4):974-80. doi: 10.20960/nh.02701
18. Cardenas D, Bermudez C, Barazzoni R. The Cartagena Declaration: A call for global commitment to fight for the right to nutritional care. Clin Nutr. 2019;38(5):2458-9. doi: 10.1016/j.clnu.2019.07.015
19. Cardenas D. La Nutrition en Médecine: Approche épistémologique, problèmes éthiques et cas cliniques. Paris: L´Harmattan; 2020.
20. Floridi L, Cowls J. A Unified Framework of Five Principles for AI in Society. Harvard Data Science Review. 2019;1(1). doi: 10.1162/99608f92.8cd550d1
21. Sicard D. L'Éthique Médicale et la Bioéthique. Paris: Presses Universitaires de France; 2009.
22. American Medical Association. Code of medical ethics. AMA Principles of medical ethics [Internet]: American Medical Association; 2001. [Cited: April 1 2021. Available from: https://www.ama-assn.org/about/publications-newsletters/ama-principles-medical-ethics
23. Potter VR. Bioethics: Bridge to the future. Englewood Cliffs, NJ: Prentice-Hall Pub; 1971.
24. Luppicini R. Technoethics and the Evolving Knowledge Society: Ethical Issues in Technological Design, Research, Development, and Innovation. United States: IGI Global; 2010.
25. Heidegger M. The Question concerning Technology and Other Essays. New York: Harper and Row; 1977.
26. Jonas H. Das Prinzip Verantwortung: Versuch einer Ethik für die technologische Zivilisation, Frankfurt/Main: Suhrkamp; extended English edition The Imperative of Responsibility: in Search of An Ethics for the Technological Age, Chicago/London: University of Chicago Press; 1984.
27. Maillard N. La vulnérabilité : une nouvelle catégorie morale? Genève: Labor et Fides; 2011.
28. Cardenas D, Díaz G, Cadavid J, Lipovestky F, Canicoba M, Sánchez P, et al. Nutrition in medical education in Latin America: Results of cross-sectional survey. JPEN J Parenter Enteral Nutr. 2021. doi: 10.1002/jpen.2107
29. Crowley J, Ball L, Hiddink GJ. Nutrition in medical education: a systematic review. Lancet Planet Health. 2019;3(9):e379-e389. doi: 10.1016/S2542-5196(19)30171-8.
30. Pelluchon C. Eléments pour une éthique de la vulnérabilité. Les hommes, les animaux, la nature. Paris: CERF; 2011.
31. Levinas E. Totalité et infini. Paris: Biblio essais; 1971.
32. Druml C, Ballmer PE, Druml W, Oehmichen F, Shenkin A, Singer P, et al. ESPEN guideline on ethical aspects of artificial nutrition and hydration. Clin Nutr. 2016;35(3):545-56. doi: 10.1016/j.clnu.2016.02.006
33. Tronto J. Un monde vulnérable, pour une politique du care. Paris: Editions La Découverte; 2009.
34. Cederholm T, Barazzoni R, Austin P, Ballmer P, Biolo G, Bischoff SC, et al. ESPEN guidelines on definitions and terminology of clinical nutrition. Clin Nutr. 2017;36(1):49-64. doi: 10.1016/j.clnu.2016.09.004
35. Cederholm T, Jensen GL, Correia MITD, Gonzalez MC, Fukushima R, Higashiguchi T, et al.; GLIM Core Leadership Committee; GLIM Working Group. GLIM criteria for the diagnosis of malnutrition - A consensus report from the global clinical nutrition community. Clin Nutr. 2019;38(1):1-9. doi: 10.1016/j.clnu.2018.08.002
36. Cardenas D, Deutz NEP. Is the definition of malnutrition a Sisyphean task? Clin Nutr ESPEN. 2019;29:246-47. doi: 10.1016/j.clnesp.2018.10.005
37. Binet JR. Droit de la Bioéthique. Lextenso: Issy les Moulineux; 2017.
38. ASPEN Nutrition Science & Practice Conference. Abstracts. Poster abstracts. Supplement: ASPEN Nutrition Science & Practice Conference [Internet]: JPEN; March 20-23, 2021; (S1-S240). [Cited: April, 2021]. doi: 10.1002/jpen.2095
39. Barrocas A, Cohen ML. Have the Answers to Common Legal Questions Concerning Nutrition Support Changed Over the Past Decade? 10 Questions for 10 Years. Nutr Clin Pract. 2016;31(3):285-93. doi: 10.1177/0884533616644439
40. Barrocas A, Farquharson J, Fernandez M. Legal considerations in Nutritional Support. Nutr Supp Serv. 1986:6(6):13.
41. Perry JE, Churchill LR, Kirshner HS. The Terri Schiavo case: legal, ethical, and medical perspectives. Ann Intern Med.

2005;143(10):744-8. doi: 10.7326/0003-4819-143-10-200511150-00012

42. Hirsch E, Mann JM. Droits de l'homme et respect de la personne. In: Hirsch E. Traité de Bioéthique: Tome I, Fondements, principes repères. Toulouse: Eres; 2010. p. 249-261.
43. Beauchamp TL, Childress FJ. Principles of Biomedical ethics. 7th ed. New York: Oxford University Press; 2012.
44. UNESCO. Universal Declaration on Bioethics and Human Rights [Internet]. UNESCO General Conference; 19 October 2005. [Cited: April 1, 2021]. Available from: https://en.unesco.org/themes/ethics-science-and-technology/bioethics-and-human-rights
45. Barrocas A, Schwartz DB, Hasse JM, Seres DS, Mueller CM. Ethical Framework for Nutrition Support Resource Allocation During Shortages: Lessons From COVID-19. Nutr Clin Pract. 2020;35(4):599-605. doi: 10.1002/ncp.10500
46. Berlinger N, Wynia M, Powell T, Hester M, Milliken A, Fabi R, et al. Ethical Framework for Health Care Institutions Responding to Novel Coronavirus SARS-CoV-2 (COVID-19). The Hastings Center. 2020:1-12.
47. Guidelines for Institutional Ethics Services Responding to COVID-19, Managing Uncertainty, Safeguarding Communities, Guiding Practice. The Hastings Center, 2020. [Internet] (June 16, 2021). Available from: https://mk0thehastingsc1jg1a.kinstacdn.com/wp-content/uploads/HastingsCenterCovidFramework2020.pdf
48. National Hospice and Palliative Care Organization's Ethics Advisory Council. Ethical Framework for Decision Making in HPC During the COVID-19 Pandemic [Internet]; March 27 2020. [Cited: June 16, 2021]. Available from: https://www.nhpco.org/wp-content/uploads/COVID-19-Ethical-Framework-Decision-Making.pdf
49. 10 Minute leader. Habit 5: Seek First to Understand Then to be Understood [Internet]; May 11 2016. [Cited: June 16, 2021]. Available from: https://www.the10minuteleader.com/habit-5-seek-first-to-understand-then-to-be-understood/