



RESEARCH

Bioethics and the human right to adequate feeding during enteral nutritional therapy

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Abstract

This study aims to reflect, in the light of bioethics, about the incorporation of the concept of human right to adequate food in the scope of enteral nutritional therapy. This is a longitudinal study performed with patients being fed through enteral nutrition who were admitted to a Brazilian University hospital. The respect for this right was checked by the analysis of the adequacy of the diet offered to the patients. The results show that less than half the patients received adequate diet (quantity and quality), mainly due to disease and treatment factors (diarrhoea, nausea and vomiting, gastric stasis, fasting for exams/procedures). However, it is observed that the limitation of financial resources and fragility in the organisation of services contribute to this reality. Enteral nutritional therapy has evolved in recent decades in relation to regulations and availability of products, but bioethical analysis shows that there are challenges to be faced in order to ensure that the right in question is also guaranteed in the clinical and therapeutic context.

Keywords: Bioethics. Enteral nutrition. Human rights.

Resumo**Bioética e direito humano à alimentação adequada na terapia nutricional enteral**

Este estudo objetiva refletir à luz da bioética a incorporação do conceito de direito à alimentação adequada no âmbito da terapia nutricional enteral. Trata-se de estudo longitudinal realizado com pacientes em nutrição enteral internados em hospital universitário brasileiro. O respeito a esse direito foi verificado a partir da análise de adequação da dieta oferecida aos pacientes. Os resultados demonstram que menos da metade dos pacientes recebeu dieta adequada (quantidade e qualidade), principalmente por fatores ligados a doenças e ao tratamento (diarreia, náuseas e vômitos, estase gástrica, jejum para exames/procedimentos). Entretanto, observa-se que limitação de recursos financeiros e fragilidades na organização dos serviços contribuem para essa realidade. A terapia nutricional enteral evoluiu nas últimas décadas em relação a regulamentações e disponibilidade de produtos, porém a análise bioética evidencia que há desafios a serem enfrentados para que o direito em questão seja garantido também no contexto clínico e terapêutico.

Palavras-chave: Bioética. Nutrição enteral. Direitos humanos.

Resumen**Bioética y derecho humano a la alimentación adecuada en la terapia nutricional enteral**

Este estudio tiene como objetivo reflexionar, a la luz de la bioética, sobre la incorporación del concepto de derecho a la alimentación adecuada en el contexto de la terapia nutricional enteral. Se trata de un estudio longitudinal, realizado en pacientes con nutrición enteral internados en un hospital universitario brasileño. El respeto a este derecho se verificó a partir del análisis de la adecuación de la dieta ofrecida a los pacientes. Los resultados muestran que menos de la mitad de los pacientes recibieron una dieta adecuada (cantidad y calidad), principalmente debido a complicaciones relacionadas con la enfermedad y el tratamiento (diarrea, náuseas y vómitos, estasis gástrica, ayuno para exámenes/procedimientos). Sin embargo, se observa que la limitación de los recursos financieros y las debilidades en la organización de los servicios contribuyen a esta realidad. La terapia nutricional enteral ha evolucionado en las últimas décadas en relación con las regulaciones y la disponibilidad de productos, sin embargo, el análisis bioético muestra que hay desafíos a ser enfrentados para que el derecho en cuestión esté garantizado en el contexto clínico y terapéutico.

Palabras clave: Bioética. Nutrición enteral. Derechos humanos.

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Declararam não haver conflito de interesse.

The *Universal Declaration of Human Rights*¹, proclaimed by the United Nations General Assembly in December 1948, recognises dignity as inherent to humanity. Therefore, human beings have equal and inalienable rights - a quest that has guided the foundation of freedom, justice and peace in the world. According to Oliveira, the principle of human dignity is *the axiological landmark of international bioethics* and the author adds that *human dignity is the most evident point of approximation between bioethics and human rights, being the fundamental principle and foundation of theoretical construction in both areas of knowledge*².

The interface between bioethics and the *Right to Adequate Food* is evidenced by the principle of “social responsibility and health” set forth in article 14 of the Universal Declaration on Bioethics and Human Rights (UDBHR) , which, among other elements, determines that scientific progress and technological developments should promote *access to adequate nutrition and water*³.

Thus, as one of the fundamental rights necessary for the promotion of human dignity, the *Right to Adequate Food* should have its ideas incorporated into social development and food and nutritional security (SAN) strategies. *Right to Adequate Food* comprehends the *human right, essential to all persons, to have regular, permanent and unrestricted access, either directly or through financial acquisitions, to safe and healthy food, in adequate and sufficient quantity and quality, corresponding to the cultural traditions of its people and that guarantees a life free of fear, dignified and full in the physical and mental, individual and collective dimensions*⁴.

The Sistema Nacional de Segurança Alimentar e Nutricional National - Sisan (National System of Food and Nutritional Security) was created by the Law 11.346 in September 2006 with the objective of ensuring the *Right to Adequate Food*, and being governed by principles that encompass *universality and equity in access to adequate food, without any kind of discrimination, as well as respect for people’s dignity*⁵ through formulations and implementations of SAN policies and plans and integration between government and civil society. The body is helped by the Conselho Nacional de Segurança Alimentar e Nutricional - Consea (National Council for Food and Nutrition Security), an instrument of the civil society that advises the presidency of the Republic in formulating policies and establishing guidelines for the Country to guarantee the human right to food⁶.

In the context of the Sistema Único de Saúde (Unified Health System -SUS), the Política Nacional de Alimentação e Nutrição (Pnan = National Food and Nutrition Policy) encompasses care for individuals with special dietary needs⁷, including patients on enteral nutrition therapy (ENT), that is, a set of therapeutic procedures to maintain or recover the nutritional status by means of a feeding tube⁷.

In the hospital environment, ENT is increasingly used as an alternative for patients who have a preserved gastrointestinal tract and can not ingest food via oral intake and / or have an insufficient oral intake⁹. The prescription of this therapy seeks to prevent deterioration of the nutritional condition; therefore, must be nutritionally complete and adequate to meet the nutritional requirements of the patient, taking into account the individual clinical conditions¹⁰ and preserving the patient’s rights and autonomy¹¹.

Thus, it is important to emphasise nutrition in all its aspects, including enteral nutritional therapy, in the context of the human right. The importance of providing sufficient amounts of nutrients and energy to the patient is related to the need to reduce the length of hospital stay, the incidence of infections and morbidity and mortality, which are responsible for affecting its clinical course¹²⁻¹⁴.

In this sense, this work had as general objective to analyse in the light of bioethics the respect to the right to adequate food of patients in ENT. Specifically, it was intended to analyse the history of the evolution of the policies related to ENT in the last decades and to demonstrate the current reality of a university hospital in relation to this procedure, verifying factors related to (in) adequacy of the diet and the nutritional needs of the studied patients.

Method

The research had a quantitative, descriptive, longitudinal approach, and was approved by the Comitê de Ética em Pesquisa da Pontifícia Universidade Católica do Paraná (Ethics Research Committee of the Pontifical Catholic University of Paraná). In order to allow a better contextualisation of the results obtained, a narrative review was carried out, addressing the history of the evolution of ENT in the Brazilian scenario, pointing to legal and political milestones, from the descriptors “enteral nutrition”, “diet by tube”, “legislation and nutritional

therapy “in the Portuguese language, without limitation of publication date. The internet search was carried out on SciELO and Lilacs databases, on sites of professional councils, associations and Brazilian societies related to enteral nutritional therapy.

At the same time, in order to demonstrate the current reality of ENT in a hospital environment, field research was conducted with enteral nutrition patients hospitalised in a Brazilian university hospital between January and April 2014. The patients agreed to voluntarily participate in the study by signing an informed consent form after having received detailed information about the study. A legally responsible family member was contacted when patients were unable to communicate. The research was explained to them and they were asked to sign the consent form.

The participants of the study were patients 18 years of age or older, of both sexes, who had been prescribed enteral nutrition via tube or gastrostomy feeding, complemented or not with oral nutritional supplementation and hospitalised by the SUS. Patients in enteral nutrition who were transitioning to oral diets, patients whose nutritional needs could not be estimated due to the impossibility of anthropometric nutritional assessment and patients in palliative care were excluded. The final sample consisted of 30 participants.

The patients were submitted to a nutritional evaluation to determine their nutritional needs when they were included in the study. An anthropometric evaluation was performed with those individuals up to 72 hours after the beginning of the ENT, and followed daily during the hospitalisation period. In addition, stature was measured using the knee height method, with a flexible and inextensible measuring tape. The ideal weight was estimated using the mean BMI for age, according to the World Health Organisation¹⁵ and Lipschitz¹⁶, for adults and the elderly, respectively. The energy requirements were determined according to the estimate per kilogram of body weight according to Martins and Cardoso¹⁷.

The enteral diet was calculated based on the analysis of the records of the patient’s daily volumes during the period in which they underwent this procedure. Oral industrialised nutritional supplementation or supplemental parenteral nutrition (including glucose solution) was also considered in order to determine macro and micronutrients administered. The caloric energy amount of these nutrients provided on the fourth

day after the beginning of the diet was compared to the nutritional needs of the patient for adequacy analysis.

The following items were described and analysed in relation to enteral nutrition: reasons for the prescription of ENT, basic pathologies, complications from enteral nutrition, patients’ type of nutritional delivery, enteral diets formulations used, caloric density of formulations, prescribed volume, administered volume, infusion rate of the diet, time (days) to achieve the total energy and protein requirements.

In order to adjust the diet, we also considered the clinical data and intercurrent related to enteral nutrition. Regarding the results, the quantitative variables were analysed by descriptive statistics and the qualitative variables were categorised and analysed by frequency distribution.

Results

The search in the literature about the history of the evolution of enteral therapy has shown that advances have intensified since the late 1970s when industries mobilised to develop nutritionally complete and lyophilised diet formulations. After this achievement, it was verified how the organisation of institutions focused on nutrition studies. In addition, there was a deepening of the discussion on the world scenario, including the Brazilian scenario, in the scientific and political fields. The main milestones of the evolution of this therapy in Brazil will be briefly presented below.

A field research involving patients in enteral nutrition was carried out at a university hospital in Curitiba in order to illustrate the reality of ENT in the Brazilian scenario. Thirty patients were evaluated, with mean age of 62 ± 11 , 21 years. The majority of patients evaluated in ENT were hospitalised due to cardiovascular disease (53%, $n = 16$), followed by neoplasia (17%, $n = 5$) and cerebrovascular accident (10%, $n = 3$), according to Table 1. Other pathologies observed in the patients were sepsis, respiratory failure, aneurysm and bariatric surgery. They represented 20% of the clinical diagnosis ($n = 6$).

The main reasons that led patients to receive ENT were respiratory failure (73%, $n = 22$) and dysphagia (17%, $n = 5$). Others refer to inappetence and postoperative fistula (10%, $n = 3$).

Table 1. Clinical characteristics of patients in hospital enteral nutrition brazilian university student, April, 2014

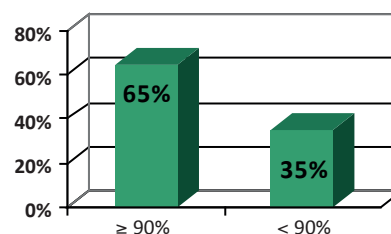
Variables	Numbers of Patients	%
Gender		
Male	20	67
Female	10	33
Reason for prescription of Enteral Nutrition		
Respiratory failure	22	73
Dysphagia	5	17
Others	3	10
Pathologic Basics		
Cardiovascular disease	16	53
Neoplasia	5	17
Cerebrovascular accident	3	10
Others	6	20

Nasoenteric tube was the most used delivery system (97% of the patients $n = 29$). Only one patient received food via gastrotomy. Enteral nutrition was exclusive for all patients, using continuous infusion pump administration. As a protocol of the nutrition service of the hospital in question, the progression of the diet is slow in order to avoid adverse events. This way, the nutritional value of the diet progresses during three days until it reaches the total nutrition recommended.

All patients started ENT with a standard diet (normocaloric/normoproteic). The enteral diets used were evaluated on the fourth day after its beginning and the following distribution was observed: hypercaloric /hyperproteic (40%); hypercaloric/hyperproteic with fibers (17%); normocaloric/normoproteic (7%); normocaloric/hyperproteic (3%). It was verified that 33% of the patients ($n = 10$) did not complete the fourth day of follow-up because they evolved to exclusive oral or parenteral nutrition or died.

The mean infusion rate of the patients feeding was 41.55 ± 6.85 ml / h, and the amount of infused diet underwent many changes, mainly as a consequence of the changes of the administered formulations and their caloric densities, in order to reach the nutritional needs of patients. During the study period, the average energy expenditure of the patients was $1,729 \pm 161,45$ kcal / day and the average energy supply was lower than that, reaching $1,260.1 \pm 348.33$ kcal/day, including energy from the glucose solution. Thus, 65% ($n = 13$) of the patients who completed at least four days of receiving the

enteral diet ($n = 20$) achieved more than 90% of the adequacy of the enteral diet on the fourth day of administration, as shown in Figure 1.

Figure 1. Percentage of enteral nutrition adequacy in the fourth day of administration to study participants (April, 2014)

The following complications or intercurrents, related or not to ENT, interfered in the inadequacy of the enteral diet and its discontinuation: diarrhoea (13%, $n = 4$); complications due to the position of the feeding tube such as haemorrhage (3%, $n = 1$), abdominal distension (3%, $n = 1$), nausea and vomiting (3%, $n = 1$); tube obstruction (10%, $n = 3$); gastric stasis (17%, $n=5$); need to rearrange the tube in patients who had removed it (7%, $n = 2$); administration of vasoactive drugs (3%, $n = 3$) and diet suspension for lab exams (7%, $n=2$).

Regarding the outcome of the hospitalisation, there was a higher frequency (33%, $n = 10$) of patients who died, followed by those who progressed to the oral diet (30%, $n = 9$). It was also noted that 13% ($n = 4$) were discharged from hospital and 20% ($n = 6$) remained under the care of the multi professional team after data collection was completed.

Discussion

The *Right to Adequate Food* has been widely discussed in our country, and many achievements have resulted from different movements of the civil society as well as governmental and non-governmental organisations. The main achievement was the inclusion of food among social rights in the Article 6 of our country's legal system in 2010. However, the discussion of enteral nutrition therapy in the context of *Right to Adequate Food* is still poorly evidenced, pointing to the need of emphasising this interface, as proposed in this article.

The brief retrieval of the evolution of enteral nutrition therapy in the scientific literature points to many advances in the scientific, industrial and

political spheres and facilitate the nutritional needs of people who depend on enteral nutrition for food.

Initially, the diets were basically composed of beef or chicken broth administered to the small intestine via jejunostomy, which caused gastrointestinal symptoms such as abdominal distension, colic, diarrhoea and flatulence¹⁸. These diets with cooked, liquefied foods and coados was denominated “artesanal”.

Industrialised enteral diets emerged in the 1980s. Waitzberg was the pioneer, in 1985, in the evaluation of the results obtained by the administration of an industrialised enteral diet to malnourished patients, who presented good tolerance and absence of side effects, unlike homemade enteral diets.

Currently, industrialised diets are presented in three forms: industrialised powdered formulas, semi ready liquid formula, and ready to use. Enteral formulas ready for use, also known as a closed system, require equipment (enteral feeding tube to connect with the formula container) specific for enteral pumps. They are expensive and are the most used in the hospital environment¹⁰.

The Sociedade Brasileira de Nutrição Parenteral e Enteral - SBNPE (Brazilian Society of Parenteral and Enteral Nutrition) was founded in 1975. It was a mark of the beginning of enteral nutrition in the Country. The Society has a multidisciplinary approach and includes doctors, nutritionists, nurses, pharmacists and students. The Society maintains initiatives of professional defence, education and nutrition activities. It also offers refresher courses and training, in addition to promoting national congresses. The inclusion of the “E” in the acronym SBNP happened only in 1981, since the technical regulation started to set the minimum requirements required for ENT¹⁹.

The Inquérito Brasileiro de Avaliação Nutricional Hospitalar - Ibranutri (Brazilian Hospital Nutrition Assessment Survey) was work of the SBNPE which, in 1996, conducted multi centric research in hospitals in the Country’s public network with the objective of identifying malnutrition in hospitalised patients²⁰. The 1999 Portaria 38 (Ordinance) of the Secretaria de Assistência à Saúde – SAS (Department of Health Assistance) of the Ministry of Health included enteral nutrition in pediatrics and adults in the SUS special procedures table and showed that the cost/benefit ratio of nutrition therapy (NT) in integral health care, as indicated by the Ibranutri,

was of R\$1.00 of investment for R \$ 4.13 of total economy²¹.

The Agência Nacional de Vigilância Sanitária (Anvisa- National Health Surveillance Agency) issued the Resolution 63 in 2000, approving a technical regulation to establish the minimum requirements for ENT. From that point onwards, hospital units and companies providing goods or services had 90 days to comply with the resolution²². The SAS established, in 2005, in the Portarias (ordinance) 343 and 131, respectively, the organisation and implementation of assistance of high complexity to EN as well as selection of the care units and reference centres of high complexity in EN in order to better serve SUS users^{23,24}.

Chart 1. Marks of the evolution of enteral nutrition therapy in Brazil

Year	Mark
1975	Foundation of the Sociedade Brasileira de Nutrição Parenteral e Enteral
1981	Change of the name of the Society to SBNPE, with the addition of “E” for enteral
1987	Realisation of the Ibranuti Study
1999	Portaria (Ordinance) 38 from 29 September 1999 - SAS
2000	Resolution 63 from 06 July 2000 - Anvisa
2005	Portaria. 343 from 07 March 2005 - SAS
2005	Portaria 131 from 08 March 2005 – SAS

In our study, it was demonstrated that the caloric needs of the patients studied were not met, and factors related to complications of the enteral diet and intercurrents interfered in the administration of the diet, corroborating the findings of Campanella et al.⁹, Nozaki and Peralta¹⁴ and Assis et al²⁵.

In some cases, ENT is the only way for the individual to remain alive by avoiding starvation. In this situation, one of the main roles of the nutritionist is to control and prevent symptoms that may interfere with the patient’s quality of life - heartburn, diarrhoea and emesis - and fulfil the patient’s nutritional needs. The intervention of the nutritionist should consider the fundamental needs of the individual, both the ones related to symptom control and those aimed at ensuring satisfaction and comfort²⁶.

In this sense, it is important to emphasise that the recommendation of nutrition through an enteral tube involves an initial discussion of the team, and later with the patient (when possible) and / or their relatives so that they are protagonists in the decision

making regarding alternative feeding. The decision to initiate enteral nutrition should meet the best interest of the patient, aiming for respect of their autonomy. It should also be noted that patients with palliative or end-of-life care were not included in this study, as in those cases the role of feeding ends up being different from the objectives of ENT presented in Anvisa's definition²².

Among the possible definitions of enteral nutrition, the Resolution 63 of the Anvisa Diretoria Colegiada - RDC (Resolution of the Board of Directors) characterises it as a *special purpose food, with controlled intake of nutrients, in an isolated or combined form, with a defined or estimated composition, specially formulated and prepared for the use by tubes or oral, industrialised or not, used exclusively or partially to replace or supplement oral feeding in patients malnourished or not, according to their nutritional needs, in a hospital, outpatient or on domicile regime, aiming the synthesis or maintenance of the tissues, organ or systems*²⁷.

ENT can be classified as an alternative food for patients with special needs, in which case it is possible to guarantee the right to adequate food. From the principles of Universal Declaration on Bioethics and Human Rights (UDBHR), it is understood that all people must have their *Right to Adequate Food* respected as an essential condition for the right to life. Thus, ENT may be the only way to maintain an individual's diet under these conditions, thus ensuring the right to *Right to Adequate Food*, even by alternative food delivery systems^{1,28}.

Among the ethical principles guiding human rights can be mentioned the principle of universality, applied to all human beings regardless of ethnicity, religion or social characteristic. The principle of indivisibility is also emphasised as civil, political, economic, social and cultural rights are also necessary to ensure a dignified life. The principle of interdependence refers to the relationship between principles because the achievement of one requires the enforcement of the others - for example, health care does not remove the need for adequate food. Finally, the principle that characterises human rights as inalienable - non-transferable, non-negotiable and unavailable - that is, can not be ceded or withdrawn from anyone²⁹.

Food nutrients are necessary for the biological and social maintenance of the human being. However, concern about hunger and access to food still persists on the global scene, characterising a situation related to social exclusion and violation of human rights¹².

According to Rosaneli et al., *The right to adequate food will only materialise when all people, regardless of social class, nationality or ethnicity, have permanent access to healthy food and adequate means for their acquisition*³⁰. In the face of this problem, the concept of food and nutritional security has three main aspects: quantity, quality and regularity of access to food³¹. In this sense, when relating the *right to adequate food* and ENT, we must reflect on the availability of this therapy to all the people who need this intervention, considering the three aspects mentioned.

In the university hospital where the research was carried out, 100% of enteral diets are industrialised. Despite the higher cost when compared to traditional diets, the industrialised diet can have some benefits in the hospital context: practicality, nutritionally complete formulas, greater safety in terms of microbiological control and centesimal composition, which can result in better immune response. In this way, they can help to reduce clinical complications, such as infections, pressure ulcers, poor healing of surgical procedures and protein catabolism. Thus, they can also reduce hospitalisation time and, consequently, the total costs of the patient to the hospital^{14,32-36}.

Citizens have a duty to demand their rights and, on the other hand, the state must guarantee those rights and must not violate them. Therefore, they are obligations of the public power: to respect the rights so as not to block directly or indirectly their effectiveness; protect the population against actions of companies or individuals that may result in violation of rights and also take preventive measures; and to promote and facilitate the access of people to different means to guarantee their rights³⁷.

In this study, all inpatients who needed alternative nutrition therapy received it. However, it is necessary to discuss whether the formulation used contemplates the needs of each patient, considering the specificities of each moment. In the study group, four different diet formulations were identified for the patients. After the treatment and initiation protocol of ENT provided by the nutrition service of the hospital in question, all the patients initiated the therapy with standard formulation (normocaloric/normoproteic), so that there would be a better acceptance and adaptation to the diet. Nevertheless, some patients presented complications related to the procedure.

A common complication in patients with ENT is diarrhoea, what has been identified in this study.

However, if we consider that 76% of the sample was hospitalised in an intensive care unit (ICU), it is questioned whether the diarrhoea was directly related to ENT, since critical patients, who usually require a ICU to recover, are individuals with high metabolic stress, high catabolism, low immunity and high chances of microbiological contamination.

In these cases, treatment with antibiotics³⁸ is frequent. Antibiotics are efficient against pathological microorganisms but kill beneficial microorganisms of the intestinal flora as well. This process of microbiological biodiversity reduction leads to an intestine with less microvilli, therefore incapable of absorbing nutrients and water, what favours diarrhoea³⁹⁻⁴².

It is known that many factors, inherent in the disease itself, can interfere in the adequacy to enteral nutrition. Factors such as gastric stasis, tube obstruction, medical exams and transfer of the feeding tube. On the other hand, decisions regarding diet formulas and the definition of the volumes offered to patients may be influenced by economic factors related to hospital revenues, according to the subsidies from the Sistema Único de Saúde (Unified Health System). The quality of care provided by hospital services, since some patients have to fast for excessive time, which is not justified by the procedures performed.

Some Brazilian studies have been conducted in the last decade to analyse the adequacy of the infused enteral diet in relation to the prescribed diet^{9,14,25}, and the results corroborate those presented in this study. Some authors have pointed out some ways to address this issue: improvement of enteral diet start time; effective presence of multi professional team of nutrition therapy; continuing education for care staff⁹; review of work processes; periodic evaluation of patients¹⁴.

From these notes new questions arise that include the reasons why the diet has not started early (or in the ideal time), explanations of why patients are not (re) evaluated periodically or even difficulties for the effective interdisciplinary work - Does the institution presents enough professionals that nutrition therapy demands? Do they have enough resources to meet the nutritional needs of patients?

In this research, we emphasise the adequacy of amounts of enteral nutrition with enough calories, but Nozaki and Peralta¹⁴ warn about other nutritional elements, such as protein content, fibers, presence of antioxidants and immunostimulant

(arginine and glutamine), for example. However, the more modified the diet, the greater the cost, which ends up restricting its use even if there is scientific evidence to justify it.

Excluding factors inherent to patients' clinical conditions, and despite all the advances of the practices and policies related to ENT, the economic dimension still seems to surpass other dimensions in this context, contributing to the violation of the *right to adequate food* of this susceptible group. Thus, we must consider the quality of enteral nutrition therapy and the *right to adequate food* as the current discussion in the field of bioethics and human rights, based on essential principles such as vulnerability, equity and justice, but based mainly on the UDBHR of Unesco⁴³. According to Carvalho and Albuquerque⁴⁴, UDBHR can be used as a theoretical-normative reference to analyse problems related to inequality in health with a focus on human rights.

Article 8 of the Universal Declaration on Bioethics and Human Rights (UDBHR) stresses that human vulnerability *should be taken into account. Individuals and groups of special vulnerability should be protected and the personal integrity of such individuals respected*⁴⁵. In the context of ENT, it is perceived that patients with special food needs due to organic dysfunction are individuals who are in a situation of vulnerability^{43,46} and therefore require special ethical conduct and clinical and hospital care.

Kottow argues that *vulnerability, dignity, and integrity may perhaps be understood more precisely as anthropological descriptions of the human condition*⁴⁷ which demand respect and protection, even if they lack a norm related to them and that guides ethical conduct. According to Hossne, this assertion reinforces the *referential theory, placing vulnerability as an essential reference for the choice of values, proper to bioethics*⁴⁸. The author considers this reference as *one of the elements (or factors) that not only justifies the existence but also subsidises normative guidelines in bioethics*⁴⁹.

Schramm points to the need to prioritise those "vulnerables", i.e. *those who are subjected not only to risks of harm, but also to damage and concrete deficiencies*⁵⁰. It is important to highlight that in our research, approximately one-third of patients, considered vulnerable, did not have their nutritional needs met, which requires action of protection by those who have the power to make decisions (both in the sense of care and in the sense of management of public policies). Therefore, it is necessary to consider at least the energy and protein demands imposed by the clinical condition that the

patient presents, and to seek ways to meet these requirements.

Vulnerability expresses biological, social, and existential values, and *biological insecurity means vulnerability*⁵¹ and, on the social level, it refers to the existence of relationships that limit people's ability to act (...) and deny the effective exercise of rights⁵².

Ethical reflection on this condition of biological and often social vulnerability of patients in ENT requires nutritional conduct based on equity, indispensable to fair actions in this context. *Equity concerns equality insofar as it treats as equal what is equal, but, when necessary, it treats in an unequal (but adequate) way what is unequal*⁴⁹. Aiming for the best clinical outcome, ENT patients should be treated in an unequal way so that their specific nutritional needs are met.

In this way, distributive justice, understood as the primary virtue of social institutions, is the fruit of human cooperation, which should aim at mutual benefits⁵³. One can then extrapolate this definition of equity to the area of ENT, since all have equal *right to adequate food* while respecting and attending to the different dietary needs of each individual.

Final considerations

Analysing the ENT in the last decades, it is observed that the regulations have evolved and there is greater availability of quality products, which facilitates the *right to adequate food* of the population that needs the therapy. However, there are still many challenges that involve access to adequate diet, exemplified in this study from the

analysis of the reality of ENT in a university hospital. Fragilities were found in the enteral nutrition offered to the patients, especially in relation to the specific quantity and quality of each one, being a recurrent problem in the different regions of Brazil.

Many factors may contribute to this inadequacy, such as complications related to the patient's own illness or to enteral nutrition. But it was observed in this study that more than half of the patients did not present evidence of clinical factors that could compromise the diet adequacy. Therefore, many questions arise. One of them is about the sufficiency of resources passed on to institutions in order to meet the *right to adequate food* and the quality of care for this population. We found that the awareness of the results of this research contributed to better guide the continued education of the group of assistant researchers.

Inadequate enteral nutrition for those who have it as the only form of nutrition generates vulnerable individuals, a situation that needs the attentive look of both care staff and public managers. It also requires actions seeking distributive justice based on respect for vulnerability and equity. Considering this study in particular, the literature on the subject and the normative references of bioethics, we must warn that there is the need to improve public and institutional policies to meet the needs of this population, considering that the violation of the *right to adequate food* can affect patients in ENT in all spheres of their lives. It is believed that the results presented here can mobilise transformations in the work processes and, thus, contribute to the guarantee of the *right to adequate food* of this population.

Referências

1. Organização das Nações Unidas para a Educação, a Ciência e a Cultura. Declaração universal dos direitos humanos [Internet]. Brasília: Unesco; 1998 [acesso 23 abr 2016]. Disponível: <https://bit.ly/1c4a30C>
2. Oliveira AAS. Interface entre a bioética e direitos humanos: o conceito ontológico de dignidade humana e seus desdobramentos. Rev. bioét. (Impr.). 2007;15(2):170-85. p.173.
3. Organização das Nações Unidas para a Educação, a Ciência e a Cultura. Declaração universal sobre bioética e direitos humanos [Internet]. Brasília: Unesco; 2005 [acesso 23 abr 2016]. Disponível: <https://bit.ly/1TRJFa9>
4. Burity V, Franceschini T, Valente F, Recine E, Leão M, Carvalho MF. Direito humano à alimentação adequada no contexto da segurança alimentar e nutricional. Brasília: Abrandh; 2010. p. 15.
5. Brasil. Lei nº 11.346, de 15 de setembro de 2006. Cria o Sistema Nacional de Segurança Alimentar e Nutricional – Sisan com vistas em assegurar o direito humano à alimentação adequada e dá outras providências [Internet]. Diário Oficial da União. Brasília; v. 143, nº 179, p.1-2, 18 set 2006 [acesso 23 abr 2016]. Art. 8º. Disponível: <https://bit.ly/2pApPdG>
6. Machado RLA. Sistema Nacional de Segurança Alimentar e Nutricional [Internet]. Brasília: Conselho Nacional de Segurança Alimentar e Nutricional; 29 maio 2017 [acesso 5 jun 2017]. Disponível: <https://bit.ly/2pE7xax>

7. Brasil. Ministério da Saúde. Departamento de Atenção Básica. Política Nacional de Alimentação e Nutrição [Internet]. Brasília: Ministério da Saúde; 2012 [acesso 23 abr 2016]. Disponível: <https://bit.ly/Zfz5nX>
8. Leandro-Merhi VA, Morete JL, Olivera MRM. Avaliação do estado nutricional precedente ao uso de nutrição enteral. *Arq Gastroenterol.* 2009;46(3):219-24.
9. Campanella LCA, Silveira BM, Rosário Neto O, Silva AA. Terapia nutricional enteral: a dieta prescrita é realmente infundida? *Rev Bras Nutr Clín.* 2008;23(1):21-5.
10. Vasconcelos MIL. Nutrição enteral. In: Cuppari L. Nutrição clínica no adulto. 2ª ed. São Paulo: Manole; 2005. p.369-90.
11. Chaves MLF. Acidente vascular encefálico: conceituação e fatores de risco. *Rev Bras Hipertens.* 2000;7(4):372-82.
12. Waitzberg DL. Nutrição oral, enteral e parenteral na prática clínica. 3ª ed. Rio de Janeiro: Atheneu; 2000.
13. Fernandes DD, Ghisleni DR, Colpo E, Lopes LFD, Rubin BA. Aporte nutricional em pacientes em terapia enteral exclusiva: recomendado x recebido. *Rev Bras Nutr Clín.* 2009;24(2):85-92.
14. Nozaki VT, Peralta RM. Adequação do suporte nutricional na terapia nutricional enteral: comparação em dois hospitais. *Rev Nutr.* 2009;22(3):341-50.
15. World Health Organization. Obesity: preventing and managing the global epidemic. Geneve: WHO; 2000.
16. Lipschitz DA. Screening for nutritional status in the elderly. *Prim Care.* 1994;21(1):55-67.
17. Martins C, Cardoso SP. Terapia nutricional enteral e parenteral: manual de rotina técnica. Curitiba: Nutroclínica; 2001.
18. Vasconcelos MIL, Coppini LZ. Terapia de nutrição enteral: preparo da nutrição enteral industrializada. In: Waitzberg DL. Nutrição oral, enteral e parenteral na prática clínica. 4ª ed. Rio de Janeiro: Atheneu; 2009. p. 823-31.
19. Sociedade Brasileira de Nutrição Parenteral e Enteral. Sobre a SBNPE [Internet]. 2014 [acesso 3 jun 2014]. Disponível: <https://bit.ly/2DTGoFS>
20. Correia MITD, Caiaffa WT, Waitzberg DL. Inquérito Brasileiro de Avaliação Nutricional Hospitalar (Ibranutri): metodologia do estudo multicêntrico. *Rev Bras Nutr Clín.* 1998;13(1):30-40.
21. Brasil. Ministério da Saúde. Secretaria Executiva. Secretaria de Assistência à Saúde. Portaria Conjunta nº 38, de 29 de setembro de 1999. Inclusão na Tabela de Procedimentos Especiais do SIH-SUS, os procedimentos de nutrição enteral em pediatria e adultos [Internet]. 13 out 1999 [acesso 23 abr 2016]. Disponível: <https://bit.ly/2rCdaaq>
22. Brasil. Agência Nacional de Vigilância Sanitária. Resolução da Diretoria Colegiada nº 63, de 6 de julho de 2000. Aprova o regulamento para fixar os requisitos mínimos exigidos para a terapia de nutrição enteral [Internet]. 7 jul 2000 [acesso 23 abr 2016]. Disponível: <https://bit.ly/2uriHp1>
23. Brasil. Ministério da Saúde. Portaria MS nº 343, de 7 de março de 2005. Institui, no âmbito do SUS, mecanismos para implantação da assistência de alta complexidade em terapia nutricional [Internet]. 8 mar 2005 [acesso 23 abr 2016]. Disponível: <https://bit.ly/2GdxN2s>
24. Brasil. Ministério da Saúde. Secretaria de Atenção à Saúde. Portaria MS nº 131, de 8 de março de 2005. Define Unidades de Assistência de Alta Complexidade em Terapia Nutricional e Centros de Referência de Alta Complexidade em Terapia Nutricional e suas aptidões e qualidades [Internet]. Diário Oficial da União. Brasília; 9 mar 2005 [acesso 23 abr 2016]. Disponível: <https://bit.ly/2Ko96Ch>
25. Assis MCS, Silva SMR, Leães DM, Novello CL, Silveira CRM, Mello ED *et al.* Nutrição enteral: diferenças entre volume, calorias e proteínas prescritos e administrados em adultos. *Rev Bras Ter Intensiva.* 2010;22(4):346-50.
26. Benarroz MO, Faillace GBD, Barbosa LA. Bioética e nutrição em cuidados paliativos oncológicos em adultos. *Cad Saúde Pública.* 2009;25(9):1875-82.
27. Brasil. Agência Nacional de Vigilância Sanitária. Op. cit. Anexo, item 3.4.
28. Nogueira SCJ, Carvalho APC, Melo CB, Moraes EPG, Chiari BM, Goncalves MIR. Perfil de pacientes em uso de via alternativa de alimentação internados em um hospital geral. *Rev Cefac [Internet].* 2013 [acesso 23 abr 2016];15(1):94-104. Disponível: <https://bit.ly/2GsBnt0>
29. Leão M, organizadora. O direito humano à alimentação adequada e o Sistema Nacional de Segurança Alimentar e Nutricional [Internet]. Brasília: Abrandh; 2013 [acesso 23 abr 2016]. Disponível: <https://bit.ly/2G5wtmj>
30. Rosaneli CF, Ribeiro ALC, Assis L, Silva TM, Siqueira JE. A fragilidade humana diante da pobreza e da fome. *Rev. bioét. (Impr.).* 2015;23(1):89-97. p. 94.
31. Belik W. Perspectivas para segurança alimentar e nutricional no Brasil. *Saúde Soc.* 2003;12(1):12-20.
32. Araújo EM, Menezes HC. Formulações com alimentos convencionais para nutrição enteral ou oral. *Ciênc Tecnol Aliment.* 2006;26(3):533-8.
33. Henriques GS, Rosado GP. Formulação de dietas enterais artesanais e determinação da osmolalidade pelo método crioscópico. *Rev Nutr.* 1999;12(3):225-32.
34. Ferreira IKC. Terapia nutricional em unidade de terapia intensiva. *Rev Bras Ter Intensiva.* 2007;19(1):90-7.
35. Pretel PRV, Lello A, Rodrigues AL, Cunha EMB, Rodrigues LP, Oliveira CC. Análise do custo e benefício de dietas enterais artesanais e industrializadas. *Nutrire.* 2009;34(Suppl):214.

36. Franzosi OS, Abrahão CLO, Loss SH. Aporte nutricional e desfechos em pacientes críticos no final da primeira semana na unidade de terapia intensiva. *Rev Bras Ter Intensiva*. 2012;24(3):263-9.
37. Albuquerque MFM. A segurança alimentar e nutricional e o uso da abordagem de direitos humanos no desenho das políticas públicas para combater a fome e a pobreza. *Rev Nutr*. 2009;22(6):895-903.
38. Liberati A, D'Amico R, Pifferi S, Torri V, Brazzi L, Parmelli E. Antibiotic prophylaxis to reduce respiratory tract infections and mortality in adults receiving intensive care. *Cochrane Database Syst Rev*. 2009;(4):CD000022.
39. Vasconcelos MIL, Tirapegui J. Aspectos atuais na terapia nutricional de pacientes na unidade de terapia intensiva (UTI). *Rev Bras Ciênc Farm*. 2002;38(1):23-32.
40. Oliveira SM, Burgos MGP, Santos EMC, Prado LVS, Petribú MMV, Bomfim FMT. Complicações gastrointestinais e adequação calórico-proteica de pacientes em uso de nutrição enteral em uma unidade de terapia intensiva. *Rev Bras Ter Intensiva*. 2010;22(3):270-3.
41. Cartolano FC, Caruso L, Soriano FG. Terapia nutricional enteral: aplicação de indicadores de qualidade. *Rev Bras Ter Intensiva*. 2009;21(4):376-83.
42. Wiesen P, Van Gossom A, Preiser JC. Diarrhoea in the critically ill. *Curr Opin Crit Care*. 2006;12(2):149-54.
43. Carvalho RRP, Albuquerque A. Desigualdade, bioética e direitos humanos. *Rev. bioét. (Impr.)*. 2015;23(2):227-37.
44. Hossne WS. Dos referenciais da bioética: a vulnerabilidade. *Bioethikos*. 2009;3(1):41-51.
45. Kottow MH. Vulnerability: what kind of principle is it? *Med Health Care Philos*. 2004;7(3):281-7. p. 286.
46. Hossne WS. Op. cit. p. 48.
47. Hossne WS. Dos referenciais da bioética: a equidade. *Bioethikos*. 2009;3(2):211-6. p. 212.
48. Schramm FR. Bioética da proteção: ferramenta válida para enfrentar problemas morais na era da globalização. *Rev. bioét. (Impr.)*. 2008;16(1):11-23. p.11.
49. Malagón Oviedo RA, Czeresnia D. O conceito de vulnerabilidade e seu caráter biossocial. *Interface Comun Saúde Educ [Internet]*. 2015 [acesso 4 abr 2016];19(53):237-49. p.244. Disponível: <https://bit.ly/2GcMcm9>
50. Malagón Oviedo RA, Czeresnia D. Op. cit. p. 247.
51. Rawls J. Uma teoria da justiça. São Paulo: Martins Fontes; 1997.

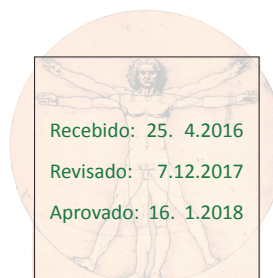
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Participation of the authors

Eloisa Cristina Gonçalves participated in the conception of the study, was responsible for collecting and analysing data and writing the first versions of the article. In addition to the conception, Ivone Mayumi Ikeda Morimoto was responsible for Eloisa's academic orientation, data analysis and writing of the first versions of the article. Cilene da Silva Gomes Ribeiro participated in the data analysis and final essay of the article. Thiago Rocha da Cunha collaborated with the writing and final revision of the article, and with the construction of the arguments on bioethics. Carla Corradi-Perini was responsible for the conception of the study, academic orientation of Eloisa Cristina Gonçalves, data analysis, essay and final revision of the article.



Annex

Table 2. Percentage of adequacy of enteral nutrition on the fourth day of administration to study patients (April, 2014)

Identification of the patient	% of adequacy on the 4th day
1	Did not complete the days
2	90.9
3	100
4	Feeding tube obstruction
5	66
6	100
7	100
8	100
9	Did not complete the days
10	100
11	Did not complete the days
12	60
13	Fasting
14	Did not complete the days
15	90.9
16	100
17	33.3
18	90.9
19	Did not complete the days
20	Did not complete the days
21	Did not complete the days
22	100
23	Did not complete the days
24	42
25	100
26	100
27	Did not complete the days
28	100
29	41.3
30	Did not complete the days