

Original

# The burden of hospital malnutrition in Spain: methods and development of the PREDyCES® study

M. Planas Vila<sup>1</sup>, J. Álvarez Hernández<sup>2</sup>, A. García de Lorenzo<sup>3</sup>, S. Celaya Pérez<sup>4</sup>, M. León Sanz<sup>5</sup>, P. García-Lorda<sup>6</sup> and M. Brosa<sup>7</sup>

<sup>1</sup>Escola de Ciències de la Salut. Universitat de Vic. Barcelona. <sup>2</sup>Hospital Universitario Príncipe de Asturias. <sup>3</sup>Hospital Universitario La Paz. Madrid. <sup>4</sup>Hospital Clínico Universitario Lozano Blesa. Zaragoza. <sup>5</sup>Hospital Universitario 12 de Octubre. Madrid. <sup>6</sup>Departamento Médico. Nestlé Healthcare Nutrition, S. A. Iberia. <sup>7</sup>Oblikue Consulting. Authors 1 to 6 constituted the PREDyCES® Scientific Committee.

## Abstract

It is well known that hospital malnutrition is a highly prevalent condition associated to increase morbidity and mortality as well as related health-care costs. Although previous studies have already measured the prevalence and/or costs of hospital nutrition in our country, their local focus (at regional or even hospital level) make that the true prevalence and economic impact of hospital malnutrition for the National Health System remain unknown in Spain. The PREDyCES® (Prevalence of hospital malnutrition and associated costs in Spain) study was aimed to assess the prevalence of hospital malnutrition in Spain and to estimate related costs. Some aspects made this study unique: a) It was the first study in a representative sample of hospitals of Spain; b) different measures to assess hospital malnutrition (NRS2002, MNA as well as anthropometric and biochemical markers) were used both at admission and discharge and, c) the economic consequences of malnutrition were estimated using the perspective of the Spanish National Health System.

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Key words: *Malnutrition. Prevalence. Cost of illness. Health-care costs. Method studies.*

## Introduction

Malnutrition is a clinical situation caused by an insufficient nutrient intake increased requirements or

## EL COSTE DE LA DESNUTRICIÓN HOSPITALARIA EN ESPAÑA: MÉTODO Y DESARROLLO DEL ESTUDIO PREDyCES®

### Resumen

Es bien sabido que la desnutrición hospitalaria es un proceso altamente prevalente asociado al aumento de la morbilidad y mortalidad, así como a elevados costes sanitarios. Aunque estudios previos han medido la prevalencia y/o los costes de la nutrición hospitalaria en nuestro país, su enfoque local (regional o incluso a nivel hospitalario) hacen que la verdadera prevalencia e impacto económico de la desnutrición hospitalaria para el Sistema Nacional de Salud sean aún desconocidos en España. El objetivo del estudio PREDyCES® (Prevalencia de la Desnutrición hospitalaria y los Costes asociados en España) fue evaluar la prevalencia de la desnutrición hospitalaria en España y estimar sus costes asociados. Algunos aspectos de este estudio lo hicieron singular: a) Fue el primer estudio de este tipo con una muestra representativa de los hospitales de España, b) se utilizaron diferentes medidas para evaluar la desnutrición hospitalaria (NRS 2002, MNA, así como marcadores antropométricos y bioquímicos) tanto en el momento del ingreso como al alta hospitalaria y, c) se estimaron las consecuencias económicas de la desnutrición desde la perspectiva del Sistema Nacional de Salud español.

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loses. In developed countries, malnutrition is usually due to alterations in the population's eating habits or the presence of disease, with an especially significant impact on hospitalized subjects. The causes of hospital malnutrition are multiple, among them: disease itself anorexia, digestive symptoms, therapeutic procedures, drug treatments and in many cases a lack of knowledge and interest of hospital staff regarding the nutritional status of hospitalized patients.<sup>1</sup> Prior studies have reported that approximately up to 75% of hospitalized patients whose biochemical nutritional markers were normal on admission presented a decrease in one or

**Correspondence:** Merce Planas Vila.  
Avenida Mare de Deu de Montserrat, número 10, 6 piso, puerta 3.  
08024 Barcelona (Spain).  
E-mail: mplanas.vila@gmail.com

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more of such markers, indicating the development of malnutrition during their hospital stay.<sup>2-5</sup>

Hospital malnutrition is associated with delays in recovering from illness, increased morbimortality, and increased in-hospital length as well as related healthcare costs.<sup>3-5</sup>

Early nutritional assessment would allow malnutrition to be diagnosed as well as to identify patients needing nutritional therapy.<sup>6</sup> No ideal nutritional marker exists, but a combination of several single parameters including anthropometric parameters<sup>7</sup>, biochemical data,<sup>8,9</sup> immunological parameters, functional tests and prognostic scores are available for screening, diagnosis and therapeutic evaluation.<sup>10-13</sup> Nevertheless prior studies have reported hospital staff paying low attention to inpatients nutritional status screening, therefore making hospital malnutrition prevention an unreachable goal.<sup>14</sup> However, an early nutritional intervention has significant benefits in undernourished patients.<sup>15</sup>

Worldwide reports on malnutrition prevalence are high.<sup>16,17</sup> In Spain, several studies have shown that the prevalence of malnutrition in hospitalized patients ranges between 30% and 50%,<sup>4,18-20</sup> increasing as the hospital stay lengthens. However, these studies generally refer to single institutions and the true extent of the problem in our country remains unknown, both from a healthcare (prevalence) and an economic (costs) perspective.

In short, hospital malnutrition involves both a lengthening of hospital stays and an increase in associated costs.<sup>4,5,20</sup> The PREDyCES (PREvalencia de la Desnutrición hospitalaria y Costes asociados en España; Prevalence of hospital malnutrition and associated costs in Spain) study objective is to quantify the prevalence of hospital malnutrition and its associated costs in a nationwide project to increase the knowledge about this condition in our milieu, expecting further knowledge would help to institute measures that ensure early detection and timely treatment of these patients within regular clinical practice.

## Study objectives

The main objective of this study is twofold: to determine and analyze the prevalence of hospital malnutrition in Spain and to estimate related costs. Secondary objectives are to estimate the prevalence of malnutrition according to hospital services, diagnosis, and the use and impact of nutritional interventions on hospital malnutrition costs in Spanish hospitals.

## Study characteristics

### Study design

The study is a cross-sectional, observational, multi-centre study under clinical practice conditions, which will assess the prevalence of hospital malnutrition at both patient admission and discharge. Patients included

went through an anthropometric and biochemical assessment as well as specific malnutrition screening tools using both NRS-2002<sup>13</sup> and MNA screening tests,<sup>10</sup> within the first 48 hours after admission and at discharge (or at 28 days after admission if hospitalisation duration was longer).

A study extension determined the incidence of complications associated with malnutrition, the excess hospital stay and healthcare costs associated with hospital malnutrition. This extension is based on a nested case and control design within a prospective cohort of patients (a subset of those included in the prevalence study described above). Cases identified consecutively within the cohort correspond to patients presenting malnutrition at hospital admission. Control group were patients without malnutrition either at admission or at any other time until discharge. Controls were individually paired according to main diagnosis, sex and age ( $\pm 10$  years). Use of resources related to nutritional intervention was recorded at discharge (or at 28 days from admission if discharge was later). Any incremental or additional cost resulting from the difference between cases and controls was considered to be attributable to hospital malnutrition.

Results of the cost study were extrapolated to the overall population with hospital malnutrition according to the prevalence study data, applying a bottom-up approach to estimate the healthcare cost of hospital malnutrition in Spain.

### Subjects

Patients were recruited in a consecutive manner during the first 48 hours after admission at different hospital services. Site-specific lists with the number of patients to be recruited at different services were provided, based on the number of discharges during the last year, in order to improve the representativeness of the sample at a hospital level and avoiding unbalanced situations regarding the casemix of recruited patients.

Table I depicts inclusion and exclusion criteria for the PREDyCES<sup>®</sup> study. All patients included in the study met all inclusion criteria and none of the exclusion criteria.

### Variables and measurements

Study variables were collected online using Data Case Report Forms (CRFs) specifically designed for this study. Three different CRFs were developed for admission, discharge and related costs in the extension subset. Variables recorded include:

- **Patient identification variables:** patient code, inclusion date, admission date, location inside hospital, reason for admission, socio-demographic variables (age, sex, educational background, employment status and type of residence).

**Table I**  
*Selection criteria*

*Inclusion criteria*

- Subjects aged 18 years or over.
- Inpatients admitted to hospital before 48 hours when the recruitment is performed.
- Before any study-specific data is collected, appropriate written informed consent (patient or proxy) was obtained.

*Exclusion criteria*

- Pregnant women.
- Subjects admitted in one of the following services: intensive care unit, obstetrics, dermatology, ophthalmology, short-stay unit, paediatrics, emergency unit, palliative care, burn unit, psychiatry and eating disorders unit.
- Patients unable to collaborate in the study (mental disorder, not willing to participate, difficulties to understand written language).
- Patients with an expected short length of stay (< 48 h).
- Patients with eating disorders (anorexia or bulimia)
- Patients admitted for a weight-loss procedure.

- **Anthropometric variables:** height, weight and body mass index (BMI).
- **Screening methods:** NRS-2002<sup>13</sup> and MNA.<sup>10</sup>
- **Clinical variables:** Patient basic pathology as per ICD-9 classification, concomitant diseases, biochemical parameters, digestive tract alterations, intake of toxic products, and physical activity and drug treatments.
- **Variables referring to the nutritional intervention and associated costs** (only in patients included in the cost study): drugs (antibiotics, iv fluids, albumin, vitamins, oligoelements, other drugs), oral supplements, enteral, peripheral parenteral and central parenteral nutrition, complications related to malnutrition occurring during hospitalization (infectious and non-infectious complications), emergency-room stay in days since admission, in-ward stay since admission, professionals involved during stay (visits/interconsultations) and complementary tests.

*Sample size*

The sample size for the main prevalence analysis was calculated based on the prevalence of hospital malnutrition in local studies carried out in different hospitals and regions in Spain. Although the actual prevalence is unknown, some regional studies have estimated hospital malnutrition to be present in 23% to 56%.<sup>18</sup> Based on this prevalence, assuming an accuracy of 2.75% and a significance level of 5%, a sample of 1,252 patients was required. With an estimated 25% drop-out and/or invalid CRF rate, the final sample calculated to be included in the study was 1,700 patients.

To estimate the resource use and associated costs, the sample size was based on data indicating that mal-

nutrition involves a 3-4 day increase in hospital stay.<sup>4,5,20</sup> With these data, a sample of approximately 350 patients (confidence level 95%, strength 90% and replacement 25%) was required.

In order to avoid biased results because of eventual differences of hospital malnutrition according to geographical areas and/or hospital size, 4 geographical areas (North, South, Center and Mediterranean region) and 3 groups of hospitals (less than 200 beds, 200-500 beds and > 500 beds) were identified to select sites included in the study. In Spain, 62% of hospital discharges correspond to only 25% of hospitals. Thus, about 1,000 patients were recruited in big hospitals (> 500 beds), 380 in medium-size hospitals (200-500 beds) and 320 patients were included in small hospitals (< 200 beds).

A subset of participating sites was randomly selected to carry out the costs study, following the same criteria to ensure representativeness.

*Statistical analysis*

A descriptive analysis of the socio-demographic and clinical characteristics of the study population was conducted.

Analysis consisted of a descriptive and inferential analysis for the entire sample of all variables included at various levels: benchmarking analysis and aggregate analysis. Benchmarking analysis compared individual hospital results with overall results. Aggregate analysis integrated all patients' data checking for structural variables that could be considered confusing factors (type of center, number of beds, etc.).

The prevalence of hospital malnutrition was calculated as the percentage of patients showing malnutrition at inclusion with respect to the total number of patients included (screened). An alternative measure calculated malnutrition prevalence as the percentage of patients showing malnutrition at inclusion and/or at discharge.

The NRS-2002 questionnaire and the MNA questionnaire were used to assess nutritional status. Information on NRS-2002 and MNA can be found elsewhere.<sup>13,16</sup>

Assessment of the frequency of use of nutritional interventions was calculated to be the percentage of inpatients with nutritional intervention respect to the total of undernourished patients at the time of inclusion in this study, and with respect to all patients included.

Prevalence rates were stratified according to sex, age group, hospital department, and the existence or not of a nutritional support unit at the hospital. Prevalence rates between strata were compared by means of the Chi-square test. Total cost and average cost per patient associated with hospital malnutrition was calculated based on the amount of healthcare resources that were used and attributed to malnutrition.<sup>21</sup> Cost variables between services and hospitals were compared by means of the Student's t test and variance analysis (ANOVA). Results were extrapolated to the overall

**Appendix I**  
*Participant sites*

<i>Centro Sanitario</i>	<i>Investigador</i>	<i>Monitor</i>
Complejo Hospitalario De Especialidades Torrecárdenas	Francisco Moreno Baró	José Luís Esteller Ortiz
Complejo Hospitalario De Cáceres	Fidel J. Enciso Izquierdo	María De Los Desemparados González-Quijano Díaz
Complejo Hospitalario Regional Carlos Haya	Gabriel Oliveira Fuster	Francisca Linares Parrado
Hospital Universitario Insular De Gran Canaria	Fátima La Roche Brier	María Araceli García Nuñez
Hospital Virgen Del Camino	Ana Zugasti Murillo	María Estrella Petrina Jáuregui
Complejo Hospitalario Universitario De Vigo - Hospital Meixoeiro	Mª José Martínez Vázquez	José Manuel Sierra Vaquero
Hospital Clínico Universitario Lozano Blesa	Julia Ocón Bretón	Laura Sallan Díaz
Complejo Hospitalario Universitario De Albacete	Francisco Botella Romero	Marta Milla Tobarra
Complejo Asistencial De León	María D. Ballesteros Pomar	Alicia Calleja Fernández
Hospital Universitario Ramón Y Cajal	Clotilde Vázquez Martínez	Borja Iglesias Rodríguez
Hospital Universitario 12 De Octubre	Miguel León Sanz	Isabel Higuera Pulgar
Hospital Universitario De Salamanca	Mª Victoria Calvo Hernández	Natalia Ramos Pérez
Hospital General La Mancha Centro	Álvaro García-Manzanares Vázquez De Agredos	Natalia Martínez Amorós
Hospital Universitario Son Dureta	Juan Ramón Urgelés Planella	Maria Teresa Colomar Ferrer
Hospital Universitari Vall D'hebron	Rosa Burgos Peláez	Miguel Giribés Veiga
Hospital Universitario Virgen De La Arrixaca	Mercedes Ferrer Gómez	Lydia Rivera Marco
Hospital Clínico Universitario Valencia	Alfonso Mesejo Arizmendi	Teresa Pedro Font
Hospital Marina Baixa (Vilajoiosa)	Máxima Mateo García	Marta López Peinado
Hospital Universitari Dr. Josep Trueta	Silvia Mauri Roca	Cristina Planella Farrugia
Hospital Provincial Santa Caterina. Parc Hospitalari Martí I Julià	Emilia De Puig De Cabrera	Magdala Perpinyà Gombau
Hospital De Manacor	Rosa Mª Gastaldo Simeón	Josefina Giménez Castellanos
Hospital Universitario Marqués De Valdecilla	Fco. Javier Ordóñez González	Fabiola Irene Cruz Tamayo
Hospital Del Henares	Raquel Mateo Lobo	Mª Victoria Sanz Lobo
Hospital Universitario Nuestra Señora De Valme	José Antonio Irlés Rocamora	Emilio Bernal López
Hospital Costa Del Sol	Vicente Fauf Felipe	Jimena Abilés
Hospital General D' Igualada	Gracia Enrich Pola	Judit Mayolas Corbella
Hospital Neurotraumatológico. Complejo Hospitalario De Jaén	Mª José Martínez Ramírez	M.ª J. Sánchez Liébana/Mercedes Fernández Quesada
Hospital San Agustín De Linares	Juan Bautista Molina Soria	Sonia Eva Sueza Espejo
Hospital San Juan De Alicante	Carmen Ballesta Sánchez	Ester Santoro Sánchez
Hospital Sierrallana	Coral Montalbán Carrasco	José Mª Castillo Oñ
Hospital Comarcal D'inca	José Moreiro Socias	Begoña Alonso Zulueta

population according to the malnutrition prevalence data obtained in this study using a bottom-up approach.

### Study organisation and planning

The board of the Spanish Society for Parenteral and Enteral Nutrition (SENPE) formed a Scientific Committee responsible for the design and supervision of the whole project. The Scientific Committee prepared the study protocol and CRF and supervised recruitment, and training of health professionals involved in data collection. This study was approved by La Paz University Hospital Ethics Committee, in Madrid.

### Participating hospitals

A random sample of 31 hospitals belonging to the National Health System were selected from the directory of hospitals of the Ministry of Health. Hospitals invited to participate that did not accept were replaced by another with similar characteristics as described above. Final participating sites with corresponding investigators and research assistants are shown in appendix 1.

### Study investigators and research assistants (RA)

Site investigators were medical doctors in all hospitals, working at the Clinical Nutrition Unit, (when available) and were responsible for recruitment and data collection procedures. For each site, RAs (mostly nurses end/or nutritionists) were recruited and trained, so that study procedures would be correctly undertaken. Two one-day workshops (Madrid and Barcelona) were carried out to train study research assistants in order to ensure that patients' selection criteria, anthropometric measurements and screening methods were performed under homogeneous criteria. Training was carried out by two members of the Scientific Committee (MP and JA) and the research assistants (RAs) coordinator.

### Field work: data collection and monitoring

As mentioned above Study Investigators were responsible for recruitment and data collection carried out by site-specific RAs, including patients' informed consent document. eCRF was published in a website with restricted access, and made available to all study

investigators and RAs using center-specific login data. The same website was used to provide the RA and study investigators with real-time data on patient's and study documentation.

A call center was set-up with two main purposes: first to help RAs with eCRF operation problems and minor technical questions regarding data collection that were directly solved by trained staff from a local CRO, whilst questions regarding data interpretation –anthropometric/nutrition or other clinical issues- were derived to the RA Coordinator; second was as well to help ensure that study procedures were followed by all participating sites.

### Final comment

The PREDyCES<sup>®</sup> study was an ambitious, nationwide project aimed to assess the prevalence and economic impact of hospital malnutrition in the Spanish National Health System. Some study characteristics make this project unique and challenging: a) It was the first study of these characteristics carried out in a representative sample of hospitals of Spain; b) although NRS2002 has been chosen as the gold standard to measure hospital malnutrition for the main study objective, additional screening methods (like MNA) and other nutrition indicators were used in all patients included; c) sampling methods and the national representativeness of the participating sites will provide valuable information on the economic consequences of hospital malnutrition at a national level, avoiding hospital-specific results that although very useful at a local level, may not give a reliable estimate of the global burden of the disease.

It is acknowledged that the Spanish National Health System, among others, lacks of relevant information for decision making and implementation of health programmes at different levels.<sup>22</sup> The results of the PREDyCES<sup>®</sup> study should provide with valuable information on the health and socio-economic magnitude of hospital malnutrition in Spain.

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