

**CLINICAL CLASSIFICATION OF ADULT PATIENTS WITH CHRONIC INTESTINAL FAILURE: AN INTERNATIONAL CROSS-SECTIONAL SURVEY TO COMPARE THE HOME PARENTERAL NUTRITION ACTIVITY AMONG COUNTRIES**

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**The Home Artificial Nutrition & Chronic Intestinal Failure special interest group of ESPEN**

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**Background**

ESPEN has recently devised the recommendation on “definition and classification of intestinal failure in adults”(attached). The document consisted on definition of IF, a functional and a pathophysiological classification for both acute and chronic IF and a clinical classification of chronic IF.

The clinical classification of CIF was intended as an instrument to facilitate communication and cooperation among professionals through an objective and easy-to-do categorization of patients.

The development of the “clinical classification” was derived from the common experience of the panel of experts, because no published data were available to be used as a starting point.

A consensus was reached for a classification based on the requirements for energy and the volume of the home parenteral nutrition (HPN) supplementation, calculated as “daily mean” of the total infused per week:

- Energy, kcal/Kg BW/day = (kcal per day of infusion x n. of infusions per week) / 7
- Volume, ml/day = ( ml per day of infusion x n. of infusions per week) / 7

IV energy supplementation <sup>b</sup> (kcal/kg Body Weight)	Volume of the IV supplementation <sup>a</sup> (ml)			
	≤1000 [1]	1001–2000 [2]	2001–3000 [3]	>3000 [4]
0 (A)	A1	A2	A3	A4
1–10 (B)	B1	B2	B3	B4
11–20 (C)	C1	C2	C3	C4
> 20 (D)	D1	D2	D3	D4

The HPN supplementation and management may differ according to the pathophysiological cause of CIF (short bowel, entero-cutaneous fistulae, dysmotility, mechanical obstruction, extensive mucosal disease) as well as the benign or malignant nature of the underlying disease. (Pironi L et al. AIF and HAN&CIF working groups of ESPEN. ESPEN endorsed recommendations: definition and classification of intestinal failure, Clin Nutr 2015. Published ahead of print)

Furthermore, a previous benchmarking study showed a wide range in HPN prevalence figures and consistent differences in provision of HPN across the countries. (Baxter J et al. HAN&CIF working group of ESPEN. Home parenteral nutrition: An international benchmarking exercise. eSPEN 2013)

**Aim**

**The aim of this international survey is to compare the HPN activity among Countries through the analysis of the ongoing patients according to the ESPEN clinical classification of CIF.**

## Material and Methods

**Type of study:** observational, cross sectional

**Patient inclusion criteria:** adults (> 18 years) currently on HPN for CIF, due to either benign or malignant (active cancer) disease.

**Data collection:** structured questionnaire (excel file, attached) ; see below for the requested data

## Data collection modality and schedule:

**March 1<sup>st</sup> 2015**, list of the ongoing patients on HPN (by the participating centers)

**March 1<sup>st</sup> – April 30<sup>th</sup>**, 2015 data collection (participating centers)

**May 15<sup>th</sup> 2015**, deadline to return the filled in excel file to [loris.pironi@unibo.it](mailto:loris.pironi@unibo.it)

## Authorship rules

**First Author:** the study proposer

**Second and last Authors:** the Coordinators of the Centers that will enroll the greatest and second greatest number of patients (who will be the second and the last one, to be agreed)

**Other co-Authors between the second and the last:** in order of the number of patients enrolled (from greatest to smallest)

## Data ownership

The data will be used only for the study purpose; for the data analysis the contributing centers will be anonymized.

## Expected results

Overall comparison of the clinical classification of patients with CIF due to different pathophysiological mechanisms and underlying disease nature

Comparison among Countries and within Countries of:

- the clinical classification of patients with CIF
- the modalities of providing the HPN programs

Evaluation of the potential usefulness of including the clinical classification of CIF in the ongoing ESPEN registry for CIF

Data to be collected in the excel questionnaire, as observed on March 1<sup>st</sup> 2015 (remember to fill in also the author and affiliation center section):

Data	Value or Acronym to be reported in the excel file
Patient-ID	According to the center practice
DATE of starting HPN	DD/MM/YYYY
Gender (M,F)	M, F
Age at time of filling in the questionnaire (yr)	Years
BW (Kg)	Kg
Height (cm)	cm
IF-Pathophysiological CLASSIFICATION ( <u>primary</u> mechanism; secondary mechanism if any): short-bowel without jejunostomy (SBS-J) short-bowel with jejunocolic anastomosis (SBS-JC) short-bowel with jejunioileal anastomosis with an intact colon (SBS-JIC) fistulas (F) dysmotility (Mot) mechanical obstruction (O) mucosal disease (MD)	SBS-J SBS-JC  SBS-JIC F Mot O MD
Underlying disease (that causes the IF)	benign disease: to be reported according to the <u>list in table 5</u> of the ESPEN recommendations active cancer: to be reported as the <u>primary site of the tumor</u>
Benign Disease (BD) or Active Cancer (AC)	BD AC
HPN program provider: - Local health care system Pharmacy - Home Care Company	LP HCC
Ongoing intravenous supplementation; as some patients may infuse more than one type of PN-admixture (ie. admixture without lipids for 3 days a week and admixture with lipids for 2 days a week; admixture with macronutrients for 4 days a week and fluid-electrolytes alone for 4 days a week), <u>more than one description are allowed</u> :  PN-admixture (1,2,3) : total Volume (ml) total Energy (glucose+lipids+aminoacids) kcal days of infusion per week (n)  type of admixture (see legend below): - premixed admixture alone (PA) - premixed admixture plus extra fluids and/or electrolytes (PAFE) - fluids-electrolytes alone (FE) - customized admixture alone(CA) - customized admixture plus extra fluids and/or electrolytes (CAFE)	          ml kcal n  PA PAFE FE CA CAFE

**Legend for the types of PN Admixtures:**

- **premixed admixture (PA)** = commercially available premade (premixed) parenteral nutrition admixture
- **premixed admixture plus extra fluids and/or electrolytes (CSFE)** = infusion of saline and/or other electrolyte solutions in addition to the premixed parenteral nutrition admixture
- **fluids-electrolytes alone (FE)**
- **customized admixture (CA)** = PN admixture compounded according to the single patient needs
- **customized admixture plus extra fluids and/or electrolytes (CAFE)** = infusion of saline and/or other electrolytes solutions in addition to the customized parenteral nutrition admixture