



## Trabajo Original

Nutrición artificial

### Adequacy of financing and prescription of home enteral nutrition. Are things being done right?

*Adecuación de la financiación y prescripción de la nutrición enteral domiciliaria. ¿Se están haciendo las cosas bien?*

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#### Abstract

**Introduction:** this study focuses on Home Enteral Nutrition (HEN), whose use has grown enormously in recent years.

**Objective:** to analyze the prescriptions and, in addition, determine whether National Health System (NHS) funding criteria are met and to explore whether overcosts exist.

**Methods:** a retrospective observational study was conducted on 844 patients (895 episodes) who received HEN, using information obtained from the healthcare database. Demographic, clinical, dietary, and economic data were analyzed.

**Results:** in 9.7 % of the episodes analyzed, the funding criteria were met; in 15.1 %,  $\geq 50$  % kcal/day required was provided through HEN. During the 3 months of the study an average of  $118.1 \pm 86.8$  units/patient were dispensed, which resulted in an average monthly expenditure of  $\text{€ } 69.9 \pm 66.3$ /patient. To go to the hospital to collect HEN, an average of  $78.1 \pm 69.5$  km/patient was traveled, with an associated average monthly fuel cost of  $\text{€ } 2.65 \pm 2.39$ /patient. The additional expenditure associated with prescriptions not aligned with the funding criteria was estimated at  $\text{€ } 574,259.44$ /year in the health area analyzed, with a quota of 200,000 inhabitants.

**Conclusions.** the results of this study show a divergence in the use of HEN compared to the conditions established by the NHS for the funding of this treatment. Given the low compliance rate and the current scientific evidence on the use of HEN, it may be necessary to re-evaluate the funding criteria to make them more representative of clinical evidence and actual practice.

#### Keywords:

Malnutrition. Enteral nutrition. Economics. Cost. Home care.

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## Resumen

**Introducción:** este estudio se centra en la nutrición enteral domiciliaria (NED), cuyo uso ha crecido enormemente en los últimos años.

**Objetivo:** analizar las prescripciones y determinar si se cumplen los criterios de financiación del Sistema Nacional de Salud (SNS) explorando la existencia de sobrecostes.

**Métodos:** se realizó un estudio observacional retrospectivo sobre 844 pacientes (895 episodios) que recibieron NED, utilizando información de la base de datos de asistencia sanitaria. Se analizaron datos demográficos, clínicos, dietéticos y económicos.

**Resultados:** en el 9,7 % de los episodios analizados se cumplieron los criterios de financiación; en el 15,1 % se proporcionó  $\geq 50$  % de las kcal/día requeridas a través de NED. Durante los 3 meses del estudio se dispensaron una media de  $118,1 \pm 86,8$  unidades/paciente, lo que supuso un gasto medio mensual de  $69,9 \pm 66,3$  €/paciente. Para acudir al hospital a recoger NED se recorrió una media de  $78,1 \pm 69,5$  km/paciente, con un gasto medio mensual asociado en combustible de  $2,65 \pm 2,39$  €/paciente. El coste adicional asociado con prescripciones no alineadas con los criterios de financiación se estimó en 574.259,44 €/año en el área sanitaria analizada, con un cupo de 200 000 habitantes.

**Conclusiones:** los resultados de este estudio muestran una divergencia en el uso de NED comparado con las condiciones establecidas por el SNS para la financiación de estos tratamientos. Dada la baja tasa de cumplimiento y la evidencia científica actual sobre el uso de HEN, puede ser necesario reevaluar los criterios de financiación para hacerlos más representativos de la evidencia clínica y la práctica real.

### Palabras clave:

Desnutrición. Nutrición enteral domiciliaria. Costo. Económico. Atención domiciliaria.

## INTRODUCTION

Enteral nutrition (EN) is a nutritional support technique using chemically defined formulas indicated for patients who cannot meet their nutritional needs with regular oral intake, but who have a functioning gastrointestinal tract capable of digesting and absorbing the formula introduced (1,2). EN is administered orally or through nasoenteral tubes or ostomies (3).

Home enteral nutrition (HEN) involves the administration of these formulas in the patient's home to prevent or correct malnutrition (4). It allows patients to remain in their environment, reducing the likelihood of complications associated with hospital stays, reducing healthcare costs, and increasing health-related quality of life (5). In addition, healthcare professionals must carry out home monitoring of the patient and the correct maintenance of the treatment to ensure nutritional efficacy and avoid possible complications (6). The treatment consists of selecting the enteral formula adapted to the pathology/clinical condition and the access route for each case (2,7,8).

In recent years, an increase in the prescription of HEN has been reported. For example, a study in Italy following 3246 patients over 11 years observed an average incidence of  $406 \pm 58$  patients per million inhabitants per year (9). In the United States, there was a significant increase in the estimated prevalence of patients with HEN rising from 597 per million inhabitants in 1992 to 1385 per million inhabitants in 2013 (10). Another study in France indicates a prevalence of 740 per million inhabitants (11), while in Spain, research carried out in 2015 reports a higher incidence rate of 2290 per million inhabitants per year (12). These figures not only indicate the increase but also the great variability in prescription between different countries.

One of the causes of this variability lies in the fact that funding conditions vary greatly between countries, as therefore do professionals' incentives to prescribe it. In most countries, EN is funded in the hospital setting. However, in community and outpatient settings, funding is lower, limiting coverage to specific diseases or conditions (in Japan, for example, only patients who are fed through nasoenteral tubes or ostomies are funded) or to specific subsets of patients (for example, in Belgium, HEN funding is restricted to patients discharged from hospital and, in Singapore,

to low-income patients). In Italy and China, HEN in outpatient patients is not funded, while, in other European countries, including France, Germany, Spain, and the Netherlands, HEN is funded in all 3 settings (hospital, community, and outpatient) (13).

For Spain, HEN is included and regulated in the portfolio of services of the National Health System (NHS) (14). In 15 of the 17 Spanish regions and in the autonomous cities of Ceuta and Melilla, HEN is purchased in pharmacies by the patient or a family member with an official medical prescription and visa from the pharmaceutical inspection. One of the exceptions is in the region of Galicia, where it is issued in hospital pharmacy services (14).

In 2008, the Spanish Ministry of Health published a guide that provides, based on the latest scientific evidence, clear guidelines for the prescription of HEN, the choice of the most suitable diet for each clinical situation, the controls and measures to be adopted in case of complications, the follow-up of the treatment, and the training that the patient and their caregivers must receive (15). Based on the guide, and according to Spanish legislation, patients' treatments must be funded. These funding criteria are set out in the descriptive guide to the provision of dietary products in the National Health System (16).

One of the most restrictive criteria for HEN funding in this guideline is the established calorie threshold, which justifies funding only in patients who do not meet 50% of their daily caloric requirements from ordinary food. However, current scientific evidence supports the use of HEN in certain patients even if their calorie intake from ordinary food is between 60 % and 75 % of their daily requirements (17).

With this background, the main objective of this study is to analyze the degree of compliance with the NHS funding criteria in HEN prescriptions, estimating their costs as well as the excess or defect of costs if inadequate public funding is revealed. Other objectives of this study are to determine the percentage of patients with HEN prescribed for pathologies eligible for treatment funded through the NHS, to determine the percentage of patients who receive at least 50 % of the necessary kcal/day through HEN, and to analyze the adequacy of the HEN prescribed to the patient's clinical situation and to the service responsible for the prescription.

## METHODS

### STUDY DESIGN AND SAMPLE

This is a retrospective observational study of HEN dispensed to patients who attended the outpatient pharmaceutical care consultation at a tertiary hospital over a three-month period (April 1-June 30, 2023).

The sample size was calculated to achieve a precision of 2.5 % in the estimation of a proportion using a 95 % bilateral asymptotic normal confidence interval. A compliance of 15 % was expected, and so it was necessary to include at least 783 patients. The 3-month period allowed us to meet this objective, and we thus selected the subjects from that period.

All the patients aged over 18 years that came to collect HEN formulas during the study period were included (see the formulas included in Supplementary Table I). Pediatric patients and patients that collected modules (protein module, lipid module, and thickening module) and complete diets indicated in the perioperative environment (Impact<sup>®</sup>, Optisource<sup>®</sup>) were excluded.

The data were extracted from the healthcare and management databases of the Complejo Hospitalario Universitario de Lugo (Spain) and were pseudonymized.

**Supplementary Table I.**  
HEN included in the study

<i>Standard HEN formulas:</i>
<ul style="list-style-type: none"> <li>• High calorie/high protein with fiber</li> <li>• High calorie/high protein without fiber</li> <li>• Hypercaloric/normoprotein with fiber</li> <li>• High calorie/normoprotein without fiber</li> <li>• Normocaloric/normoprotein with fiber</li> <li>• Normocaloric/normoprotein without fiber</li> </ul>
<i>Specific HEN formulas:</i>
<ul style="list-style-type: none"> <li>• Intestinal mucosal dysfunction<sup>a</sup></li> <li>• Dysphagia<sup>b</sup></li> <li>• High-calorie/high-protein diabetes <i>mellitus</i> with fiber<sup>c</sup></li> <li>• Normocaloric/high protein diabetes <i>mellitus</i> with fiber<sup>c</sup></li> <li>• Liver failure<sup>d</sup></li> <li>• Chronic kidney failure<sup>e</sup></li> <li>• Malabsorption syndrome<sup>f</sup></li> </ul>

<sup>a</sup>Normocaloric and normoprotein polymeric formula with 100 % soluble fibre; <sup>b</sup>hypercaloric and hyperproteic formula, moderately thick, with fibre; <sup>c</sup>hypercaloric and hyperproteic formula with fibre, formulated with slow absorption carbohydrates; <sup>d</sup>hypercaloric and normoproteic formula enriched in branched-chain amino acids; <sup>e</sup>hypercaloric formula with low protein content; <sup>f</sup>hypercaloric and hyperproteic oligomeric formula without fibre.

### STUDY VARIABLES

The sociodemographic variables of age (years), sex, and place of residence (municipalities in the province of Lugo) were ob-

tained from the database. As for the clinical variables, the indication for HEN (Yes/No), prescribing medical service, *exitus* in the first 90 days from the start of HEN (Yes/No) and death (Yes/No, referring to whether the patient was deceased at the time of data analysis) were extracted. Regarding the diet, the type of HEN prescribed (Standard/Specific; Supplementary Table I), volume and kcal prescribed, route of administration (oral/tubes or ostomies), and number of containers dispensed were obtained.

For the indication of HEN, we analyzed whether the patients met the diagnosis, that is, if they presented any of the pathologies eligible for HEN financed by the NHS. These may be a) patients with mechanical alterations of swallowing or transit, who have aphagia or severe dysphagia and require a tube; b) patients with neuromotor disorders that prevent swallowing or transit and require a tube; c) patients with special energy and/or nutrient requirements; d) patients in clinical situations involving severe malnutrition. For a more detailed description, see the supplementary table II.

Specific HEN prescription was considered appropriate for patients with any of the following clinical conditions: intestinal mucosal dysfunction, dysphagia, diabetes *mellitus*, liver failure, chronic renal failure and/or malabsorption syndrome.

To calculate caloric requirements, a table was created based on the average energy requirements (kcal/day) of the European Food Safety Authority (EFSA), included in the report by the Scientific Committee of the Spanish Agency for Food Safety and Nutrition (AESAN) on Nutritional Intake References for the Spanish population (Supplementary Table III). As for the activity factor (AF), which adjusts the necessary kcal/day based on physical activity performed, since we lacked this data in our patients, an AF of 1.4 was considered, which corresponds to the sedentary group (18).

The variable "meets funding" (Yes/No) was determined based on the HEN funding requirements included in the guide published by the Spanish Ministry of Health (16). As candidates to receive funded HEN, we considered patients who: a) present any of the following pathologies: patients with mechanical alterations of swallowing or transit, who have aphagia or severe dysphagia and require a tube, with neuromotor disorders that prevent swallowing or transit and require a tube, with special requirements of energy and/or nutrients and/or in clinical situations involving severe malnutrition (Supplementary Table II); and b) patients who receive at least 50 % of the necessary kcal/day through HEN (the guide indicates that it should only be financed in patients who, despite the implementation of dietary manipulations, do not reach this 50 %), defining this variable as "meets kcal objective" (Yes/No).

The number of containers dispensed in the study period was obtained by reviewing the records of the healthcare database. The cost per container was obtained from the management data of the Silicon<sup>®</sup> program. The total cost of HEN dispensed in the study period and the cost of HEN prescribed in patients who did not meet the funding criteria were calculated. It is worth mentioning that the selling prices to hospitals of the different types of HEN are negotiated directly with the distributor and can have average discounts of approximately 60 % compared to pharmacy selling prices.

To evaluate the cost associated with patients traveling to the hospital to collect their HEN, the number of dispensations per patient was obtained and the number of km separating their homes from the hospital was calculated (taking into account that for

each dispensation the patients had to make two trips, round trip). These were multiplied by the average price of fuel at the time of travel (€ 1.54/liter). To obtain the estimated expenditure, we took the average car fuel consumption of 7 liters/100 km.

**Supplementary Table II. Pathologies eligible for home enteral nutrition financed by the National Health System (Royal Decree 1030/2006, of September 15, which establishes the portfolio of common services of the National Health System and the procedure for its update)**

<p>1) Patients with mechanical swallowing or transit disorders, who present with severe aphagia or dysphagia and require a probe:</p> <ul style="list-style-type: none"> <li>• Head and neck tumors</li> <li>• Tumors of the digestive system (esophagus, stomach)</li> <li>• Otorhinolaryngology and maxillofacial surgery</li> <li>• Non-tumoral esophageal stenosis</li> </ul> <p>Exceptionally, in cases of severe dysphagia and if the tube is contraindicated, enteral nutrition without a tube may be used, following a justifying report from the doctor responsible for the indication of the treatment.</p>
<p>2) Patients with neuromotor disorders that prevent swallowing or transit and require a feeding tube:</p> <ul style="list-style-type: none"> <li>• Neurological diseases that cause aphagia or severe dysphagia: <ul style="list-style-type: none"> <li>- Multiple sclerosis</li> <li>- Amyotrophic lateral sclerosis</li> <li>- Myastheniform syndromes</li> <li>- Guillain-Barré syndrome</li> <li>- Sequelae of infectious or traumatic diseases of the central nervous system</li> <li>- Severe mental retardation</li> <li>- Severe degenerative processes of the central nervous system</li> </ul> </li> <li>• Cerebrovascular accidents</li> <li>• Brain tumors</li> <li>• Cerebral palsy</li> <li>• Neurological coma</li> <li>• Severe intestinal motility disorders: Intestinal pseudo-obstruction, diabetic gastroparesis</li> </ul>
<p>3) Patients with special energy and/or nutrient requirements:</p> <ul style="list-style-type: none"> <li>- Severe malabsorption syndrome</li> <li>- Severe short bowel syndrome</li> <li>- Intractable diarrhea of autoimmune origin</li> <li>- Lymphoma</li> <li>- Postgastrectomy steatorrhea</li> <li>- Pancreatic carcinoma</li> <li>- Wide pancreatic resection</li> <li>- Mesenteric vascular insufficiency</li> <li>- Amyloidosis</li> <li>- Scleroderma</li> <li>- Eosinophilic enteritis</li> <li>• Neurological diseases that can be treated with ketogenic diets: <ul style="list-style-type: none"> <li>- Refractory epilepsy in children</li> <li>- Glucose transporter type I deficiency</li> <li>- Deficiency of the pyruvate-dehydrogenase complex</li> </ul> </li> <li>• Diagnosed allergy or intolerance to cow's milk proteins in infants, up to two years if there is nutritional compromise</li> <li>• Malnourished patients who are to undergo scheduled major surgery or transplants</li> <li>• Patients with chronic hepatic encephalopathy with intolerance to dietary proteins</li> <li>• Patients with X-linked adrenoleukodystrophy, neurologically asymptomatic</li> </ul>
<p>4) Clinical situations when patients present with severe malnutrition:</p> <ul style="list-style-type: none"> <li>• Inflammatory bowel disease: Ulcerative colitis and Crohn's disease</li> <li>• Cancer cachexia due to chronic enteritis caused by chemotherapy and/or radiotherapy treatment</li> <li>• Infectious medical pathology that involves severe malabsorption: AIDS</li> <li>• Cystic fibrosis</li> <li>• Low output enterocutaneous fistulas</li> <li>• Childhood kidney failure that compromises the patient's growth</li> </ul>

**Supplementary Table III.** Average energy requirements (kcal/day) of the European Food Safety Authority (EFSA) included in the report by the Scientific Committee of the Spanish Agency for Food Safety and Nutrition (AESAN) on Nutritional Reference Intakes for the Spanish population, taking into account an activity factor of 1.4 depending on age and sex and kcal below which we consider supplementation (< 50 % of daily caloric requirements)

Age	Average energy requirements (kcal/day) (AF = 1.4) Sedentary group		kcal considered as supplementation (< 50 % of daily requirements)	
	Male	Female	Male	Female
18-29	2,341	1,887	< 1,170	< 943
30-39	2,269	1,815	< 1,134	< 907
40-49	2,221	1,791	< 1,110	< 895
50-59	2,197	1,791	< 1,098	< 895
60-69	2,006	1,624	< 1,103	< 812
70-79	1,982	1,624	< 991	< 812
80-89	1,883	1,543	< 941	< 771
90-99	1,789	1,466	< 894	< 733
100-110	1,700	1,393	< 850	< 696

AF: activity factor.

**STATISTICAL ANALYSIS**

We conducted a descriptive analysis of the sociodemographic and clinical variables of the study population. Categorical variables were presented using absolute and relative frequencies. In the case of continuous variables, their fit to normality was studied and they were presented using means and standard deviations (SD) or medians and interquartile ranges (IQR), depending on the results. For our comparative analyses, the chi-square test was used for categorical variables, the Mann-Whitney test for comparisons of continuous variables over 2 variables with 2 categories or the Kruskal-Wallis test in case of more than 2 categories.

As for the costs, the average costs per patient of HEN and car fuel consumption were calculated. The total actual costs were obtained by adding both items (HEN and fuel) for all patients. The expected costs were obtained by adding both items for all the patients, according to the following groups: 1) those who met the kcal objective; 2) those who met the diagnostic criterion, and 3) those who met the funding criteria. Finally, the overcosts and the percentage of overcost were obtained through the difference between the total costs and the expected ones as.

$$(C_{overcost} / C_{expected}) \times 100$$

The Ethics Committee for Drug Research of Galicia (CEIm-G) approved this study. Registration Code 2023/544. The data obtained were entered in a database in Microsoft Excel®, and used for subsequent statistical analysis with IBM SPSS® Statistics V29 software.

**RESULTS**

A total of 844 patients were analyzed, generating a total of 895 episodes, given that a small number of patients were given different prescriptions (HEN types and/or guidelines) during the study period, generating more than one episode. The average age of the patients was 79.6 ± 14.1 years (range 22-105). Of the total number of patients included, 409 were men (48.5 %) and 435 were women (51.5 %). Table I shows the main characteristics of the patients. The prescriptions of HEN were issued by 13 different medical services; in 90.6 % of the cases, however, they were concentrated in the endocrinology and geriatrics services.

**Table I.** Characteristics of patients (n = 855) and episodes with home enteral nutrition

	n	%
Sex		
Male	435	51.54
Female	409	48.46
Age*	79.6 (14.1)	
≤ 80 years	359	43.94
> 80 years	458	56.06
Episodes		
1	795	88.83
2	94	10.5
3	6	0.67
Total episodes	895	

\*Mean and standard deviation.

The 26.4 % of the patients had died at the time of data review, of which 63.2 % corresponded to exitus in the 90 days following the last dispensation of HEN. Regarding the funding criteria of the NHS, these were met in 9.7 % ( $n = 87$ ) of the episodes analyzed. Statistically significant differences were observed between the  $\leq 80$  years and  $> 80$  years groups, with a compliance with the funding criteria of 13.9 % and 6.3 %, respectively ( $p < 0.001$ ). In 13.6 % ( $n = 122$ ) of the episodes, the patients met the diagnosis. Analyzing this variable by age group, statistically significant differences were also observed between the  $\leq 80$  years group, with a compliance of 20 % and 13.5 % in those  $> 80$  years ( $p < 0.001$ ) (Table II). In 760 episodes (84.9 %), the HEN prescribed did not reach the kcal objective. These prescriptions generated 1040 dispensations. The median kcal provided in the form of HEN in these patients was 21.4 % (IQR = 18.1-33.5). In 135 episodes (15.1 %) in which this minimum kcal requirement was reached, the patients received a median of 68.5 % (IQR = 54.4-92.3) of kcal ( $p < 0.001$ ) (Table III).

The average kcal provided by the HEN in the prescriptions analyzed was  $563 \pm 366$  kcal, with a median of 420 kcal (IQR = 360). Analyzing separately, depending on whether the kcal objective was met, in the prescriptions where it was reached, the patients received an average of  $1223 \pm 446$  kcal/day, with a median of 1200 (IQR = 700). Meanwhile, the patients that did not reach the kcal objective received an average of  $446 \pm 178$  kcal, with a median of 330 (IQR = 300).

In the analysis by age group, in patients  $\leq 65$  years, the % of kcal provided by the HEN was 29.9 % of the necessary kcal/day, in patients between 65 and 80 years it was 24.2 %, and in those  $\geq 80$  years it was 22.5 % ( $p = 0.008$ ).

A total of 9.2 % of the patients were fed through nasogastric tubes or ostomies. Additionally, 99 % of the patients that did not reach the kcal objective with HEN were able to use the oral route to feed themselves.

The most common pattern in patients that did not reach the kcal objective was 1 container/day (58.7 %). On average, they received  $1.59 \pm 0.77$  containers/day.

**Table II. Relationship of prescriptions ( $n$  episodes) by age, sex and clinical service complying with the SNS funding conditions for HEN\***

	Episodes <i>n</i> (%)	Meets kcal target $\geq 50$ % kcal/día in HEN		Meets the diagnostic		Meets the funding conditions				
		<i>n</i> (%)	<i>p</i> -value	<i>n</i> (%)	<i>p</i> -value	<i>n</i> (%)	<i>p</i> -value			
<i>Sex</i>										
Males	437 (48.8)	54 (12.3)	0.025	60 (13.7)	0.933	43 (9.8)	0.906			
Females	458 (51.2)	81 (17.7)		62 (13.5)		44 (9.6)				
<i>Age</i>										
$\leq 80$ years	394 (44.0)	70 (17.7)	0.046	79 (20)	$< 0.001$	55 (13.9)	$< 0.001$			
$> 80$ years	501 (56.0)	65 (13)		43 (13.5)		32 (6.3)				
<i>Clinical service</i>										
Cardiology	1 (0.1)	0	$< 0.001$	0	$< 0.001$	0	$< 0.001$			
Surgery	3 (0.3)	0		0		0				
Digestive	10 (1.1)	0		5 (50)		0				
Endocrinology	377 (42.1)	90 (23.9)		86 (22.8)		65 (17.2)				
Geriatrics	434 (48.5)	39 (9)		28 (6.5)		20 (4.6)				
Home hospitalization	3 (0.3)	0		0		0				
Hematology	1 (0.1)	0		0		0				
Infectious diseases	2 (0.2)	0		0		0				
Internal medicine	36 (4.0)	5 (13.9)		2 (5.5)		2 (5.5)				
Nephrology	2 (0.2)	0		0		0				
Neurology	2 (0.2)	0		0		0				
Oncology	20 (2.2)	1 (5)		1 (5)		0				
Palliative care unit	4 (0.4)	0		0		0				
Total	895	135 (15.1)				122 (13.6)			87 (9.7)	

*HEN: home enteral nutrition; p-value calculated with the chi-square test. \*SNS funding conditions for HEN: patients who a) present any of the following pathologies: patients with mechanical alterations of swallowing or transit, who have aphagia or severe dysphagia and require a tube, with neuromotor disorders that prevent swallowing or transit and require a tube, with special requirements of energy and/or nutrients and/or in clinical situations involving severe malnutrition, and b) patients who receive at least 50 % of the necessary kcal/day through HEN.*

**Table III.** Distribution of patients with HEN prescription based on compliance with the target kcal and % of kcal provided in the form of HEN

	Do not meet target kcal	Meet target kcal	p-value
HEN contribution ≥ 50 % kcal/day <i>n</i> episodes (%)	760 (84.9)	135 (15.1)	< 0.001
% kcal provided in the form of HEN Median (IQR)	21.4 (18.1 to 33.5)	68.5 (54.4 to 92,3)	< 0.001

IQR: interquartile ranges; p-value calculated with the Mann-Whitney test. HEN: home enteral nutrition.

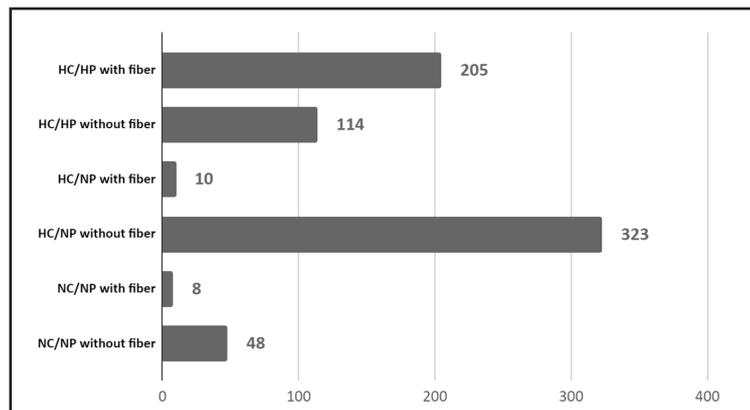
As for the type of HEN dispensed, in 708 episodes (79.1 %), standard formulas were prescribed, compared to 187 in which specific formulas were prescribed (20.9 %). Figure 1 shows the distribution of prescriptions by type of standard HEN prescribed. Of the 187 prescriptions of specific HEN (20.9 %), this was completely consistent with the clinical situation of the patient in 134 (72 %) (Fig. 2).

A total of 99,650 units of HEN were dispensed, with an average of 118.1 ± 86.8 units/patient. The average cost of the HEN dispensed per patient in the study period was € 209.8 ± 198.9 and the total cost, € 177,043.89, corresponding to 67.5 % (€ 119,507.71) of the amount of HEN prescribed without reaching the kcal objective. Meanwhile, the cost of the prescriptions in which the diagnosis was not met was € 129,642.78 (73.2 %). Finally, the cost of the prescriptions that did not meet the funding criteria (i.e., neither diagnosis nor kcal objective), was € 137,245.84 (77.5 %) (Table IV).

The average number of dispensations made per patient in the quarter of the study was 1.4, meaning, therefore, that an average of 2.8 trips per patient was necessary. Taking into account the patients' place of residence, a total of 65,908 km/quarter were traveled, with an average of 78.1 ± 69.5 km/patient.

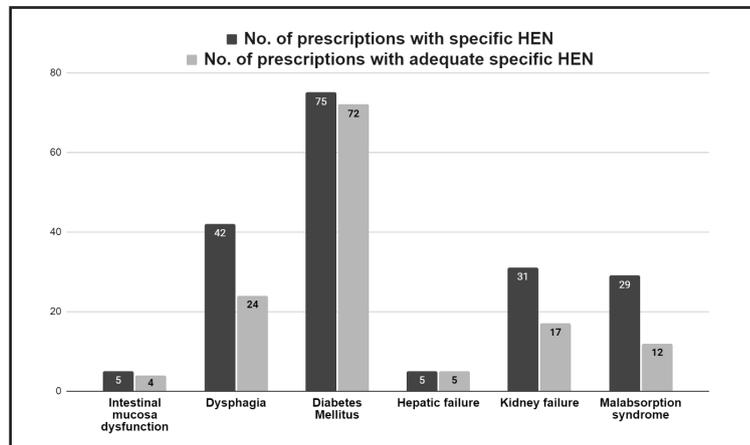
Based on the average fuel consumption of vehicles at that time, a total fuel cost of € 7,104.88/quarter (€ 7.94 ± 7.18/patient) was estimated. Of the total, € 6,319.02 corresponds to journeys that do not meet the funding criteria. Therefore, added to the costs of the dispensations that do not meet funding criteria, this represents an excess expenditure of € 143,564.86/quarter (Table IV).

Finally, and extrapolating our estimates to an annual level, the excess expenditure derived from the inappropriate prescription of HEN in cases not meeting the funding criteria is € 574,259.44/year in the health area analyzed, which attends to around 200,000 people. This represents an overcost of 353.7 %.



**Figure 1.**

Number of prescriptions depending on the type of standard HEN prescribed (HC: hypercaloric; HP: hyperproteic; NC: normocaloric; NP: normoproteic). The total number of standard HEN prescriptions in the study period was 708.



**Figure 2.**

Number of pathology-specific HEN prescriptions (dark grey) and their relationship to prescriptions completely adequate to the clinical situation of the patients (grey) (HEN: home enteral nutrition). The total number of specific HEN prescriptions in the study period was 187.

**Table IV.** Overcost, expected costs and percentage of overfinancing in response to compliance with the calorie target, diagnosis, and funding criteria

	HEN	Fuel	Total
Total actual costs (€)	177,043.00	7,104.88	184,147.88
<i>Overcosts* (€)</i>			
kcal target	119,507.71	5,949.48	125,457.19
Diagnosis	129,642.78	5,952.93	135,595.71
Funding criteria	137,000.00	6,319.02	143,319.02
<i>Expected costs† (€)</i>			
kcal target	57,535.29	1,155.40	58,690.69
Diagnosis	47,400.22	1,151.95	48,552.17
Funding criteria	40,043.00	785.86	40,828.86
<i>Overcosts / Expected costs x 100</i>			
kcal target	207.70	514.90	213.80
Diagnosis	273.50	516.80	279.30
Funding criteria	342.10	804.10	351.00

\*Costs of episodes in which the kcal or diagnostic objective or the funding criteria are not met. †Costs of episodes in which the kcal or diagnostic target or funding criteria are met. HEN: home enteral nutrition.

## DISCUSSION

The results show that only 9.7 % of patients meet the NHS funding criteria considering the pathology they present and the kcal provided by the HEN. This percentage increases slightly to 13.6 % and 15 %, respectively, if we analyze these two conditions separately. These results indicate a mismatch between the conditions of use of a resource and those funded by the NHS, with an associated health expenditure of € 574,259.44/year for a health area of approximately 200,000 patients (€ 2.87/inhabitant and year).

Various studies carried out in recent years have linked malnutrition to an increase in patient morbidity and mortality (15,19). Due to the high prevalence of malnutrition and the significant advances in the field of nutrition in recent years, the worldwide use of HEN has grown enormously (9-12).

In our study, a notable characteristic of the sample was the elevated age of the population. The median age was 83 years (IQR = 72-90), higher than that in other studies carried out in Spain, where the median was 71 years (IQR = 57-82) (20). This contrasts with the data from a study conducted in China to determine the epidemiology of HEN, in which the median age of the patients was 59 years (IQR = 46-72) (21). The older age in our sample may be attributed to the high percentage of elderly population in the province under study, as well as the possibility that the use of HEN is due to the ageing process itself, perhaps reflecting a misuse of this treatment.

During the study period, 20,405 units of specific HEN were dispensed, 4,257 (20 %) were used in patients who, due to their clinical characteristics, should have used a standard formula. In a

study carried out by Ferrer et al. in the Spanish region of Murcia, a reduction in the use of specific formulas of 55 % was observed after the implementation of a program to improve compliance with the NHS rules on the use of HEN (22). Both results show an overuse of these types of formulas. It is important to emphasize that specific formulas tend to have a significantly higher cost compared to standard formulas, which implies that their inappropriate use contributes to unnecessary expenditure in the health-care system.

In the total of prescriptions analyzed, the median kcal provided by the HEN was 420 (IQR = 360) kcal/day, 1200 (IQR = 700) kcal/day in the patients that reached the kcal objective through HEN and, for the 84.9 % of patients that did not reach that objective, 330 (IQR = 300) kcal/day. These contributions are substantially lower than those obtained by Villar Taibo et al. in a study carried out in the city of Santiago de Compostela (region of Galicia, Spain). In this case, the caloric intake was distributed in two groups, intake of more than 1000 kcal/day (38.8 % of the patients) and less than 1000 kcal/day (61.2 % of the patients). The results show that, in the first group of patients, the median kcal/day provided by the HEN was 1500 (IQR = 1560) kcal while in the second group, it was 600 (IQR = 827) kcal (12). It is important to consider that the differences in caloric intake observed between our study and that of Villar Taibo et al. could be due to several factors. Firstly, there may be differences in the demographic and clinical characteristics of the populations studied, such as age, baseline nutritional status or comorbidities, which may influence caloric requirements. In addition, there may be differences in HEN prescription protocols between hospitals.

As for the route of administration, 90.8 % of the patients were fed orally and 9.2 %, through enteral tubes or ostomies. These results are consistent with those reported by Storck et al. in a study carried out in Switzerland, where 87.1 % received HEN orally and 12.9 % through nasoenteral tubes or ostomies (23). It is important to consider that the percentage of patients who met calorie targets (9.7 %) is comparable to the percentage of patients who received enteral feeding (9.2 %). This may be due to the fact that patients who are exclusively tube or ostomy fed are completely dependent on HEN formulas to meet their calorie requirements.

The average cost of the HEN dispensed per patient in the study period, considering only the price of the formulas, was € 209.8 ± 198.9 and the average monthly cost, € 69.9 ± 66.3/patient. In the study conducted by Villar Taibo et al., a total monthly cost of approximately € 266/patient was obtained, but in this case, the costs of the necessary materials for administration were also included, and so their obtaining a higher cost is logical (12).

In our study, only 13.6 % of the prescriptions were associated with pathologies eligible for funded HEN. In the study by Ferrer et al., this percentage was 44 %, and, after implementing the program for compliance with the NHS rules, this percentage increased to 98.5 % ( $p < 0.001$ ). The implementation of a similar program in our population might save costs.

Regarding the expenditure for patients, it is essential to take into account the considerable cost associated with traveling from the different municipalities to the hospital to collect HEN in the autonomous community under study, unlike most communities where patients collect it in pharmacy offices in the cities or towns where they live. In addition, the health area analyzed covers an extensive geographical region, which involves patients traveling longer distances compared to other health areas.

As regards the limitations of our study, the first lies its design. To obtain more consistent data, a multi-hospital study should be carried out. Another is that we based the calculation of caloric requirements on the average requirements of the EFSA, which estimates the energy expenditure considering age, sex, and AF. Since we did not have our patients' AF, we considered the recommendations for the sedentary group, which may have underestimated the number of patients that did not reach the kcal objective. Another important limitation of this study is the use of an average calculation of daily calorie requirements based on the age and sex of the patients, without taking into account the body weight of each patient. In clinical practice, the calculation of kcal to be provided by the HEN is based on the weight of the patient. In addition, for patients over 80 years of age, as they are not included in the recommendations of the AESAN, the requirements were estimated considering that the energy needs in this group of patients decrease by about 5 % per decade (24).

Furthermore, it would be interesting to calculate the total cost associated with the administration of HEN, since our study only includes the cost of the formulas. The cost of equipment, indirect costs, and costs of the professionals involved in dispensing are

not included. Regarding the cost associated with travel to the hospital, this was approximate, since the municipality of origin of the patients was taken into account instead of their specific address. The overcost involved in the prescriptions of specific HEN not adapted to the clinical situation of the patient was also not taken into account, since we did not individually assess whether or not they met the funding criteria for standard HEN, and if so, which would be appropriate.

Finally, our study did not assess patients' satisfaction with the way the HEN are dispensed. It is likely that their perspective would improve if we could bring the HEN closer to their homes. One possible option in our autonomous community, where the NED is dispensed from hospital pharmacy services, could be the implementation of a telepharmacy system and home delivery of the HEN.

## CONCLUSION

Due to the advances in the field of nutrition and the importance of managing patients at home, the use of HEN has grown exponentially in recent years. The results of this study show a divergence in the use of HEN compared to the conditions established by the NHS for the funding of this treatment. One of these conditions is the caloric threshold, which justifies the funding of HEN only in patients who do not reach 50 % of their daily caloric requirements from ordinary food. However, current scientific evidence supports the use of HEN in certain patients even when their caloric intake from ordinary food is between 60 % and 75 % of their daily requirement. Although our study focused exclusively on assessing compliance with the funding criteria, it is important to note that the evidence suggests that these may be too restrictive. Given the low compliance rates observed and the current scientific evidence, it may be necessary to re-evaluate the funding criteria to make them more representative of clinical evidence and actual practice.

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