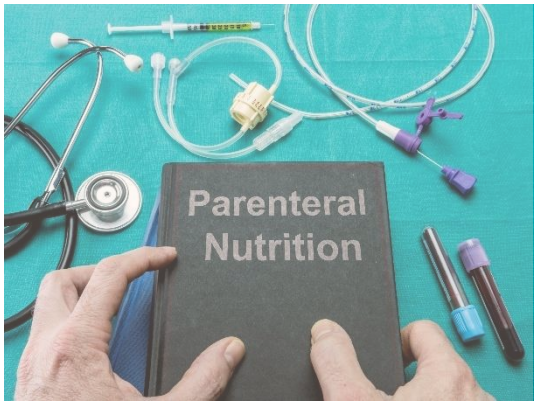
Medical Nutrition International Industry

Factors contributing to unequal access to home parenteral nutrition in Europe

A white paper







January 2023

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Factors contributing to unequal access to home parenteral nutrition in Europe: A white paper

Executive summary

Parenteral nutrition (PN) refers to the intravenous administration of nutrition for the prevention or treatment of malnutrition. It is used in patients who cannot eat by mouth or who do not absorb sufficient nourishment from formula administered via enteral tube.

Whereas normally PN is administered in hospital, in some circumstances it is possible – and indeed preferable – to administer PN outside the hospital, either at home or at a nursing home, i.e. as home parenteral nutrition (HPN).

Despite the proven benefits of HPN, the extent to which it is used across Europe varies markedly. Reasons for this include:

- **The absence of legislative frameworks to support the provision of HPN**
- **Inconsistent enforcement of legislation when such a framework does exist**
- **Mixed acceptance and implementation of HPN clinical guidelines**
- **A lack of reimbursement for the intervention**

In this white paper, with the goal of achieving equal patient access to HPN across Europe, the Medical Nutrition International Industry association (MNI) issues three crucial calls to action:

1. To achieve equitable patient access to HPN across Europe:
   - Common frameworks for supportive legislation need to be established
   - HPN clinical guidelines need to be more consistently implemented
   - Further reimbursement for HPN must be provided
   - The management, organisation, and delivery of HPN all need to improve

2. Greater efforts are needed to better educate and inform decision-makers of current evidence and expert opinion in treatment guidelines. Improving adherence with treatment guidelines will lead to improved access to HPN among those patients who need it. ESPEN guidelines provide evidence-based recommendations on the appropriate and safe use of HPN. Nonetheless, the degree to which these guidelines are used across Europe varies.

3. Action is needed by payers to address setting, indication, and regional reimbursement limitations to improve patient access to HPN.

1. Introduction

What is home parenteral nutrition?

Parenteral nutrition (PN) refers to the intravenous administration of nutrition for the prevention or treatment of malnutrition. It is used in patients who cannot eat by mouth or who do not absorb sufficient nourishment from formula administered via enteral tube.[1]

Whereas normally PN is administered in hospital, in some circumstances it is possible – and indeed preferable – to administer PN outside the hospital, either at home or at a nursing home, i.e. as home parenteral nutrition (HPN).

There are four clinical categories in which the European Society for Clinical Nutrition and Metabolism (ESPEN) recommends HPN is suitable for use: 1) in patients with chronic intestinal failure (CIF) due to benign disease, 2) in patients with CIF due to malignant disease, 3) as part of palliative care for incurable malignant disease to avoid death from malnutrition, and 4) to prevent or treat malnutrition in patients with a functioning intestine but who decline other types of medical nutrition.[1]

The benefits of HPN

When prescribed appropriately, HPN may be associated with substantial clinical, humanistic and economic benefits.

For patients with CIF due either to malignant or non-malignant disease, HPN is the primary life-saving therapy.[2-4] Before the availability of HPN, effective delivery of long-term PN was not possible and patients with CIF due to major intestinal resection, fistulas, or immature development of the gastrointestinal (GI) tract, died within a few months of diagnosis from malnutrition, dehydration, and/or electrolyte disturbances.[5] Advances in the preparation and administration of HPN over the past four decades, however, have led to dramatic improvements in survival for these patients – now measured in decades – and has enabled many to resume normal activities, including employment, within the constraints of their underlying disease.[6]

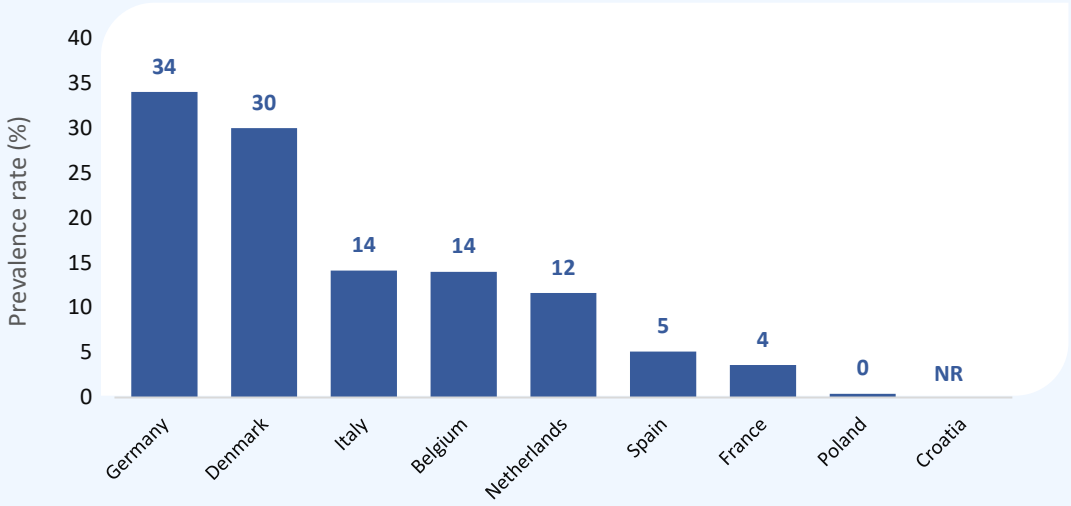
While on HPN, about two-thirds of adults are able to partly or fully recommence normal social and working activities.[7] Furthermore, large proportions of patients on HPN improve over time and are able to resume normal feeding, such as those with hyperemesis gravidarum (100%), Crohn's disease (70%), chronic pancreatitis (82%), and chronic adhesive obstruction (47%).[6, 8]

For patients with cancer otherwise at risk of death from malnutrition rather than disease progression, HPN provision is recommended and may be life-prolonging.[3, 8] Conversely, cancer-associated weight loss resulting from malnutrition impairs patients' ability to receive, tolerate, and respond to anticancer therapy and predicts poor clinical outcomes independently of other risk factors.[9-13] Studies suggest that malnourished patients have a 2–5-fold higher risk of dying than patients with little or no evidence of malnutrition.[14-16] In patients undergoing surgery for cancer, two multivariate analyses have shown that undernutrition is an independent risk factor for complications, as well as increased mortality, length of hospital stay, and healthcare costs.[17-19] Even minimal weight loss during chemotherapy and/or radiotherapy has been shown to be associated with significantly shorter survival.[20]

HPN also plays a key role in shortening the length of hospital stay for patients who are ready to be discharged medically but who still require intravenous nutrition – likely yielding considerable cost savings for healthcare systems.[21] An economic analysis in Canada, for instance, showed that HPN was significantly cost saving compared with hospital-based PN.[22] When direct medical costs were estimated for the 2 weeks before hospital discharge and for the first month after discharge home, HPN was estimated to realise monthly savings of $4,860 per patient compared with provision of PN in hospital, with even greater savings in elderly patients and those with underlying malignancy.[22]

Not only is HPN cost-saving at initiation, it becomes increasingly cost-effective with duration of use. A cost-utility analysis from the perspective of the UK

Figure 1. Prevalence rate (%) of HPN use (per million people) among patients with chronic intestinal failure or short bowel syndrome by selected European country



Abbreviations: HPN, home parenteral nutrition; IF, intestinal failure; NR, not reported. Source: ATLAS (IF treatment and care across Europe).[23]

National Health Service, demonstrated that HPN was 65% more cost-effective than hospital care in patients with intestinal failure.[24] The longer a patient survived, the more cost-effective HPN became. Weaning from HPN because of intestinal adaptation reduced costs per quality-adjusted life year even further.

The recent Covid-19 pandemic further highlighted the value of HPN. With HPN, patients with CIF could be discharged from hospital, freeing critical care and general hospital ward beds for use by patients with Covid infection. HPN provision during the pandemic was met with challenges, however. Initiating patients on HPN, and ongoing monitoring of existing HPN patients both required hospital visits and/or stays which were difficult to accommodate, particularly with HPN healthcare staff often having been redeployed to care for Covid-19 patients.

Home parenteral nutrition use varies greatly across Europe

Despite the proven benefits of HPN and the clear ESPEN guidelines on when it is appropriate to prescribe, the extent to which it is used across Europe varies markedly. A 2017 survey of 22 European countries, for instance, revealed that, while PN (and enteral nutrition) were available in all countries, access was mostly restricted to hospitalised patients. Patients in chronic care facilities or at home tended only to have access in countries with higher national incomes where enteral/parenteral nutrition was reimbursed.[25] Recent (2020) data published by ATLAS on the prevalence of HPN use across Europe serve to highlight the extent to which access to HPN varies by country. In Germany, for instance, the estimated prevalence of HPN use is 34/million people, whereas in Poland, it is just 0.4/million (Figure 1).[23]

Who is MNI and why this white paper?

The Medical Nutrition International Industry association (MNI) acts as the global voice of the medical nutrition industry. It represents the collective view, knowledge, and expertise of companies that provide solutions for nutritional therapy including oral nutrition supplements, enteral and parenteral nutrition formulas, as well as suppliers of ingredients and medical devices for nutritional care. The goal of the MNI is to achieve better care through better nutrition, across all ages and healthcare settings.[26]

The MNI recently sought an up-to-date understanding of the current landscape of HPN use across Europe, specifically among adult patients falling within one of the ESPEN-defined categories of patients suitable for HPN. A qualitative survey was therefore carried out between February and July of 2021. The survey comprised a total of 22 interviews

across nine European countries including Belgium, Croatia, Denmark, France, Germany, Italy, Netherlands, Poland, and Spain. Stakeholders of interest included clinicians, specialist nurses, or academic HPN experts. In each country, at least one payer or policy-maker was interviewed.

This white paper presents the key findings of the survey, outlining how the lack of common legislative frameworks, inconsistent implementation of clinical guidelines, and varying levels of reimbursement are undermining access to HPN among patients in Europe that would otherwise benefit from it.

In this white paper, some important calls to action are issued that MNI believes are crucial to achieving equitable access to HPN across Europe.

2. A legislative framework is an important basis for the provision of HPN – but availability and enforcement varies across countries

The existence and enforcement of national legislation varies by country

A key finding of the MNI survey was variation between the European countries of interest in terms of the existence (or not) of a formal legal framework underpinning the provision of HPN. Of the nine countries surveyed, only five (Belgium, Denmark, France, Italy, Poland) were found to have legislation in place. The remaining four countries, Croatia, Germany, Netherlands, and Spain, had no such legislation (Table 1).

Legislation, where it exists, covers such aspects of HPN provision as the organisation of care and infrastructure, which healthcare professionals can legally prescribe HPN, the expected standards of care for HPN patients, and reimbursement provision.

Table 1 highlights that, although legislation demanding nation-wide availability and access is established in some countries, the enforcement of these legislations varies, with interviewees estimating that between 0% and 39% of eligible patients do not receive HPN despite legislation being in place. By contrast, in Spain and Croatia where no legislative frameworks exist, interviewees felt that as many as 47% and 80%, respectively, of HPN-eligible patients were not receiving this life-saving therapy.

The availability and enforcement of legislative frameworks on HPN varies across countries. In Croatia, Germany, Netherlands, and Spain, national legislation and legal coverage for HPN use still do not exist. Even in countries where there is a legal framework, different levels of regulations restrict the use of HPN to certain hospitals, indications, or geographies.

It is interesting to note that Germany, despite having no specific legislative framework, still maintains very good access to HPN. Poland, on the other hand, does have legislation but access to HPN is limited by other factors such as the requirement that patients first spend 10–14 days in an HPN centre receiving extensive training before they can be discharged home – a bottleneck that has given rise to a waiting list to be initiated on HPN.

CALL TO ACTION: To achieve equitable patient access to HPN across Europe, common frameworks for supportive legislation need to be established, HPN clinical guidelines need to be more consistently implemented, further reimbursement for HPN must be provided, and the management, organisation, and delivery of HPN all need to improve.

Legislation should guarantee access to HPN for all eligible patients but with restrictions to specific indications, hospitals, or jurisdictions

While having legislation in place should guarantee access to HPN for all suitable patients, access to it is restricted on the basis of indications in which it can be prescribed, and/or the hospital centres in which HPN can be initiated and overseen.

Table 1. Overview of legislation (where it exists) for the provision of HPN by European country

	Belgium	Croatia	Denmark	France	Germany	Italy	Netherlands	Poland	Spain
Is there legislation supporting HPN use?	Y	N	Y	Y	N	Y	N	Y	N
If yes, at which level?	National	NA	National	National	NA	National and regional	NA	National	NA
Does legislation demand nation-wide availability & access?	Y	NA	Y	Y	NA	Y	NA	Y	NA
Limitations to access at regional/local levels?	N	Y	N	N	N	Y (Regional)	N	Y	Y
Restrictions/ regulations on/for HPN use?	Y	Y	N	Y	N	Y	Y	Y	Y
If yes, at which level?	Specific diagnoses	Hospital Specific diagnoses Region	NA	Hospital Specific diagnoses	NA	Region	Hospital	Hospital Specific diagnoses	Hospital Specific diagnoses
National/ international clinical guidelines adopted in the country?	ESPEN	ESPEN	National guidelines	National guidelines ESPEN	National guidelines ESPEN	ESPEN	ESPEN	National guidelines	ESPEN
*Estimated HPN-eligible patients who currently do not receive it**	0%	80%	14%	Possibly 20% benign	0%	39%	5%	27%	47%

Abbreviations: ESPEN, European Society for Clinical Nutrition and Metabolism; HPN, home parenteral nutrition; N, no; NA, not applicable; Y, yes.
* Based on interviewee responses.

Belgium, Croatia, France, Poland, and Spain all restrict the use of HPN to certain indications. In France, legislation requires that only patients with long-term or permanent gut insufficiency needing more than 3 months of HPN are to be referred to one of 20 licensed specialist HPN centres. Patients not meeting this criteria can still access HPN but only via non-specialist hospitals. In Belgium, legislation permits the use of HPN in defined groups of patients including those with/on 1) temporal or permanent intestinal insufficiency (radiology induced, pancreatitis, Crohn's disease or colitis, severe malabsorption, intestinal lymphomas, chronic pancreatitis, or peritoneal carcinomatosis with bowel obstruction), 2) fistulas or complications arising from any of the above conditions, 3) intradialytic PN. It was only in 2018 that a fourth group of patients was added to the list of permitted indications, that being any patients with a functional disorder of the intestine impacting on nutritional status and which cannot be corrected with enteral nutrition. Any hospital in Belgium may initiate HPN so long as they have an experienced nutrition team. In reality, however, this requirement is poorly enforced and sufficiently vague that any specialist in any hospital can prescribe HPN.

In Denmark, France, Italy, and Poland, national legislation requires that specialist HPN centres are available for the initiation (and ongoing supervision) of patients onto HPN. Specialists interviewed from countries in which there were specialist centres indicated that such centres helped to consolidate expertise, training, and exploration of best practice, and that typically these centres were where patients with longer term, or more complex needs, were managed.

Despite all countries included in the survey having adopted ESPEN and/or their own national guidelines for the provision of HPN, their acceptance, implementation, and enforcement vary by country and by indication.

In Denmark, there are four specialist HPN centres which are required by law to accept any suitable HPN patients into their care. Patients are initiated on HPN (and trained on its use) in hospital first and then referred to one of the four specialist centres for ongoing supervision.

In Poland, there must be at least two hospitals capable of delivering HPN care in each of the country's 16 regions, according to the National Health Insurance Fund 'Narodowy Fundusz Zdrowia' (NFZ). To be HPN-capable, the hospital must staff Polish Society of Parenteral Nutrition, Enteral Nutrition and Metabolism (POLSPEN)-certified clinicians and have bed space for HPN patients undergoing the mandatory 10–14 day induction training. According to the interviewees in Poland, however, only one region in Poland so far has two such centres with the remaining regions each having just one.

Figure 2. Categories of patients suitable for HPN according to ESPEN guidelines and examples of their underlying aetiologies

Category 1: Benign GI disease

- Crohn's disease
- Colitis
- Mesenteric ischaemia
- Pseudo-obstruction
- Malabsorption
- Traumatic short bowel
- Fistulas arising from above conditions
- Neurological conditions affecting gut function
- Acute intestinal failure following gut surgery

Category 2: CIF due to malignant disease

- Post bowel surgery
- Post radioactive colitis
- Preconditioning before surgery or chemotherapy
  Palliative care for end stage patients

Category 3: Palliative care

- Usually end stage oncology

Category 4: Treatment of malnutrition in patients with partially functional intestine (supplement feeding)

- Short bowel syndrome patients
- Chemotherapy patients
- Patients being weaned off PN back on EN after gut surgery

Abbreviations: CIF, chronic intestinal failure; ESPEN, European Society for Clinical Nutrition and Metabolism; GI, gastrointestinal; HPN, home parenteral nutrition; PN, parenteral nutrition.
Example aetiologies based on interviewee responses.

HPN provision in Italy is governed both by national legislation and regional legislation, reflective of the fact the country consists of a federation of semi-autonomous regions. National legislation requires regions provide at least one specialist human nutrition centre per 2 million people. These specialist centres are responsible for prescribing HPN then referring patients to their Local Health Care Unit (Azienda Sanitaria Locale) for ongoing supervision. Despite the legal requirement for even distribution of these centres, however, in reality, wealthier regions in the north have many such centres (Piedmont has 13) whereas poorer regions in the south have few to none. In regions lacking specialist centres, individual clinicians can still prescribe HPN to patients, but the patients miss out on the HPN expertise available in specialist nutrition centres. Regional legislation in Italy goes into more detail about local organisation of HPN care and which indications and patients are eligible for treatment.

3. The level of acceptance and implementation of clinical guidelines for the provision of HPN is mixed, varying both by country and by indication

ESPEN guidelines define four categories of patients suitable for HPN

In their latest (2020) guidance, ESPEN defines the four categories of patients for which HPN should be prescribed (example aetiologies are listed in Figure 2):[1]

- Patients with CIF due to non-malignant disease (Category 1).
- Patients with CIF due to malignant disease (Category 2).
- Patients with advanced cancer and CIF with a life expectancy longer than 1–3 months and who would otherwise suffer an earlier death from malnutrition (Category 3).
- Patients without intestinal failure but who are not able or do not want to meet their nutritional requirements via the oral/enteral route (Category 4).[1]

Table 2. Clinical guideline use for the provision of HPN by European country

	Belgium	Croatia	Denmark	France	Germany	Italy	Netherlands	Poland	Spain
Clinical guidelines adopted	ESPEN	ESPEN	National guidelines	National guidelines ESPEN	National guidelines ESPEN	ESPEN	ESPEN	National guidelines	ESPEN
Estimated HPN-eligible patients who currently do not receive it	0%	80%	14%	Possibly 20% benign	0%	39%	5%	27%	47%
Category 1: Benign GI disease	Y	Y (when possible)	Y	Y	Y	Y	Y	Y	Y
Category 2: CIF due to malignant disease	Y	Very rarely	Y (but less frequently)	Y	Y	Y	Y (but less frequently)	Y (but less frequently)	Y (but less frequently)
Patient split by indication receiving HPN (benign GI disease vs malignant):									
According to Pironi 2019[27]	100% vs 0%	100% vs 0%	88.9% vs 11.1%	92.3% vs 7.7%	10% vs 90%	90.1% vs 9.9%	89.1% vs 10.9%	79.2% vs 20.8%	93.0% vs 7.0%
According to interviewees	Unclear. Mostly short term use*	90% vs 10%	60–70% vs 30–40%	20–25% vs 75–80%	10–20% vs 80–90%	39% vs 60.3% (based on published data**)	85% vs 15%	65% vs 35%	38.3% vs 40.5% + 21.2% other (unspecified)
Category 3: Palliative care (life expectancy in months)	Y (>1m)	N	Y (>3m)	Y (>1m)	Y (>1m)	Y	Y (>1m)	Y (>3m)	Y (>6m)
Category 4: Treatment of malnutrition in patients with partially functional intestine	Y	N	At specialist's discretion	Y	Y	Unclear	At specialist's discretion	No (NFZ won't allow)	At specialist's discretion

Abbreviations: CIF, chronic intestinal failure; ESPEN, European Society for Clinical Nutrition and Metabolism; GI, gastrointestinal; HPN, home parenteral nutrition; M, month; N, no; NFZ, Narodowy Fundusz Zdrowia; Y. yes.
* Belgian legislation permits use of HPN in the following: Temporal or permanent intestinal insufficiency (radiology induced pancreatitis, Crohn's disease or colitis, severe malabsorption, intestinal lymphomas, chronic pancreatitis, or peritoneal carcinomatosis with bowel obstruction); fistulas or complications arising from any of the above; intradialytic TPN; any functional disorder of the intestine with impact on nutritional status that cannot be corrected with enteral nutrition.
** Pironi et al 2017.[21]

Clinical guidelines are important because they provide evidence-based recommendations on the appropriate and safe use of HPN informing physicians, nurses, dieticians, pharmacists, caregivers, and other HPN providers, as well as healthcare administrators and policy-makers.

Most – but not all – countries surveyed adopt ESPEN guidance

In the nine European countries surveyed, seven reported adopting ESPEN guidelines as the basis for their provision of HPN, using them either alone (Belgium, Italy, Netherlands, Spain, Croatia) or in conjunction with national guidelines (France, Germany). Two countries, Denmark and Poland, used only their own national guidelines for HPN (Table 2).

Irrespective of whether ESPEN and/or national guidelines are used, in all nine countries, patients matching the description of Category 1 of the ESPEN guidelines (CIF due to non-malignant disease) are able to access HPN.

Patients in ESPEN Category 2 (CIF due to malignant disease) are recommended for HPN only in Belgium, France, Germany, and Italy, and to lesser extents in Denmark, the Netherlands, Poland, and Spain.

HPN provision for CIF due to benign GI failure is included in all countries, but, for CIF due to malignant disease, is only included in France, Germany, and Italy, while less frequently in Belgium, Denmark, Netherlands, Poland, Spain, and very rarely in Croatia.

Only very rarely are patients with CIF due to malignant disease offered HPN in Croatia mainly because they are prone to complications for which there is insufficient funding to manage (Table 2).

ESPEN guidelines recommend the provision of HPN for patients with advanced cancer and CIF with a life expectancy longer than 1–3 months and who would otherwise suffer an earlier death from malnutrition (Category 3). Despite this, interviewees stated that, in Denmark and Poland, HPN is provided only to patients with a life expectancy longer than 3 months, and in Spain, to those with a life expectancy longer than 6 months (Table 2).

In Denmark, an interviewee remarked that caution is exercised before prescribing HPN to palliative care cancer patients because of the increased risk of complications in these patients and that the preference was to reserve it for patients with a life expectancy longer than 3 months. Nonetheless, they said that Denmark was a liberal society and clinicians could apply their own judgement in this regard.

In Poland, the month-long waiting list for a bed to become available in an HPN centre in order that the mandatory induction training can be given means that, inevitably, patients with a short life expectancy (less than 3 months) die before HPN can be given. By default, therefore, the situation in Poland is that Category 3 patients typically have a life expectancy longer than 3 months when receiving HPN.

ESPEN guidelines recommend that for Category 3 patients, HPN be given only when life expectancy is longer than 1–3 months. Although some countries prescribe from the 1 month minimum, others reserve it for patients with longer life expectancies.

In Spain, the oncologist interviewed stated that the reserving of HPN in oncology for just those patients with a life expectancy greater than 6 months was based on their interpretation of the data regarding HPN complication rates in patients with end-stage disease. Patients with CIF and a life expectancy less than 6 months are typically referred to hospice care.

Only France and Belgium provide HPN to ESPEN Category 4 patients.

In Croatia, HPN is not provided at all to Category 3 patients. This is for the same reason it is withheld from Category 2 patients with malignant disease – cancer patients are prone to complications with HPN and there is insufficient funding to manage them.

HPN, for the treatment of malnutrition in patients with a partially functional intestine and who are not able or do not want to meet their nutritional requirements via oral or enteral routes (Category 4), is available only in France and Belgium.

CALL TO ACTION: Greater efforts are needed to better educate and inform decision-makers of current evidence and expert opinion in treatment guidelines. Improving adherence with treatment guidelines will lead to improved access to HPN among those patients who need it. ESPEN guidelines provide evidence-based recommendations on the appropriate and safe use of HPN. Nonetheless, the degree to which these guidelines are used across Europe varies.

4. While the majority of European countries surveyed reimburse HPN, not all costs are covered

In some instances, patients pay out of pocket costs for consumables

Of the nine European countries included in the MNI survey, most provide full reimbursement for HPN and all associated costs via national health insurance funds (or similar) with or without top-ups from hospital budgets. The exceptions to this were:

- Poland: Specialist HPN centres are deliberately under-funded to limit the number of patients that can access HPN. Excess costs come from hospital budgets but may be reclaimed at the end of each year. Resources, e.g. infusion pumps are also limited, restricting the number of patients that can receive HPN. Only flat tariffs for nutrition

bags are provided, regardless of their cost, and wasted bags are not refunded.
- Belgium: Patients contribute 62 cents per day and also pay for their pump and drip stand.
- Germany: Patients contribute €5–10 of the cost per pack in the pharmacy up to a maximum of 1% of their income, after which their care is free.
- Spain: Some patients have to pay for magnesium, loperamide, some disposables, and certain infusion systems.
- Croatia: Patients pay for some disposables, including gauzes, syringes, disinfectants, sterile gloves and facemasks, chlorohexidine, or antimotility drugs.

Reimbursement of HPN does not necessarily mean all costs are covered. Furthermore, reimbursement is sometimes limited by setting, indication, or region.

Reimbursement limitations

The survey highlighted instances in which reimbursement for HPN is limited, usually on the basis of treatment setting, indication, and country region.

Setting: In France, while patients pay nothing for HPN, reimbursement rarely covers the full cost of HPN from the prescribing hospital's perspective, meaning that hospital budgets must make up the deficit. As a result, HPN is frequently unpopular with hospital administrators.

In the Netherlands, HPN reimbursement, provided by health insurance companies, is limited only to hospitals that have specific contracts in place with the insurers to provide HPN care.

Indication: Examples of HPN reimbursement being restricted in certain clinical categories/indications were observed in Belgium, Croatia, Poland, and Spain.

In Belgium and in Croatia, funding restrictions deter the use of HPN in patients with CIF and malignant disease. Whereas a 2009 Royal Decree in Belgium released additional funding to support HPN in patients with CIF with non-malignant disease, no such funding or specific decree is extended to those with malignant CIF. In Croatia, as mentioned previously, funds do not cover the costs of managing HPN complications that typically arise much more frequently in malignant (as opposed to non-malignant) CIF patients. As a result, in Croatia, HPN is rarely provided to these patients.

In Spain, interviewees stated that reimbursement for HPN may be refused for patients with a life expectancy less than 6 months or when enteral nutrition is considered a viable alternative. Interviewees in Poland report that periodic retrospective audits of HPN patient selection are carried out by the NFZ to ensure prescribing is in line with national guidelines (POLSPEN). One respondent commented that these audits cause a degree of stress to clinicians even to the extent they are deterred from prescribing HPN.

In some countries, national health insurance funds closely scrutinise adherence with clinical guidelines, using them as a means of limiting spending on HPN, thereby reducing patient access to it.

Regional: The most significant regional variation in HPN reimbursement occurs in Spain. Only some hospitals (approximately 1 in 3) in Spain have the multidisciplinary team (MDT) expertise necessary to deliver HPN. As such, Spain's National Health Fund recognises these centres (45 in total) as HPN specialist centres of sorts and awards them extra funding to support HPN care. However, the Spanish healthcare system only reimburses hospital treatment when it is administered to patients residing in the hospital's catchment area. Consequently, patients residing in areas without an HPN hospital centre cannot be referred to another centre for HPN as it will not be reimbursed. Access to HPN in Spain, therefore, depends entirely on whether the patient lives in a funded hospital catchment area or not.

Minor regional differences in HPN reimbursement also exist in Germany and Italy. In Germany, HPN is reimbursed across all 16 federal states but with subtle differences across statutory health insurance

funds. In Italy, in regions without a specialist nutrition centre, patients can still receive HPN directly through the Local Health Care Unit, Azienda Sanitaria Locale, but without the same level of support and services.

CALL TO ACTION: Action is needed by payers to address setting, indication, and regional reimbursement limitations to improve patient access to HPN.

Figure 3. The current landscape of HPN provision in select European countries

Netherlands:
- High access for benign CIF but less for oncology patients
- No Legislation

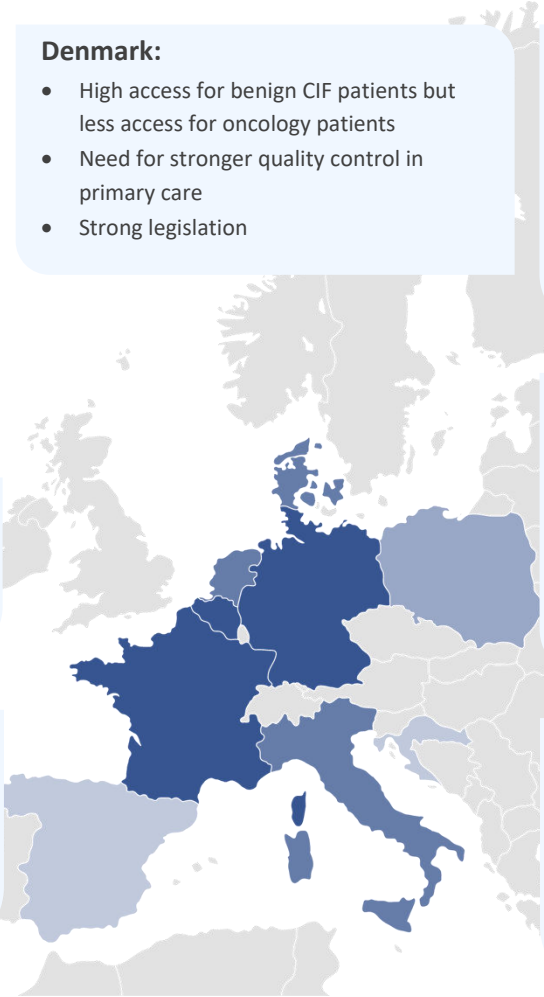
Denmark:
- High access for benign CIF patients but less access for oncology patients
- Need for stronger quality control in primary care
- Strong legislation

Germany:
- High level of access
- Specialists believe they reach all suitable patients
- There is no legislation, and there are no HPN centres.
- Any physician can initiate HPN from any centre

Belgium:
- High access
- Well organised homecare
- Strong legislation

Poland:
- Mid level of access. Many potential patients still do not have access
- Overall capacity is limited
- No private homecare provision and no primary care support
- Legislation exists but funding is tightly controlled

France:
- High access
- Well organised homecare
- Strong legislation



Spain:
- Low access
- Capacity is limited
- No private homecare provision and no primary care support
- No legislation

Croatia:
- Very low level of access
- Overall capacity is limited
- No private homecare provision and no primary care support
- No legislation and very limited funding

High level of access
Mid level of access
Low level of access

Italy:
- Well organised but variability in access remains
- Legislation exists but implemented differently in regions

Abbreviations: CIF, chronic intestinal failure; HPN, home parenteral nutrition.

Conclusions

The objective of the research informing this white paper was two-fold: 1) to gain an up-to-date assessment of the degree of unequal access to HPN across Europe, and 2) to understand how equal access to HPN might, in future, be achieved.

The research clearly demonstrates that substantial inequality in access to HPN among eligible patients persists across Europe, as is illustrated in Figure 3.

Three key factors are contributing to unequal access to HPN in Europe:

- **Only some countries have legislative frameworks in place to support the provision of HPN. Even in countries where legal frameworks exist, the degree to which they are enforced varies.**
- **The level of acceptance and implementation of clinical guidelines for the provision of HPN is mixed, varying both by country and by indication.**
- **Reimbursement for HPN varies depending on treatment setting, indication, and country region. Furthermore, in some instances, patients pay out of pocket as co-payments for consumables.**

By publishing this white paper, and with a clear goal of achieving equitable patient access to HPN across Europe, the MNI issue three calls to action:

1. To achieve equitable patient access to HPN across Europe:
    a. Common frameworks for supportive legislation need to be established
    b. HPN clinical guidelines need to be more consistently implemented
    c. Further reimbursement for HPN must be provided
    d. The management, organisation, and delivery of HPN all need to improve
2. Greater efforts are needed to better educate and inform decision-makers of current evidence and expert opinion in treatment guidelines. Improving adherence with treatment guidelines will lead to improved access to HPN among those patients who need it. ESPEN guidelines provide evidence-based recommendations on the appropriate and safe use of HPN. Nonetheless, the degree to which these guidelines are used across Europe varies.
3. Action is needed by payers to address setting, indication, and regional reimbursement limitations to improve patient access to HPN.

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