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Federaal Kenniscentrum voor de Gezondheidszorg
Centre Fédéral d'Expertise des Soins de Santé
Belgian Health Care Knowledge Centre

ORGANIZATION AND REIMBURSEMENT OF ENTERAL AND PARENTERAL NUTRITION IN AND OUTSIDE THE HOSPITAL IN BELGIUM

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'All experts and stakeholders consulted within this report were selected because of their involvement in the topic of (par)enteral nutrition. Therefore, by definition, each of them might have a certain degree of conflict of interest to the main topic of this report'

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- **The external experts were consulted about a (preliminary) version of the scientific report. Their comments were discussed during meetings. They did not co-author the scientific report and did not necessarily agree with its content.**
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- **Finally, this report has been approved by common assent by the Executive Board (see http://kce.fgov.be/content/the-board).**
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LIST OF ABBREVIATIONS

ABBREVIATION	DEFINITION
EN	Enteral Nutrition
ICU	Intensive Care Unit
NST	Nutrition Support Team
NICE	National Institute for Health and Care Excellence
PN	Parenteral Nutrition
RCT	Randomized Controlled Trial
TPN	Total Parenteral Nutrition
UK	United Kingdom

GENERAL INTRODUCTION

Malnutrition refers to deficiencies, excesses or imbalances in a person's intake of energy and/or nutrients. The term malnutrition covers 2 broad groups of conditions. One is 'undernutrition', the other is overweight. In this study we only focus to the undernutrition component.

According to the European Society of Enteral and Parenteral Nutrition (Cederholm *et al.*, 2017) malnutrition (undernutrition) can be defined as "a state resulting from lack of intake or uptake of nutrition that leads to altered body composition (decreased fat free mass) and body cell mass leading to diminished physical and mental function and impaired clinical outcome from disease"; malnutrition can result from starvation, disease or advanced ageing (e.g. >80 years), alone or in combination. Criteria for the potential diagnosis of malnutrition are among others low energy intake, weight loss, loss of muscle mass, loss of subcutaneous fat, fluid accumulation, and hand grip strength. There exist validated instruments to assess (risk for) malnutrition.

Malnutrition is both a cause and a consequence of ill health. It is common and increases a patient's vulnerability to disease. Malnutrition can adversely affect every organ in the body, and can lead to far-reaching physical and psycho-social consequences, such as impaired immune response, impaired wound healing, reduced muscle strength and fatigue, inactivity, apathy, depression and self-neglect. Malnourished hospital patients experience significantly higher complication rates than well-nourished patients. In case malnutrition is not treated, it may lead to complications, increased length of stay and even increased mortality (Thomas *et al.*, 2016). Also increased healthcare cost are involved (Abizanda *et al.*, 2016).

Prevalence of malnutrition

Malnutrition is a common, but frequently undetected, problem (Barker *et al.*, 2011) in residential care, home care and the hospital setting.

Cereda et al. (Cereda *et al.*, 2016) studied the literature on malnutrition in elderly across settings and, based on 240 articles, they found that prevalence of malnutrition differed significantly across the healthcare settings considered: community, 3.1% (95%CI, 2.3-3.8); outpatients, 6.0% (95%CI, 4.6-7.5); home-care services, 8.7% (95%CI, 5.8-11.7); hospital, 22.0% (95%CI, 18.9-22.5); nursing homes, 17.5% (95%CI, 14.3-20.6); long-term care, 28.7% (95%CI, 21.4-36.0); rehabilitation/sub-acute care, 29.4% (95%CI, 21.7-36.9). For patients admitted to hospitals worldwide, malnutrition prevalence is estimated to be as high as 50% (Correia *et al.*, 2014).

A Belgian study found that 51% of patients had (risk for) malnutrition on admission to a hospital (Geurden *et al.*, 2015) while another found a prevalence of 33% malnourished patients in Belgian hospitals (Vanderwee *et al.*, 2010). In Belgian residential care 57% of the residents were at risk for malnutrition and 16% de facto malnourished. In elderly residing still at home 49% were at risk and 12.8% malnourished (Van Gossum and Vandewoude, 2013).

Many people suffer from, or are at risk, for nutritional deficiencies due to certain illnesses, medical procedures or insufficient selfcare (e.g. in elderly). Enteral or parenteral nutrition may be needed for persons that undergo major abdominal surgery, chemo- or radiotherapy or have conditions in which the oropharyngeal-intestinal tract is damaged (e.g. in patients with cystic fibrosis (Schwarzenberg *et al.*, 2016) or amyotrophic lateral sclerosis (ALS) (Katzberg and Benatar, 2011)). Some people need artificial feeding for only a limited time, while others may be dependent on artificial feeding for years.

Malnutrition is a problem that generally cross the hospital borders and needs to be looked at from a transmural perspective.

Interventions for malnutrition

There is a lot of literature on different aspects of nutritional support, enteral and parenteral nutrition, including well developed international guidelines from European and USA origin (e.g. (Arends *et al.*, 2017;Boullata *et al.*, 2017;Cederholm *et al.*, 2017;Correia *et al.*, 2014;McClave *et al.*, 2016;Singer *et al.*, 2009;Staun *et al.*, 2009;Taylor *et al.*, 2016;Turck *et al.*, 2016)).

Interventions for people with (risk for) malnutrition start with screening and if necessary further assessment and then in order of preference:

- Nutritional advice and support
- Fortified food
- Oral nutritional supplements (ONS)
- Enteral nutrition (EN)
- Parenteral nutrition (PN)

In case artificial food supply is needed, one can opt for oral supply of clinical nutrition (oral nutritional supplements ONS) and when the oral way is not possible, for enteral nutrition (via nasogastric tube or percutaneous endoscopic gastrostomy (PEG)) or parenteral nutrition (directly in the bloodstream)[a]. According to international guidelines (Arends *et al.*, 2017;Elke *et al.*, 2016;McClave *et al.*, 2016;McClave *et al.*, 2016;Turck *et al.*, 2016;Weimann *et al.*, 2017;Worthington *et al.*, 2017) the oral way, if possible, is in general preferred above the enteral way and the enteral way is preferred above the parenteral route, summarized in a frequent used adagio “if the gut works, use it”.

In this study, we focused on enteral and parenteral nutrition, because there are concerns in Belgium about the current reimbursement rules and financial impact. Moreover, lack of data concerning other interventions as dietary advice or ONS prohibited to study these. Also the utility and effectiveness of other nutritional interventions have already been studied extensively elsewhere (e.g. (Cawood *et al.*, 2012;Elia *et al.*, 2016;Elia *et al.*, 2016;Elia *et al.*, 2018;Stratton, 2005;Stratton *et al.*, 2013)). We realize that this is a limit of our study, especially in cases where several nutritional interventions coincide or overlap.

There are recent systematic reviews demonstrating the effectiveness of (different forms of) **enteral and parenteral nutrition** (Chow *et al.*, 2016;Deane *et al.*, 2013;Doyle *et al.*, 2017;Elke *et al.*, 2016;Feinberg *et al.*, 2017;Lan *et al.*, 2017;Martin and Gardner, 2017;Mitchell and Porter, 2016;Muscaritoli *et al.*, 2017;Wong *et al.*, 2017), and in specific populations such as dementia (Goldberg and Altman, 2014). However, according to a recent Cochrane review, there is no firm evidence on the comparative effectiveness of different nutritional support interventions (Feinberg *et al.*, 2017). Also Chow et al (Chow *et al.*, 2016) found in their review no difference in the endpoints between the parenteral and enteral nutrition for cancer patients, except that PN resulted in more infections when compared with EN. The review of Zhang et al.(Zhang *et al.*, 2018) found that for critically ill patients, the two routes of nutrition support had no different effect on mortality rate, but that the use of EN could decrease the incidence of bloodstream infections and was associated with a reduced hospital length of stay but also was associated with increased risk of gastrointestinal complication.

In addition, the international literature advises to install **nutrition support teams** to tackle and coordinate the malnutrition problem.

This has also been recognized in the Belgian situation and led to several governmental policies (a.o. (Gerkens, 2015;Van den Brandt and Bertels, 2017). Since 2007 projects were started with the installation of nutrition support teams in acute care general hospitals and since 2014 every acute care hospital is structurally financed to organize a nutrition support team. The main tasks of this team are developing a nutritional policy in the hospital, screening for malnutrition, giving nutritional advice to healthcare professionals and giving nutritional advice to and follow-up of malnourished patients. One of the important roles of nutritional support teams in hospitals is thus to develop a nutritional policy that supports the appropriate use of

[a] Belgian legislation uses the term ‘medical nutrition’ or ‘diet-nutrition for medical purposes’ (http://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=nl&la=N&cn=2002102445&table_name=wet last accessed 19/03/19); The list of reimbursable medical nutrition products is kept current at RIZIV/INAMI (https://www.inami.fgov.be/nl/themas/kost-terugbetaling/door-ziekenfonds/gezondheidsproducten/voeding/Paginas/dieetvoeding-bestemd-bijzonder-medisch.aspx, last accessed 19/03/19)

(par)enteral nutrition in case of malnutrition. Part 1 describes the current legislation and the presence and composition of NSTs in Belgian hospitals and presents the results of systematic review regarding the effectiveness of NSTs.

Prevalence of enteral and parenteral nutrition

A screening of the international literature shows that there are large variations in **prevalence of (par)enteral nutrition** between and within countries, type of care setting, type of nursing ward, type of disease and type of intervention.

According to Defloor et al. (Defloor *et al.*, 2010) 2% of patients in Belgian hospitals received enteral and 1.2% parenteral nutrition.

Other estimates on EN/PN in Belgium are provided by the hospital St Lucas Brugge (van Schaik *et al.*, 2016) and show a decreasing prevalence of 2.7% patients with PN in 2009 to 1.3% in 2014, while the prevalence of patients on EN remained stable on about 1.1%; of those patients very few left the hospital with PN (9 (2.4%) in 2009 and 1 (0.5%) in 2014) or with EN (1 (0.26%) in 2009 and 16 (8.4%) in 2014).

Estimates on EN in the Belgian home care setting provided by IMA (Intermutualistisch Agentschap IMA, 2016) show that around 6000 patients per year received a lump sum reimbursement for home EN.

Estimates on parenteral nutrition in the Belgian home care setting are scarce. A Brussels university hospital reported that in 20 years (1987-2007), 125 patients were included in a Home Parenteral Nutrition (HPN) programme; 65 patients had benign diseases and 60 advanced cancer (Vafa *et al.*, 2010).

Further exploration of prevalence rates of EN and PN in Belgium is presented in Part 2 of this report.

Reimbursement and economic aspects

Belgian reimbursement rules for EN and PN differ according to type of administration way (enteral versus parenteral) and according to setting (hospital versus home) and even sometimes according to type of disease and age category. The current RIZIV/INAMI reimbursement rules for PN and EN are complex and incoherent (De Block, 2015;Onkelinx, 2009;Rommel *et al.*, 2017). These aspects were further explored and are presented/discussed in Part 3 of this report.

Research objective

The objectives of this project are:

1. to describe the Belgian situation on presence and composition of nutrition support teams in hospitals
2. to analyse the (patient) effects of a nutrition support team,
3. to analyse the current prevalence of adult patients with (par)enteral nutrition, both inside and outside the hospital,
4. to analyse the variability in EN/PN prevalence across hospitals
5. to describe the organisation of care for adult patients with (par)enteral nutrition, including the affiliated financing/reimbursement rules in different healthcare settings

in order to harmonize and optimize future (par)enteral nutrition care in Belgium.

The target population of this study are adult patients receiving or in need of (par)enteral nutrition, regardless the setting were they are. We excluded children as target population since nutritional interventions are much different than those for adults (e.g. (Gaynor and Sullivan, 2015;Green Corkins and Teague, 2017;Picot *et al.*, 2012;Tette *et al.*, 2015))

Targeted audience/users of this study are governmental bodies involved in regulation and policy making related to detection and treatment of malnutrition. Next to these, nutrition support teams in hospitals, as well medical prescribers of artificial nutrition, nurses and dieticians may benefit in their daily practice from the study results. And of course, this study aims to facilitate patients in obtaining the most appropriate nutritional care at the lowest costs.

All of these stakeholders were involved and consulted in this study (as listed in the Colophon).

Research questions

Nutrition support teams

- What is the presence and composition of nutrition support teams in Belgian hospitals?
- What is the evidence on the (patient) effects of nutrition support teams?

Prevalence (par)enteral nutrition in belgium

- How many and what type of patients receive enteral and/or parenteral nutrition (in hospital, residential care and home care)?
- Is there a longitudinal trend?

Financing & reimbursement (par)enteral nutrition

- What is the cost-effectiveness of PN compared to EN?
- What are the regulations and financing/reimbursement rules in Belgium regarding (par)enteral nutrition in different settings?
- What is the budget impact for harmonizing reimbursement rules for EN and PN across settings?

Structure of the report

For each of above questions the methodology and results are discussed in consecutive parts of this report. Part 1 describes the presence and composition of NST in Belgian hospitals and a systematic review on effects of nutrition support teams is discussed; exploration of prevalence rates of EN and PN in Belgium is presented in Part 2 and Part 3 concerns the economic aspects of EN and PN.

After those specific parts, general conclusions are presented.

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1 PART 1 NUTRITIONAL SUPPORT TEAMS

1.1 Background nutritional support teams

As stated in the general introduction, malnutrition is a common problem across care settings and not always adequately prevented or treated. To tackle this problem the concept of a **'nutrition support team'** was introduced at the end of the twentieth century in the USA and Europe. A nutrition support team (NST) consists of several disciplines such as dieticians, nurses, gastro-enterologists, endocrinologists and others. They are supposed to develop organizational policies regarding screening for malnourishment and appropriate nutritional care interventions and to advice bed-side health care professionals in providing adequate nutritional interventions (e.g. dietary advice, enriched regular food, oral nutritional supplements, enteral tube feeding or intravenous parenteral nutrition).

Nutrition support teams are seen as an important intervention/tool and are assumed to improve nutritional status of malnourished patients (Brill et al. 2010, Delegge et al. 2010, DeLegge and Kelly 2013, Dinenage et al. 2015, Guenter et al. 2015, Hall et al. 2014, Howard 2001, Kennedy and Nightingale 2005, NICE 2006, Nightingale 2010, Schneider 2006, Worthington et al. 2017). Expected/assumed effects of NSTs (DeChicco and Steiger 2016, Desport et al. 2009, Nightingale 2010) are, among others, less (inappropriate) prescribing of (par)enteral nutrition, fewer bags of parenteral nutrition, less percutaneous endoscopic gastrostomies, and costs savings.

NSTs originated in the 80's and there are some reviews (e.g. (Gales and Gales 1994, Payne-James 1997)) of the 90's that showed effectiveness and from then on the NST came widespread across the world. NSTs are recommended by international authoritative organizations such as the UK National Institute for Health and Care Excellence (NICE 2006, NICE 2017), the American Society for Parenteral and Enteral Nutrition (Boullata et al. 2017, Worthington et al. 2017), the European Society for Parenteral and Enteral Nutrition (Cederholm et al. 2017, Gomes et al. 2017), and the American College of Gastroenterology (McClave et al. 2016). Most NSTs work in hospital, but also some in the home care setting (Scott et al. 2005).

A conference in Belgium in 2007 (Arvanitakis et al. 2008) influenced the conception of NST in Belgium and since 2014, there is an amount of money included in the budget of financial means (BFM) for each acute care hospital in Belgium to organize a NST[b] and some recent publications from Belgian origin appeared in which the concept of NST was commented positively (Boeykens and Van Hecke 2018, Dauw et al. 2018, Michel et al. 2017, van Schaik et al. 2016) .

And although it seems there is more recent evidence on effectivity of NSTs (e.g. (Attanasio et al. 2009, Braun et al. 2016, Caccialanza et al. 2010, Chuah et al. 2013, Declercq et al. 2015, Furtado et al. 2016, Hvas et al. 2014b, Hvas et al. 2015, Kennedy and Nightingale 2005, Kohli-Seth et al. 2009, Martin et al. 2011, Parent et al. 2016, Park et al. 2017, Peterson et al. 2010, Scott et al. 2005, Senesse et al. 2017, Sriram et al. 2010, Steele et al. 2016, van Schaik and Niewold 2014a, Vashi et al. 2015, White et al. 2008, Youngman et al. 2015)), there is, to our knowledge, no recent systematic review on the effectivity of NSTs.

We are aware of some related reviews, e.g.:

- Feinberg et al. (Feinberg et al. 2017) performed a Cochrane review on the effectivity of nutritional interventions but they did not look at the effect of NSTs
- Walzer et al. (Walzer et al. 2014) performed a systematic review on health economics evidence regarding medical nutrition interventions but NST was not included as an intervention

b http://www.ejustice.just.fgov.be/cgi/article_body.pl?language=nl&caller=summary&pub_date=15-01-27&numac=2015024034 http://www.ejustice.just.fgov.be/cgi/article_body.pl?language=fr&caller=summary&pub_date=15-01-27&numac=2015024034

- Majka et al. (Majka et al. 2014) focused on the effect of care coordination by a multidisciplinary nutritional team, but did only so for long-term and only for patients on EN
- The papers of Arvanitakis et al. (Arvanitakis et al. 2008, Arvanitakis et al. 2009) analysed the literature on undernutrition in home care and care home settings only and potential useful interventions, but it was not focused on the effectivity of NST, although they suggest it as one of the promising interventions
- Fernandez et al. (Fernandez et al. 2003, Naylor et al. 2004) performed a systematic review on the effectiveness of NST, but this study dates already from 2003 with inclusion date up to 2001; moreover, they conclude that the general effectiveness of the Total Parenteral Nutrition team has not been conclusively demonstrated and more research is needed
- The systematic review of Wong et al. (Wong et al. 2017) determined the total costs, the cost-effectiveness and other economic outcomes of interventions (including NST) but for home enteral nutrition only; with regard to NST they conclude, based on 5 included studies (but these were, according to Wong et al., of poor study quality), that availability of a nutrition support team may lead to cost savings and improved clinical outcomes.

Therefore, in this part 1 we aimed

- **to describe the current status of nutrition support teams in Belgium and**
- **to perform a systematic review on the effectiveness of nutrition support teams with regard to the prevalence of adult patients with (par)enteral nutrition.**

1.2 Nutrition support teams in Belgium

The FPS Public Health started in October 2007 a pilot project to prevent and manage malnutrition within the hospital by appointing a nutritional manager and a nutritional team. Since the 1st of July 2014 (KB, 8-1-2015) all non-psychiatric hospitals are financed by the government for a nutrition support team (NST): the pilot project is converted to a structural financing of nutritional support teams as part of the hospital financing (art. 63septies of the royal decree of the 25th of April 2002 on the establishment and liquidation of the financial budget of hospitals)[c].

According to that decree, the NST is a multidisciplinary team and should be composed by at least a dietician, a nurse, a doctor, a pharmacist and the kitchen manager of the hospital. At least once per trimester, the head of the NST has to organise a meeting with all the members to discuss their interventions in the hospital. These NSTs have multiple objectives, including the following:

- To develop, within the hospital, a strategy to improve the screening of patients at risk of obesity or malnutrition (development of screening tools)
- To develop a targeted nutritional intervention followed by a personalised nutritional plan for patients at risk of obesity or malnutrition based on a complete nutritional examination by a dietician
- To ensure the follow-up of the implementation of these procedures by recording all the information on a database
- To write and keep up-to-date a nutritional policy manual , based on evidence based guidelines concerning special nutritional therapy
- To ensure the follow-up of all the patients with parenteral or enteral nutrition including the preparation of patients for hospital discharge

[c] http://www.ejustice.just.fgov.be/cgi/article_body.pl?language=nl&caller=summary&pub_date=15-01-27&numac=2015024034

- To be involved in meetings about nutrition support team organised by FPS Health, Food Chain Safety and Environment (SPF-FOD) and send them data to assess the activity of the NST in hospital.

The NST is funded by a lump sum based on the number of justified beds (C, D, C+D, I, E, G, Sp, Sp palliative care, A, Aj, An, T, K, Kj et Kn). According to the risk of malnutrition, a certain amount of points is linked to each type of justified bed. Thus, hospitals can estimate their total number of points. The first 800 points are covered by a fixed amount of €15 000. Then, a complementary amount is calculated by multiplying €2.60 by the number of additional points (over the 800). The number of justified beds is updated every 2 years since July 2014.

1.2.1 Registration

As stipulated in the royal decree on NST, hospitals need to submit a survey each year on the composition and the patient-directed activity of the NST.

1.2.1.1 Composition of NST

For the composition of the NST, a survey form is completed by the hospitals with information on:

- the contact details of all members of the NST;
- profession, FTE and number of years work experience per team member;
- information of the situation of the NST in the organigram of the hospital;
- frequency and procedure of meetings of the NST;
- missions taken up by the NST;
- screening and follow-up activities of the NST and the way they are documented;
- collaboration with and integration in other services within the hospital;
- sensibilisation and preventive activitivities organised by the NST;
- training followed by members of the NST

We received from FPS Public Health per year which hospitals had an NST between 2010 and 2016: 96 between 2010 and 2013 and all non-psychiatric hospitals from 2014 onwards as from that year, all non-psychiatric hospitals are financed for an NST.

For 2016, we received a more detailed analysis on the NST composition in 105 hospitals (of 123 invited) that completed the survey. There exists much difference between NST's in the number of members and what professions are part of the NST (see Figure 1). Relatively few NST's report a full 'Royal Decree staffing' (13.3%), but this seems mainly due to few NST's mentioning a kitchen manager as part of the team. When leaving out this profession, 45.7% have at least all other professions as specified in the Royal Decree on NST.

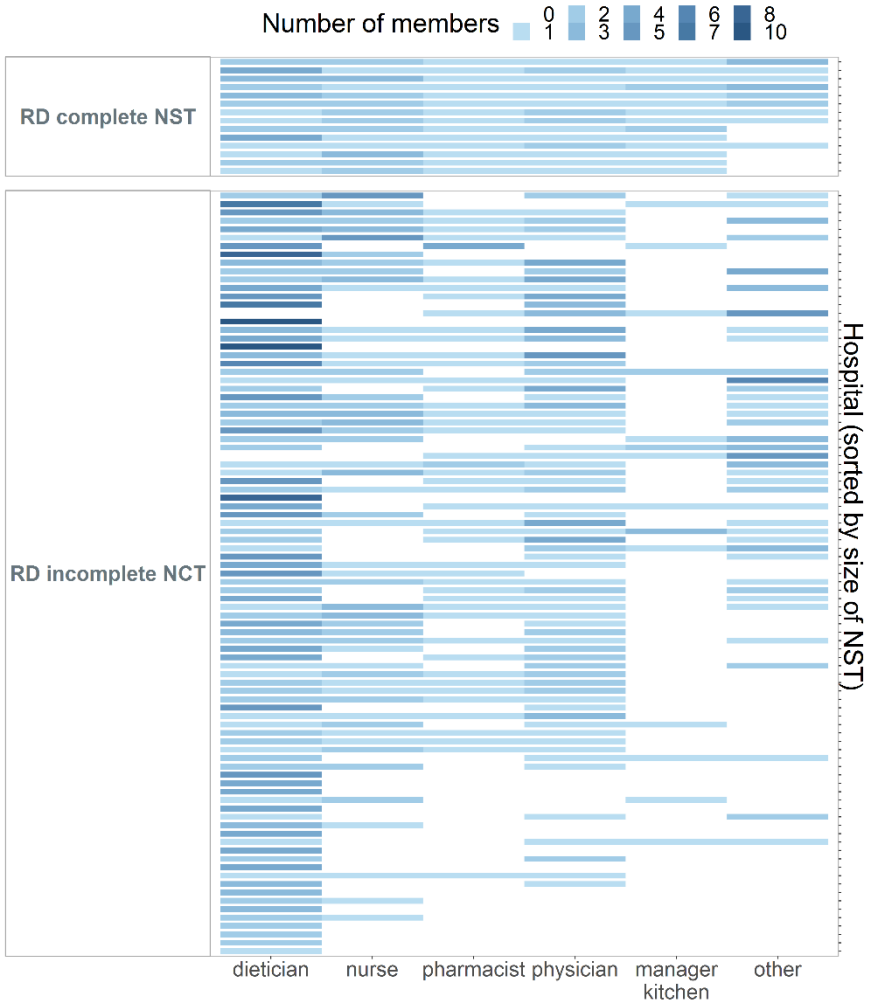
We have no structured information on further (nutritional) qualifications of the NST-members.

Table 1 shows that most NST's employ a dietician. In the category 'other', professions such as speech therapist, occupational therapist, social worker, and patient representative are reported.

Table 1 – Professions part of NST in 2016

Profession	% of hospitals
Dietician	98.1%
Physician	76.2%
Nurse	63.8%
Pharmacist	58.1%
Other	44.8%
Manager kitchen	26.7%

Figure 1 – Members of the NST per hospital in 2016 by Royal Decree (RD) completeness (hospitals are sorted by NST number of members)



In 2016, 82.1% of hospitals reported they organised at least four meetings as stipulated in the Royal Decree on NST.

Table 2 shows that NST differ in the type of tasks they take up in the hospital, with the majority engaging both in dietary treatment and in development of nutritional policy.

Table 2 – NST tasks in 2016

Dietary treatment			Nutritional policy development	% of hospitals
Ambulatory consultation	Day care	Hospitalisation		
✓	✓	✓	✓	38.3%
	✓	✓	✓	16.8%
		✓	✓	15.0%
			✓	13.1%
✓		✓	✓	6.5%
		✓		4.7%
✓	✓	✓		2.8%
	✓	✓		2.8%

Half of the NST in 2016 where coordinated by the dietician, followed by the physician in a third of the NST (see Table 3).

Table 3 – Coordinator NST in 2016

Coordinator NST	% of hospitals
dietician	50.0%
physician	31.7%
nurse	13.5%
pharmacist	2.9%
manager kitchen	1.9%

1.2.1.2 Patient directed activity of NST

For the patient directed activity of the NST, hospitals have a choice between using Nubel PRO or a survey format provided by the FPS Public Health. However, we encountered several data related issues in analysing these activity data in concertation with FPS Public health:

- Not all hospitals submitted a patient directed activity report in the latest years. Detailed data were available for 2015 to 2016 included.
- The use of the two registration systems gives partial but incomplete overlap in what data are available.
- The unit of registration differs per hospital: some hospitals submit one record per patient, others multiple records but no more than one per day, others multiple per day.
- For almost all hospitals, a unique patient identifier is missing from some to many records.
- Many of the fields are not standardised. E.g. for the following fields some hospitals provide a yes/no answer, while others provide a score: used screening tool, weight, height, BMI. Other fields are free text, e.g. if the patient is at risk of malnutrition, referrer, nutrition state.

For these reasons, we decided not to include further analysis on the activity registration on NST's. The registration will be mentioned in the data analysis chapter (see Part 2), but no results are included.

1.3 Systematic review NST

1.3.1 Method

Although a good nutritional status of patients is the ultimate goal for the existence of NSTs, direct relationship between the two is difficult to demonstrate due to the many other interventions and variables that influence nutritional status. The easiest measurable proxy measure for effectivity of NST is the number of patients with enteral (EN) or parenteral nutrition (PN) and the ratio between them; these were also seen as good outcome-indicators for a NST in a Belgian study (Baillieul 2009) and suggested by others elsewhere as well (Bischoff et al. 2009, Delegge et al. 2010, Nightingale 2010, Schneider 2006, Senesse et al. 2017). Also orientation site-visits to Belgian hospitals with a NST confirmed that an increasing rate of EN/PN can be seen as a good indicator of NST-effectivity.

Studies as mentioned above concluded that by introducing NST the prevalence and duration of parenteral nutrition dropped and the ratio of enteral/parenteral nutrition reversed. For this review we assume that a decreased prevalence of parenteral nutrition after introduction of a NST does not compromise nutritional status of patients, since the (de)prescription of (par)enteral nutrition is monitored by the most knowledgeable people in this field. However, because of the limitations of our primary outcome 'prevalence of (par)enteral nutrition' we also looked at secondary outcome parameters of nutritional status and the appropriateness of (par)enteral nutrition in the included studies.

This review did not look at the (comparative) effectiveness of the nutritional interventions themselves, since this was already covered by the Cochrane review of Feinberg et al. (Feinberg et al. 2017).

1.3.1.1 PICOts

- Population/patients:
  - Adult malnourished patients or patients with risk for malnutrition or patients receiving nutritional intervention
- Intervention: nutrition support team
  - Either working as a team for making organization-wide nutritional policies
  - Or as clinical advice and support team for other professionals regarding nutritional interventions
  - Or as clinical unit, taking care of patients themselves
  - Minimal requirements to be considered as NST is at least involvement of 2 disciplines (e.g. dieticians, medical specialists, nurses, pharmacists)
- Control: no nutrition support team/ usual care
- Outcome
  - Primary: prevalence (trend) of (par)enteral nutrition or ratio between enteral/parenteral prevalence (either in number of patients, number of days or number of bags)
  - Secondary:
    - Duration of (par)enteral nutrition
    - Appropriateness of (par)enteral nutrition
    - Nutritional status
    - Complications
    - % patients screened for malnutrition
    - % patients receiving some type of nutritional intervention
    - Quality of life
    - Costs for nutrition for hospital/care organization
    - Costs for nutrition for patients
- Type of studies
  - Systematic reviews
  - Comparative research designs, such as RCTs, pre-post studies or comparison between hospitals with NST versus without NST
- Setting
  - NST is working either in a hospital, primary care or residential care setting
  - Study is done in a western country (EU28/EEA, USA, Canada, Australia and New Zealand)

1.3.1.2 Limits/exclusion

- time period: publications <2000
- patients < 18 year
- patients with (risk for) obesity
- language: reports in other languages than English, French or Dutch
- opinion articles, qualitative research
- post-only studies (even with multiple post-measurements)
- studies in which only changing characteristics of NST were studied (e.g. adding an additional discipline to the team, change in protocol, …)
- animal studies
- non-western countries

1.3.1.3 Data sources

STEP 1

- Pubmed
- Cinahl
- Embase
- Cochrane Database of Systematic Reviews (all databases)
- Trial registers
  - International Clinical Trials Registry platform (ICTRP) (http://apps.who.int/trialsearch/)
  - ClinicalTrials.gov (http://www.clinicaltrials.gov/)
- Review register
  - Prospero (https://www.crd.york.ac.uk/PROSPERO/)
- References from included systematic reviews obtained by search strategy

STEP 2

- References obtained by forward citing searches of included references after step 1

1.3.1.4 Search strategies

- Pubmed
  - “nutrition team” OR “nutrition support team” OR "nutritional team" OR "nutritional support team" OR “malnutrition task force” OR “nutrition task force” OR (team[Ti] AND nutrition[Ti]) OR (team[Ti] AND malnutrition[Ti]) OR (NST AND nutrition) OR (NST AND malnutrition) OR “enteral nutrition use” OR “parenteral nutrition use” OR ((("Enteral Nutrition/epidemiology"[Mesh] OR "Enteral Nutrition/trends"[Mesh] OR "Enteral Nutrition/utilization"[Mesh])) OR ("Parenteral Nutrition/epidemiology"[Mesh] OR "Parenteral Nutrition/trends"[Mesh] OR "Parenteral Nutrition/utilization"[Mesh])) (limited to year=>2000)
- CINAHL
  - “nutrition team” OR “nutrition support team” OR "nutritional team" OR "nutritional support team" OR “malnutrition task force” OR “nutrition task force” OR (TI “team” AND TI “nutrition”) OR (TI “team” AND TI “malnutrition”) OR (NST AND nutrition) OR (NST AND malnutrition) OR (MH "Nutritional Support Team") OR “enteral nutrition use” OR “parenteral nutrition use” OR TI "tube feeding" OR (MH "Parenteral Nutrition/SN/UT/TD") OR (MH "Enteral Nutrition/SN/TD/UT") (limited to year=>2000 and MEDLINE records excluded)
- EMBASE
  - ('nutrition support team' OR 'nutrition team' OR 'nutritional team' OR 'nutritional support team' OR 'malnutrition task force' OR 'nutrition task force' OR (nst AND nutrition) OR (nst AND malnutrition)) AND ('enteric feeding'/exp OR 'enteral feeding' OR 'enteral nutrition' OR 'enteric feeding' OR 'enteric nutrition' OR 'feeding, enteric' OR 'feeding, intragastric' OR 'intestinal feeding' OR 'intragastric feeding' OR 'intraintestinal feeding' OR 'tube feeding' OR 'parenteral nutrition'/exp OR 'enteral nutrition use' OR 'parenteral nutrition use') AND [embase]/lim AND [2000-2018]/py
- Cochrane Database of Systematic Reviews (all databases)
  - "nutrition team" or "nutrition support team" or "nutritional team" or "nutritional support team" or "malnutrition task force" or "nutrition task force" or (team:ti,ab,kw and nutrition:ti,ab,kw) or (team:ti,ab,kw and malnutrition:ti,ab,kw) or (NST:ti,ab,kw and nutrition:ti,ab,kw) or (NST:ti,ab,kw and malnutrition:ti,ab,kw) (limited to 2000-2018)

- Trial and review-registers:
  - (Nutrition OR nutrition*) AND team, in title
    - International Clinical Trials Registery platform (ICTRP
    - ClinicalTrials.gov
    - Prospero
- STEP 2: forward searches in Google scholar (via Publish or Perish) with the references that were included in step 1

1.3.1.5 Inclusion process

- Deduplication and initial shifting 1 reviewer
- Title/abstract (TIAB) assessment: 1 reviewer: YES/NO/DOUBT; in case of DOUBT: second reviewer
- Full text assessment: 2 independent reviewers
- Inclusion criteria:
  - About an expert team that give advice/consultations to health care professionals regarding nutritional interventions and screening for malnutrition, in general or patient specific, and/or that makes nutritional policies for a healthcare organization
  - AND
    - Concerns either a systematic review[d] that contains primary studies fulfilling the inclusion criteria
    - OR
    - Primary study applying a comparative design (such as RCTs, pre-post studies or comparison between hospitals with NST versus without NST; only-post studies are excluded)
  - AND
    - Team is at least targeted to adult patients with (risk for) malnutrition
  - AND
    - Contains at least outcome data regarding prevalence of (par)enteral nutrition (number of patients, number of days, number of bags)
  - AND
    - Study is performed in a western country
  - AND
    - Study is reported in English, French or Dutch

With regard to step 2: all included references from step 1 were entered in 'Publish or Perish' program and used to search for references in which the articles were cited; then obtained results were deduplicated, screened if they were already in the initial dataset, and then assessed on title/abstract by one reviewer, followed by assessment on full text by 2 independent reviewers using the inclusion criteria as mentioned above.

[d] Based on Francke et al. (Francke et al. 2008) we considered a review or meta-review to be systematic if at least two of the following three criteria were satisfied: (a) search terms are presented; (b) Pubmed/Medline, at least, has been searched; (c) the methodological quality of the included studies has been assessed by the reviewer(s).

1.3.1.6 Methodological assessment

- 2 reviewers independently
- Comparative studies were assessed by using the criteria of the Cochrane EPOC group (Suggested risk of bias criteria for EPOC reviews/appendix 2[e])

1.3.1.7 Data-extraction and analysis

Data-extraction was done by a single reviewer in Excel and checked by a second reviewer.

As research hypotheses, we expected that NST would lead to:

- a decreasing prevalence of parenteral nutrition over the observed years[f]
- a reversed ratio enteral/parenteral nutrition (from mainly parenteral to mainly enteral)
- an increased prevalence of enteral and parenteral nutrition that is prescribed appropriately (as measured by the authors)
- a decreased prevalence of inappropriate use of (par)enteral nutrition (as measured by the authors)
- a comparable or improved nutritional status of patients (as measured by the authors)
- comparable or decreased nutritional costs for health care organizations
- comparable or decreased nutritional costs for patients

Data were extracted on:

- the intervention and control condition (in protocol intended by use of the TIDIER checklist (Hoffmann et al. 2014))
- study design
- patient population
  - setting (e.g. hospital, home, residential care)
  - age (mean, median, min/max)
  - gender
  - primary diagnosis
  - medical discipline
  - type of nursing ward (e.g. ICU, general surgery, oncology, geriatrics)
  - main medical treatment (.e.g. surgery, chemotherapy, radiotherapy)
  - nutritional status (e.g. body weight, BMI)
- outcomes as mentioned above
- risk of bias (cfr methodological assessment)
- country of study origin
- date period of study, date of publication

Analyses are in first instance descriptives on all extracted data, divided by intervention and control group. Where possible and appropriate, meta-analyses were intended after checking for clinical and statistical heterogeneity; however, there was too much heterogeneity to do so.

[e] http://epoc.cochrane.org/sites/epoc.cochrane.org/files/public/uploads/Resources-for-authors2017/suggested_risk_of_bias_criteria_for_epoc_reviews.pdf and http://epoc.cochrane.org/resources/epoc-resources-review-authors

[f] According to a recent ASPEN paper, parenteral nutrition is often not needed, or not appropriate and therefore a decreasing trend of PN is seen as a positive trend in more appropriate PN (Worthington et al. 2017)

1.3.2 Results

1.3.2.1 Inclusion flow

All searches were done in the last week of January 2018 and limited to the years 2000-2018. The step 2 forward searches were done in the first week of July 2018.

Table 4 – Inclusion flow

STEP 1						
	Sources Flow	**CINAHL**	**COCHRANE**	**EMBASE**	**PUBMED**	**TRIAL-REGISTER**
	INITIAL N hits	262	215	445	945	6
				TOTAL 1873		
AFTER DEDUPLICATION				1630		
INCLUDED AFTER TITLE/ABSTRACT ASSESSMENT				106		
FULL TEXT OBTAINED				104		
INCLUDED AFTER FULL TEXT ASSESSMENT				34		
		PRIMARY RESEARCH: 29 references on 24 studies			REVIEWS: 5 references on 4 studies	
STEP 2 (forward searches with 34 references included in step1)						
				TOTAL 1577		
INCLUDED AFTER TITLE/ABSTRACT ASSESSMENT				41		
FULL TEXT OBTAINED				41		
INCLUDED AFTER FULL TEXT ASSESSMENT				4		
STEP 1 AND 2				34+4=38		
		PRIMARY RESEARCH: 33 references on 27 studies			REVIEWS: 5 references on 4 studies	

As shown in Table 4, the searches from step 1 resulted in a total of 1873 references, of which 1630 unique. After assessment of title and abstract 106 references remained, of which 104 were obtained in full text. Two references (CEDIT 2005, CEDIT 2006) could not be obtained through interlibrary loan, nor by trying several times to contact the authors.

After assessment of the full texts by two reviewers independently and after discussion of disagreements, 34 references fulfilled the inclusion criteria. Five references (DeLegge and Kelly 2013, Fernandez et al. 2003, Naylor et al. 2004, Pironi et al. 2016, Watterson et al. 2009) considered 4 reviews[g] that were checked on the included studies; this gave no additional primary studies that fulfilled the inclusion criteria, on top of the ones we already included.

The forward searches from step 2 resulted in an additional 4 references of primary research (Boitano et al. 2010, Compton et al. 2014, Soguel et al. 2012, van Schaik et al. 2016), of which one (van Schaik et al. 2016) concerned an extra publication of a study that was already included in step 1.

So, for analyses there remained 33 references (Arsanious et al. 2012, Baugh et al. 2000, Boitano et al. 2010, Caccialanza et al. 2010, Caccialanza et al. 2007, Compton et al. 2014, Eaton et al. 2016, El-Alem et al. 2012, Fettes and Lough 2000, Hamid et al. 2012, Hearnshaw and Thompson 2007, Heyland et al. 2003, Hvas et al. 2014a, Hvas et al. 2014b, Hvas et al. 2015, Johansen et al. 2004, Kennedy and Nightingale 2005, Kob et al. 2016, Lamure et al. 2015, Lopez-Martin et al. 2013, Mackenzie et al. 2005, Martin et al. 2011, Massanet et al. 2012, Mistry et al. 2014, Newton et al. 2001, Parent et al. 2016, Piquet et al. 2004, Rezannah and Loeliger 2012, Soguel et al. 2012, van Schaik and Niewold 2014a, van Schaik and Niewold 2014b, van Schaik et al. 2016) about 27 studies (in the following text we will refer to studies with double publications, only with the main reference[hi]).

Of the 33 references, 12 (Arsanious et al. 2012, Eaton et al. 2016, El-Alem et al. 2012, Hamid et al. 2012, Hvas et al. 2014a, Hvas et al. 2015, Kob et al. 2016, Lamure et al. 2015, Lopez-Martin et al. 2013, Mistry et al. 2014, Rezannah and Loeliger 2012, van Schaik and Niewold 2014b) were published as conference abstracts, 3 as letters (Caccialanza et al. 2007, Newton et al. 2001, Piquet et al. 2004), and 18 as full research articles (Baugh et al. 2000, Boitano et al. 2010, Caccialanza et al. 2010, Compton et al. 2014, Fettes and Lough 2000, Hearnshaw and Thompson 2007, Heyland et al. 2003, Hvas et al. 2014b, Johansen et al. 2004, Kennedy and Nightingale 2005, Mackenzie et al. 2005, Martin et al. 2011, Massanet et al. 2012, Parent et al. 2016, Senkal et al. 2002, Soguel et al. 2012, van Schaik and Niewold 2014a, van Schaik et al. 2016).

All were written in English except one in French (Massanet et al. 2012).

A list with the studies that were excluded based on the full-text assessment, can be found in the appendix.

g In further text we use Naylor_2004 to refer to the two references (Fernandez et al. 2003, Naylor et al. 2004) publishing the same review

h So Caccialanza_2010 refers to (Caccialanza et al. 2010) and (Caccialanza et al. 2007); Eaton_2016 refers to (Eaton et al. 2016) and (Arsanious et al. 2012); Hvas_2014 refers to (Hvas et al. 2014b) and (Hvas et al. 2014a, Hvas et al. 2015); van-Schaik_2016 refers to (van Schaik et al. 2016) and (van Schaik and Niewold 2014a) and (van Schaik and Niewold 2014b)

i (van Schaik et al. 2016) is an extended study with a longer follow-up period, but contains all and more detailed data that were already in the 2 other publications from van Schaik et al. (van Schaik and Niewold 2014a, van Schaik and Niewold 2014b)

1.3.2.2 Descriptives of the included studies

Country of origin

The included studies originated from 11 different countries, but almost half of them from the UK and USA; see table 5.

Table 5 – Country of origin

Country	N	references
Australia	2	(Mistry et al. 2014, Rezannah and Loeliger 2012)
Belgium	1	(van Schaik et al. 2016)
Canada	2	(Heyland et al. 2003, Mackenzie et al. 2005)
Denmark	1	(Johansen et al. 2004)
France	2	(Lamure et al. 2015, Massanet et al. 2012)
Germany	2	(Compton et al. 2014, Senkal et al. 2002)
Italy	2	(Caccialanza et al. 2010, Kob et al. 2016)
Spain	1	(Lopez-Martin et al. 2013)
Switzerland	2	(Piquet et al. 2004, Soguel et al. 2012)
UK	8	(Eaton et al. 2016, El-Alem et al. 2012, Fettes and Lough 2000, Hamid et al. 2012, Hearnshaw and Thompson 2007, Hvas et al. 2014b, Kennedy and Nightingale 2005, Newton et al. 2001)
USA	4	(Baugh et al. 2000, Boitano et al. 2010, Martin et al. 2011, Parent et al. 2016)

Study design and methodological assessment

Only one (Johansen et al. 2004) of the included studies was a randomized trial; the others had a pre-post design (n=17) or compared groups in a non-randomized way or compared hospitals with a NST versus hospitals without a NST. Two studies (Heyland et al. 2003, Senkal et al. 2002) were based on questionnaires, while others gathered data from patient records or specially developed data collection tools. Outcome assessors were not blinded to the type of intervention.

So all but one studies have a high risk of bias, due to the chosen study design. The methodological assessment of the only RCT revealed that this study had a low risk of bias.

Care setting

All but two studies concerned acute care (university) hospitals; one study (Rezannah and Loeliger 2012) was done in a specialized cancer center and another (Hamid et al. 2012) in specialist regional center for intestinal failure and home parenteral nutrition.

Five studies (Compton et al. 2014, Heyland et al. 2003, Mackenzie et al. 2005, Massanet et al. 2012, Soguel et al. 2012) focused on intensive care patients only.

Research population sizes

First of all, there is heterogeneity in the outcomes the studies analyzed, varying from prevalence of PN use to percentage of inappropriate PN or percentage of patients on PN with complications. And accordingly the target group, c.q. the type of the denominator may vary. In Table 6 the type of denominator is given and the numbers of patients on which studies made their calculations, as far as those were given in the manuscripts.

As can be seen in Table 6, eleven studies lacked a clear denominator description and/or the size of the denominator groups. Consequently, outcome figures are difficult to interpret. E.g. what is the value of the statement found in Caccialanza et al. (Caccialanza et al. 2010) *'the number of patients treated with EN increased from 95 in 2004 to 190 in 2008 after*

the creation of a malnutrition task force' when the total number of admissions is not given and the numbers are not controlled for patient characteristics.

Only one study (Johansen et al. 2004) performed an a priori power calculation to estimate the necessary sample size. In addition, only one study (Mackenzie et al. 2005) discusses a potential lack of power in the samples to perform statistical analyses and to correctly interpret the results.

The potential lack of power is problematic especially related to the analyses done regarding infrequent complications and the 'no difference' found.

Three studies (Hvas et al. 2014b, Kob et al. 2016, van Schaik et al. 2016) have hospital wide admissions as denominator and very large sample sizes varying from 57815 to 206217.

Table 6 – denominators

Study	denominator type	denominator number control	denominator number experimental	denominator number total
(Baugh et al. 2000)	not mentioned	?	?	?
(Boitano et al. 2010)	• not clear for some outcomes • N patients with PN	• 30 for some outcomes • not clear for other outcomes	• 30 for some outcomes • not clear for other outcomes	• 60 for some outcomes • not clear for other outcomes
(Caccialanza et al. 2010)	not mentioned	?	?	?
(Compton et al. 2014)	•N ICU patients on mechanical ventilation for at least 5 days	107 (but only 73 analyzed)	119 (but only 87 analyzed)	226 (but only 160 analyzed)
(Eaton et al. 2016)	number of patients referred to NST for PN	75	328	403
(El-Alem et al. 2012)	not mentioned	?	?	?
(Fettes and Lough 2000)	not mentioned	?	?	?
(Hamid et al. 2012)	type 1 and 2 intestinal failure patients	?	?	?
(Hearnshaw and Thompson 2007)	patients with PN in 15 hospitals in 3 month period	132	61	193
(Heyland et al. 2003)	patients cared for at an ICU on 18 april 2001 from 66 hospitals in which a dietician was available for consult	?	?	702
(Hvas et al. 2014b)	hospital wide inpatient admissions	52496	•year1: 56399 •year2: 54501 •year 3: 42821 mean across 3 years: 51240	206217

(Johansen et al. 2004)	a random sample of patients at nutritional risk from 3 hospitals in 7 month period that fulfilled trial inclusion criteria and gave informed consent	104	108	212
(Kennedy and Nightingale 2005)	all patients in whom PN was considered	?	?	?
(Kob et al. 2016)	hospital wide inpatient admissions	29973	27842	57815
(Lamure et al. 2015)	patients requiring allogenic stem cell transplantation	29	47	76
(Lopez-Martin et al. 2013)	patients with PN in a 2 month period	24	38	62
(Mackenzie et al. 2005)	adult patients admitted in a 3 month period to ICU and that were mechanically ventilated and eligible for EN	61	62	123
(Martin et al. 2011)	a random sample of patient-EPISODES with PN from 4 hospitals in a 13 month period	111	167	278
(Massanet et al. 2012)	patients admitted to ICU for longer than 72 hours in a 2 month period	34	56	90
(Mistry et al. 2014)	patient EPISODES with PN in a 5 month period	32	24	56
(Newton et al. 2001)	number of patients referred to NST for PN	242	•advisory period: 235 •authoritative period: 156	633
(Parent et al. 2016)	number of patient DAYS	?	?	?
(Piquet et al. 2004)	unclear	?	?	?
(Rezannah and Loeliger 2012)	patients with PN	20	28	48
(Senkal et al. 2002)	unclear	?	?	?
(Soguel et al. 2012)	•N ICU pt with stay >72h •N ICU days	•198 patients •1861 days	•179 patients •1927 days	•377 patients •3788 days
(van Schaik et al. 2016)	hospital wide inpatient admissions	(3 years sum)= 40823	(5 years sum)= 70598	111421

The nutrition support teams

Names of nutrition support teams slightly differed between studies (e.g. multidisciplinary nutritional team, clinical nutrition advisory group, clinical nutrition unit, malnutrition task force, parenteral nutrition team) but the term nutrition support team was used most frequently.

Composition of NST

As far as described in the papers (and not always clear), the NST consisted mostly of a combination of dieticians, nurses, pharmacists and some type of physician (intensivist, surgeon, gastro-enterologist...), and in some cases complemented by other health care professionals (Table 7). The number and FTE's of NST-members was mostly insufficiently described.

Table 7 – composition of NST

Study	country	dieticians	nurses	physicians	pharmacists	others
(Baugh et al. 2000)	USA	yes	yes	yes	yes	?
(Boitano et al. 2010)	USA	yes	?	yes	yes	yes medication safety manager
(Caccialanza et al. 2010)	Italy	yes	?	yes	yes	?
(Compton et al. 2014)	Germany	?	yes	yes	?	?
(Eaton et al. 2016)	UK	yes	?	yes	yes	yes chemical pathologist, biochemist
(El-Alem et al. 2012)	UK	?	?	?	?	?
(Fettes and Lough 2000)	UK	yes	yes	yes	yes	yes biochemist
(Hamid et al. 2012)	UK	?	?	?	?	?
(Hearnshaw and Thompson 2007)	UK	?	?	?	?	?
(Heyland et al. 2003)	Canada	?	?	?	?	?
(Hvas et al. 2014b)	UK	yes	yes	yes	yes	?
(Johansen et al. 2004)	Denmark	yes	yes	?	?	?
(Kennedy and Nightingale 2005)	UK	?	yes	?	?	?
(Kob et al. 2016)	Italy	?	?	?	?	?

(Lamure et al. 2015)	France	?	?	?	?	?
(Lopez-Martin et al. 2013)	Spain	?	?	?	?	?
(Mackenzie et al. 2005)	Canada	yes	yes	yes	?	?
(Martin et al. 2011)	USA	?	?	?	?	?
(Massanet et al. 2012)	France	yes	yes	yes	?	yes Nurse aide
(Mistry et al. 2014)	Australia	?	?	?	?	?
(Newton et al. 2001)	UK	yes	yes	yes	yes	?
(Parent et al. 2016)	USA	yes	?	yes	yes	
(Piquet et al. 2004)	Switzerland	yes	yes	?	?	yes nutritionist
(Rezannah and Loeliger 2012)	Australia	?	?	?	?	?
(Senkal et al. 2002)	Germany	?	?	?	?	?
(Soguel et al. 2012)	Switzerland	yes	yes	yes	yes	?
(van Schaik et al. 2016)	Belgium	yes	?	yes	?	?

Task of NST

Due to lack of sufficient descriptions how the NSTs exactly functioned, it was impossible to extract data along the TIDIER-checklist as was intended.

Therefore we can only describe headlines of the tasks the NSTs performed.

In general most NSTs had three functions: **advice and consultation** to (in-hospital) health care professional regarding (parenteral and enteral) nutrition, **information to and training** of health care professionals, developing and implementing **nutrition related guidelines**.

Some NSTs also had a **clinical component**, by daily or weekly discussion on the wards of patients with artificial nutrition, or by discharge preparation of patients that would require artificial nutrition after discharge.

Some also deployed **quality assurance** initiatives regarding nutrition. In three studies (Caccialanza et al. 2010, Senkal et al. 2002, van Schaik et al. 2016) we found that the NST also **screened** patients for malnutrition at admission.

Mainly the role of the NST remained 'advisory', but in 2 studies (Kob et al. 2016, Newton et al. 2001) the NST had also an 'authoritative' function, in which parenteral nutrition could only be prescribed/initiated by the NST.

There seems to be a lot of heterogeneity in the way NSTs function.

Target population

The NSTs were mostly involved in patients having or possibly requiring parenteral nutrition and in some cases also the patients having or requiring enteral nutrition and in a few cases all patients having or being at risk for malnutrition.

Mostly the NSTs were involved for all hospital wards, but in some cases it was limited to surgical wards or ICU-wards only.

The description of diseases and medical interventions in the target population was insufficient to make general descriptions, but in some cases (Lamure et al. 2015, Rezannah and Loeliger 2012) it was only patients with cancer.

So, in conclusion, there is heterogeneity in composition, tasks and target population of the NSTs.

1.3.2.3 Effects of NST

General/overall

The authors of all but two publications concluded at the end of their manuscript **in favor of NSTs**. The two studies (Hearnshaw and Thompson 2007, Heyland et al. 2003) that conclude otherwise, found no difference between NST and non-NST groups. However, it was not always clear which results led to those positive conclusions, and at least the evidence base shown in the articles was poor and not compelling.

Several effects of NST were looked at across the studies: a.o. number of patients on PN or EN (16 studies), ratio of number of patients on EN versus patients on PN (4 studies), inappropriate use of PN (16 studies), inappropriate use of EN (2 studies), duration of PN (13 studies), nutritional status (12 studies), complications (16 studies), number (or waste) of PN bags (4 studies), quality of life (1 study) and costs (14 studies). Each of these effects are discussed more in depth below.

Due to heterogeneity in interventions and control conditions, patient populations, outcome measurement instruments and timing, no meta-analyses were attempted.

Prevalence PN or EN

Prevalence of PN or EN was measured in 16 studies.

Four studies (Boitano et al. 2010, Caccialanza et al. 2010, Eaton et al. 2016, Kennedy and Nightingale 2005) gave only absolute numbers of patients receiving PN or EN in the pre or post phases without mentioning the total number of patients and so no conclusions can be drawn from these articles. One study (Soguel et al. 2012) expressed prevalence in number of patient days and not in number of patients.

In one study (Senkal et al. 2002), using a questionnaire, 34 (72%) respondents stated that NSTs led to an increased use of EN instead of PN.

Five studies (Johansen et al. 2004, Lamure et al. 2015, Mackenzie et al. 2005, Massanet et al. 2012, Newton et al. 2001) gave relative percentages of patients receiving PN or EN, but the target population was not well described or related to a subsample of all admissions.

- Johansen (Johansen et al. 2004): patients at nutritionally risk: In the control group 6/99 patients received EN and 7/99 patients received PN, versus in the intervention (NST) group 10/103 patients received EN and 11/103 patients received PN
- Lamure (Lamure et al. 2015) studied stem-cell transplant patients and found that EN was given in 0/29 (0%) of the control and in 13/47 (28%) after introduction of the NST
- Newton (Newton et al. 2001) found that in the period with an advisory NST 221/235 of the patients that were referred to the NST received PN, while in the period with an authoritative NST the number of patients with PN dropped to 72/156 of the referred patients
- MacKenzie (Mackenzie et al. 2005) studied mechanical ventilated ICU-patients that were eligible for EN and found in pre-NST period that 5/61 received EN and 8/61 received PN, while in the post-NST period this dropped to 1/62 patients with EN and 1/62 with PN
- Massanet (Massanet et al. 2012) looked at percentage of patients that received EN within the first 48 hours of their ICU-admission: this was 42.8% pre and 51.2% in the post period (not significant)

Four studies, all with very large research populations, (Hvas et al. 2014b, Kob et al. 2016, Parent et al. 2016, van Schaik et al. 2016) gave hospital-wide prevalence rates of patients receiving PN related to total number of admissions, or number of patients-days receiving PN related to total of patient days:

- Hvas (Hvas et al. 2014b) found that more patients started PN after introduction of NST (0.34% in the year without NST, and a mean prevalence of 0.52% across the 4 years after introduction of the NST)
- Kob (Kob et al. 2016) found PN prevalence rate of 3.7% in the NON-NST period versus 1.9% in the period with mandatory NST
- Parent (Parent et al. 2016) on the other hand found a significant decrease from 1.43 per 1000 patient days that started PN in the pre-NST period to 1.04 per 1000 patients days after the NST introduction
- van Schaik (van Schaik et al. 2016) also found a decrease in patients with PN from 377/13822 (2.7%) admissions on PN in the pre-NST-period compared to 1320/70598 (1.87%) patients on PN in the 5-years (2010-2014) after NST introduction, while the prevalence of patients on EN remained stable on about 1.1%

So, three studies found a lower PN prevalence in the NST-groups than without NST, while one study found the opposite.

Remarkable is the PN prevalence rates in these hospital wide studies vary widely from 0.34% up to 3.7%; the reason for this is not clear.

Four studies (Caccialanza et al. 2010, Kob et al. 2016, Newton et al. 2001, Piquet et al. 2004) approached PN use by counting the number of PN bags used (or wasted). Caccialanza (Caccialanza et al. 2010) stated the number of bags remained stable, Kob (Kob et al. 2016) found an increase in PN bags (but a decrease in customized PN bags and a decrease in patients with PN) and Piquet (Piquet et al. 2004) a decrease. However these trends are difficult to interpret. One study (Newton et al. 2001) found a decrease in wasted PN-bags, but also here difficult to interpret since total number of patients on PN is not given.

So, in conclusion, there is conflicting evidence to wether a NST leads to a reduction or an increase in patients starting PN.

Rate EN/PN

Four studies compared the ratio between EN/PN before versus after introduction of a NST. Hvas (Hvas et al. 2014b) does not give data but only states that NST lead to an increased conversion from PN to EN; and in the questionnaire based study of Senkal (Senkal et al. 2002), 72% of respondents states that NST lead to an increased use of EN instead of PN.

The study of Soguel et al. (Soguel et al. 2012) in ICU patients found an EN/PN rate (based on patient days) of 9.2 in the control condition and 6.2 after introduction of the NST.

Only the study of van Schaik (van Schaik et al. 2016) presented real hospital wide data and found that the ratio EN/PN increased from 0.44 before NST to 0.64 in the second year after NST and to 0.83 in the fifth year after.

So, in conclusion, there is weak evidence that a NST might lead to an increase in the ratio EN/PN use

(In)appropriate use of PN

(In)appropriate use of PN was measured in 16 studies:

Table 8 – (in)appropriate use of PN

Study	out: (in)appropriate PN use definition	results outcome inappropriate PN use CONTROL	results outcome inappropriate PN use EXPERIMENTAL	results outcome inappropriate PN use according to authors	results outcome inappropriate PN use according to authors POSITIVE?
(Baugh et al. 2000)	TPN-orders were considered inappropriate if they did not meet patient nutritional needs as identified by the nutrition assessment or documented goals	Pre1: 25% Pre2: 30%	Post1: 17.5% Post 2: 10.6% Post 3: 12.3% Post 4: 10% Post 5: 10%	59% increase in appropriate PN-orders	yes
(Boitano et al. 2010)	• appropriate PN if according to ASPEN guideline 2002 • appropriate if PN is at least 5-7 days	• 60% of pt according to ASPEN Guidelines • 53% of pt received PN for at least 5 days	• 97% of pt according to ASPEN Guidelines • 83% of pt received PN for at least 5 days	less inappropriate PN use i	yes
(Eaton et al. 2016)	• not well defined • started inappropriately PN • less < 5days	• started inappropriate PN: 15 (20%) • less than 5 days: no data	• started inappropriate PN: 19 (6.7%) • less than 5 days: 76 (26.7%)	• less inappropriate PN • less patients with PN <5 days	yes
(El-Alem et al. 2012)	difficult definition and difficult to interpret data			our data demonstrates that timely involvement of the NST in feeding decisions can	yes

				avert inappropriate initiation of PN in a significant proportion of cases, which has clinical and cost-saving implications	
(Fettes and Lough 2000)	not well defined (there is something of prescribed vs required energy and nitrogen, but data can not well be interpreted	no interpretation possible	no interpretation possible	• in the hospital without NST 4 patients for whom there was no apparent indication for PN received PN • in the hospital with NST the energy content of prescribed regimens and energy intake of patients was closer to estimated requirements	yes
(Hamid et al. 2012)	not well defined	appropriate indication for PN (NCEPOD-study): 71%	appropriate indication for PN : 95%	the NST appeared to prevent inappropriate use of PN by not starting 12% of referred patients	yes
(Hearnshaw and Thompson 2007)	Appropriate PN when there is a clear indication by using the clinical indications cited in the BAPEN guidelines and by using the patient characteristics cited in the NICE 2006 guidelines; patients episodes were required to have one or more of the following to be deemed appropriate for PN (short bowel syndrome (<50cm functioning small bowel with colon or <100cm small bowel with no colon, intestinal obstruction, ileus/severe dismotility, intestinal fistulae, recent surgical resection of small bowel, diagnosed severe malabsorption, severe pancreatitis, severe mucositis and/or intestinal failure for more than 4 days as recorded in the medical notes)	Hospitals without NST: clear PN indication 108 (82%)	Hospitals with NST: clear PN indication 50 (82%)	having a NST in the hospital made no difference to the number of patients receiving PN with no clear indication	no
(Hvas et al. 2014b)	Appropriateness of PN commencement, as reflected by an increased conversion from parenteral to enteral nutrition, principally among medical teams that infrequently referred to PN. Enhanced appropriateness for PN was further reflected by a shift in the indications for PN commencement following NST implementation, in that there was a reduction in patients commencing PN owing to an insufficient oral or enteral intake, with a concomitant increase in those starting PN because of an inaccessible gut	not clear	not clear	• the frequency of patients in whom PN was started owing to an insufficient oral or enteral intake decreased from 11% to 3% (p=0.01) whereas the frequency of patients who were started on PN because of inaccessible gut increased concurrently • the overall percentage of PN referrals where PN was not started increased from	yes

				5.3% in 2009 to 10.1% in 2012 (p=0.03)	
(Kennedy and Nightingale 2005)	not well defined	not clear	not clear	in the NST year 55 (41%) of PN referrals were fed orally or enterally	yes
(Kob et al. 2016)	not well defined	N patients with PN = 1109	N patients with PN =529	involvement of NST resulted in a significant reduction of the number of patients with PN and an increase in the average PN duration, indicating indirectly an increase in appropriateness	yes
(Lopez-Martin et al. 2013)	Duration of PN < 7 days	Pre: 16/24 (67%)	Post: 8/38 (22%)	p=0.001; decrease in appropriate duration of PN	yes
(Mackenzie et al. 2005)	PN use deemed appropriate according to predetermined criteria: mechanical bowel obstruction, GI haemorrhage, high output fistula (>500 mL/24 hours), new short-bowel syndrome with <60 cm remaining small bowel.	inappropriate PN: 8/61 (13.6%)	inappropriate PN: 1/62 (1.6%)	p=0.02	yes
(Martin et al. 2011)	• PN use was considered as inappropriate when this question was answered with 'yes': "If the patient has a functional GI tract, and if enteral feedings have not been tried, could the patient be fed enterally based on your clinical opinion?" • "Number of cases determined to be inappropriate vs appropriate as determined by trained registered dieticians based on the 2002 American Society for Parenteral and Enteral Nutrition guidelines	2 hospitals without NST: rate inappropriate 23/69, 15/42 =38/111 (34%)	2 hospitals with NST: rate inappropriate 19/81, 33/86 = 52/167 (31%)	unclear conclusion, but in favor of NST	yes
(Newton et al. 2001)	Patients who received PN but who could have been fed more suitably by another route	Pre: 31%	Post 1: 21% Post 2: 3%	in favor of NST	yes
(Parent et al. 2016)	Duration of PN < 5 days	Pre: ICU: rate 1.54/1000 patient-days Pre: acute floors: rate 0.27/10000 patient-days	Post: ICU: rate 1.08/1000 patient-days Post: acute floor: Rate 0.19/10000 patient-days	the rate of patients with short duration PN use declined by 30% in the ICU (RR=0.70; 95CI:0.51-0.97) and by 27% on acute floors (RR=0.73; 95%CI 0.51-1.03)	yes
(Piquet et al. 2004)	indication of PN was considered as inappropriate when it was not required according to guidelines (Klein 1997) or when the gastro-intestinal tract could be used	19/69 (28%)	0/31 (0%)	more inappropriate PN use in control than in experimental	yes

Some authors defined inappropriate PN use as use of PN in patient categories not in correspondence with the guidelines on PN use specified for these patient groups, and/or as too short duration of PN, while others only used the term but did not define it.

As shown in Table 8, 15 of the 16 studies conclude in favor of the NST and that inappropriate use of PN decreased after introduction of the NST; one study (Hearnshaw and Thompson 2007) found no difference.

However, several studies did not perform statistical analyses on the difference found between intervention and control groups or conclude positively despite non-significant results or found differences only in a subpopulation of patients. In only 2 of the 16 studies (Lopez-Martin et al. 2013, Newton et al. 2001) a compelling difference was demonstrated found in favor of the NST: Lopez (Lopez-Martin et al. 2013) found that less patients received PN with duration <7 days and Newton (Newton et al. 2001) found that less patients with PN that could have been fed more suitably by another route.

So, overall, there is weak evidence that NST might decrease inappropriate PN use, and there are no studies that show (tendencies to) reverse effect.

(In)appropriate use of EN

Two studies (Compton et al. 2014, Massanet et al. 2012) looked at appropriate use of EN, both in ICU patients; Massanet et al. defined 'appropriate' was defined as start of EN within 48 hours after admission on ICU for patients that had a resuscitation, while Compton et al. defined as the number of patients starting with EN on the first day of ICU-admission.

Massanet et al. found that in the before phase 42.8% (total N 34) of patients started with EN within 48 hours and in the phase after introduction of a NST it was 51.2% (total N was 56): a non-significant difference. Compton et al. found that significantly more patients were started EN on day 1 (p=0.03) after NST introduction (38 vs 54%).

So, there is weak evidence that NST might increase appropriate EN use in ICU patients.

Duration of PN

Duration of PN was measured in 13 studies (Boitano et al. 2010, Eaton et al. 2016, Fettes and Lough 2000, Hearnshaw and Thompson 2007, Hvas et al. 2014b, Kennedy and Nightingale 2005, Kob et al. 2016, Martin et al. 2011, Mistry et al. 2014, Newton et al. 2001, Parent et al. 2016, Rezannah and Loeliger 2012, van Schaik et al. 2016). Three studies (Eaton et al. 2016, Kob et al. 2016, Newton et al. 2001) found an increase in PN duration, while the others found no differences. Due to differences in presentation of duration (mean, median, range), it was impossible to combine the results.

So, there is no convincing evidence that NST leads to a different PN duration.

Nutritional status

Nutritional status was measured in 12 studies; however operationalisations differed a lot, making overall conclusions difficult to draw. Eight studies conclude in favour of the NST-intervention:

- Boitano (Boitano et al. 2010) found that more (54 vs 85%) patients received adequate calories provision after NST introduction
- Fettes (Fettes and Lough 2000) found that overfeeding was more prevalent in the non-NST hospitals versus NST-hospitals
- Hamid (Hamid et al. 2012) found much lower rates of PN-related metabolic complications (5% vs 40%) in the NST condition
- Johansen (Johansen et al. 2004) found that the NST led to an intake of >75% requirements in 62% of intervention patients as compared to 36% of the control patients
- Lopez-Martin (Lopez-Martin et al. 2013) found that NST improves quality of PN (increase in albumin and pre-albumin)

- MacKenzie (Mackenzie et al. 2005) found that the percentage of patients receiving at least 80% of energy requirements was significantly higher in NST patients (60% vs 20%) and that the median proportion of prescribed calories actually received was significantly higher in NST group (0.83 vs 0.56, p<0.001)
- Massanet (Massanet et al. 2012) found that NST-intervention optimised calorie and protein intake
- Soguel (Soguel et al. 2012)found that an increase in daily energy delivery, but no difference in energy balance more patients recieved

On the other hand 4 studies found no differences in nutritional status between groups:

- Compton (Compton et al. 2014) found no differences in % of patients in which enteral feeding goal was reached during stay
- Heyland (Heyland et al. 2003) found that the presence of a NST did not seem to make a difference in optimal provision of nutrition support
- Lamure (Lamure et al. 2015) found nutritional status was comparable in both groups
- Rezannah (Rezannah and Loeliger 2012) found that percentage of patients that failed to meet 80% of their nutritional requirements was equal in both groups (35%)

In conclusion, the different operationalisations of nutritional status prohibits to draw overall conclusions, but at least there are no indications that NST may impede nutritional status.

Complications

Sixteen studies measured complications. Most (7x) were on infectious or PN-catheter related complications:

- Less in NST group:
  - Hamid (Hamid et al. 2012) found 26% of patients with catheter related complications in non-NST versus 5% in NST
  - Kennedy (Kennedy and Nightingale 2005) found 7.06 Catheter related sepsis per 100 PN days in non-NST versus 3.26 CRS per 100 PN days in NST
  - Newton (Newton et al. 2001) had 21% of patients with feeding line sepsis in the non-NST group versus 4.2% in advisory NST period and 2% in the authoritative NST-period
  - Piquet (Piquet et al. 2004) had 25 patients with catheter related infection in non-NST versus 3 patients in NST, but percentages are not given
- Equal
  - Rezannah (Rezannah and Loeliger 2012) had 5/20 patients 25% with a positive blood culture in non-NST versus 6/28 (21%) in NST-group
  - Soguel (Soguel et al. 2012) found no differences in complications related to feeding (broncho-aspiration, catheter related infections, pneumothorax, hyperglycemic events) in anonymous self reporting system
- More in NST group:
  - Fettes (Fettes and Lough 2000) found catheter removal because of suspected infection 18% in NON-NST vs 26% in NST group

So, there are tendencies that NST may improve catheter related infections.

Another complication that was measured was mortality: 4 studies (El-Alem et al. 2012, Mackenzie et al. 2005, Parent et al. 2016, Soguel et al. 2012) found no differences between groups, while Kennedy (Kennedy and Nightingale 2005) claims advantage of NST in reducing mortality 23/54 (43%) patients died in non-NST versus 18/75 (24%) in NST-group and in the questionnaire study of Senkal (Senkal et al. 2002) 4% of respondents thought that mortality decreased after introduction of NST. So, there is no convincing evidence that NST reduces mortality.

Boitano (Boitano et al. 2010) found similar rates in symptoms of refeeding.

Three other studies measured complications without clearly specifying what was meant by complications or as combination of different complications: Hearnshaw (Hearnshaw and Thompson 2007) states that the hospitals with nutrition support teams had higher complications rates, but as the actual numbers in the individual sites are small, there is insufficient power to detect significant differences; Hvas (Hvas et al. 2014b) found 18/180 (10%) of patients with complications in non-NST group versus 17/810 (2.1%) in NST group and Johansen found 23/104 patients with complications in non-NST group versus 34/108 in NST-group, but this difference was not statistically significant.

So, overall there is no convincing evidence that NSTs reduce complications, but there is a weak tendency that catheter related infections may decrease after introduction of a NST.

Quality of life

One study (Johansen et al. 2004) measured quality of life by use of SF-36 QoL on day 1 of admission and 28 days later. There was no difference between NST and non-NST groups.

Costs/savings

Financial outcome was mentioned in 14 studies. One study (Lopez-Martin et al. 2013) mentions that the benefits achieved by the NST are associated with an incremental costs of 559 euro per patient: all other studies (Baugh et al. 2000, Boitano et al. 2010, Eaton et al. 2016, Kennedy and Nightingale 2005, Kob et al. 2016, Martin et al. 2011, Mistry et al. 2014, Newton et al. 2001, Parent et al. 2016, Piquet et al. 2004, Rezannah and Loeliger 2012, Senkal et al. 2002, van Schaik et al. 2016) conclude that NSTs lead to substantial savings. However, all studies lacked a clear description on how costs and savings were calculated, prohibiting to draw conclusions.

So, despite an overall tendency of cost savings due to the NST, there is no convincing evidence.

1.3.3 Discussion & conclusion

The main findings from this review based on 27 included studies are that there is:

- **high risk of bias in the included studies due weak study designs**
- **heterogeneity in composition, tasks and target population of the NSTs**
- **conflicting evidence to weather a NST leads to a reduction or an increase in patients starting PN**
- **weak evidence that a NST might lead to an increase in the ratio EN/PN use**
- **weak evidence that NST might decrease inappropriate PN use, and there are no studies that show (tendencies to) reverse effect**
- **weak evidence that NST might increase appropriate EN use in ICU patients**
- **no convincing evidence that NST leads to a different PN duration**
- **no indications that NST may impede nutritional status**
- **no convincing evidence that NSTs reduce complications, but there is a weak tendency that catheter related infections may decrease after introduction of a NST**
- **no convincing evidence, despite an overall positive tendency, that NST leads to cost savings**

Although almost all studies conclude in favour of a NST, the evidence base is weak. Our a priori hypotheses could not be confirmed by our review results.

In our searches we identified 4 reviews (DeLegge and Kelly 2013, Naylor et al. 2004, Pironi et al. 2016, Watterson et al. 2009) that were used to track additional primary studies. Next to this, these reviews are a good source to compare our findings.

- Our findings contradict the conclusions of the review of De Legge (DeLegge and Kelly 2013), which is very positive about the effects of NSTs; however, this review does not contain a clear methodology on how the review was performed and lacks also search strategies;
- The identified ESPEN guideline on chronic intestinal failure in adults (Pironi et al. 2016) has 3 recommendations in which they recommend NST as intervention in the care for patients with chronic intestinal failure or short bowel syndrome and for patients on home parenteral nutrition; however, the publication does not list the methodology that was used to come to these recommendations and moreover, all three recommendations are labelled by the authors as ‘grade of evidence: very low’
- The practice guidelines for the nutritional management of malnutrition in adult patients across the continuum of care (Watterson et al. 2009) state that ‘ a nutrition support team may improve outcomes including energy and protein intake, complications and cost in acute care setting’ with a level C strength of evidence (meaning ‘body of evidence provides some support for recommendation but care should be taken in its application’); moreover the recommendation was based on 2 publications only
- the 2004 review of Naylor et al. (Naylor et al. 2004) is a well-performed systematic review with very similar inclusion criteria as ours; they could include 11 studies from 1980 to 2001, of which none of them were randomized trials; their conclusions are that
  - *‘the general effectiveness of the TPN team has not been conclusively demonstrated’*,
  - *‘there is evidence that patients managed by TPN teams have a reduced incidence of total mechanical complications; however, it is*

unclear if there is a reduction in catheter-related sepsis and metabolic and electrolyte complications',

- *'it was unclear if the management of the patients by the TPN team prevented the inappropriate use of TPN therapy'*
- and *'the available evidence, although limited, suggests financial benefits from the introduction of multidisciplinary TPN teams in the hospital setting.'*

These conclusions of Naylor et al. are very well in line with our findings from the 27 studies dating between 2000 and 2018.

In our review, we encountered different definitions on what is considered appropriate or inappropriate PN or EN use (e.g. is shorter or longer duration of PN good or not); this might be due to different kinds of patients and/or different kinds of interventions/procedures. However, this makes it difficult to compare and interpret the results of the different studies.

Anyhow, it is essential that more randomized studies will be attempted to proof or contradict the positive trends found in the non-randomized studies in our and in earlier reviews.

Awaiting such new results, there is currently lack of sufficient evidence either pro or contra NSTs.

Limitations: we chose 'prevalence of EN or PN' as our primary outcome; it might be the case that some studies chose other outcomes of effectiveness of NST and so we did not include those (e.g. (Braun et al. 2016, Sutton et al. 2005); however, in the studies that we included, we also analysed the other outcomes that were analysed and did not find firm evidence.

We excluded studies in which only elements of the NST functioning were changed, e.g. protocol change, order-writing privileges, adding an extra discipline; this type of studies perhaps could have given more insight into working elements of the NST concept (e.g. adding nutrition nurse (Goldstein et al. 2000) or adding a 'dedicated' dietician (Soguel et al. 2012)).

We found heterogeneity in the composition of NST and unclear description of NST tasks; for those who are interested we like to refer to articles that contain more extensive information on these aspects; see a.o. (Anderson 2017, Boeykens and Van Hecke 2018, DeChicco and Steiger 2016, Desport et al. 2009, Lee et al. 2018, Nederlands Voedingsteam Overleg 2013).

Furthermore, it should be mentioned that the concept of NST is a kind of black box, since it is a multi-component intervention, including a multitude of different compositions and a multitude of working processes. In consequence, it is difficult to attribute effects to the specific element. Moreover, some effects that we found in this review might also be the effect of something else that happened in the study environments; e.g. a changed guideline. One could question if the effect is due to the changed guideline itself or was it the NST that helped to introduce the guideline?

With regard to secondary outcomes, e.g. cost/savings, it must be kept in mind that probably there are more studies on these issues (e.g. (Dinenage et al. 2015, Hall 2015, Klek et al. 2011, Scott et al. 2005)), but were not included in our review, since they did not contain information on our primary outcome. In consequence, our conclusions related to these secondary outcomes should be read with caution. Another approach of searches and inclusion criteria and inclusion process would be needed to come to full conclusions on these aspects.

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2 PART 2: PATIENTS ON ENTERAL OR PARENTERAL NUTRITION IN BELGIUM

2.1 Introduction

In this chapter, we aimed to analyse the profile of adult patients on enteral or parenteral nutrition. The analysis of available Belgian data tries to provide an answer to the following questions:

- What is the current and past prevalence of adult patients on enteral or parenteral nutrition, both inside and outside the hospital?
- What is the duration of enteral and parenteral episodes in hospital and at home?
- What variability in prevalence exists between hospitals?

There does not exist one single data set in Belgium that contains all data available on patients with enteral or parenteral nutrition. We considered and analysed multiple data registrations so a more or less complete picture on enteral and parenteral nutrition use can be composed.

2.2 Which data exists on enteral and parenteral nutrition?

An overview Table 9 presents the measures potentially available for the analysis per data source. By potentially available we mean the measures are theoretically available in the data source but possible cover a subpopulation or are subject to limits after actual assessment of the data. The following subsection provides details on these data sources.

Table 9 – Overview of measures potentially available by data sources per setting (see the next section for a detailed description by source).

		MZG-RHM–AZV-SHA (TCT)	VG-MZG – DI-RHM	NST registration	Nutrition Day	IMA – AIM	RD 2009
Time window		2003 (2008) – 2016	2008 – 2016	2007 – 2016	2011 – 2017	2007 – 2016	2011 – 2016
Registration type		continuous	discontinuous	continuous	discontinuous	continuous	continuous
Registration unit		hospital stay	nursing episode (4 periods of 15 days) per year	patient observation	one day per year	health care act	patient
Nutritional status	Primary measure			🏥	🏥		
Prevalence	Primary measure	🏥	🏥	🏥	🏥	🏥P + 🏠	🏠P
Ratio enteral/parenteral	Primary measure	🏥	🏥	🏥	🏥	🏥P + 🏠	
Duration	Primary measure	🏥	🏥	🏥		🏥P + 🏠	
Diagnosis	Subgroup analysis	🏥	🏥				🏠P
Nutrition support team	Subgroup analysis			🏥	🏥		
Setting characteristics	Subgroup analysis	🏥	🏥			🏥P + 🏠	

🏥 = *in hospital;* 🏥P *in hospital, parenteral only;* 🏠 *= outside of the hospital;* 🏠P *= outside of the hospital, parenteral only.*

2.2.1 MZG–RHM – AZV-SHA (TCT)

2.2.1.1 Description

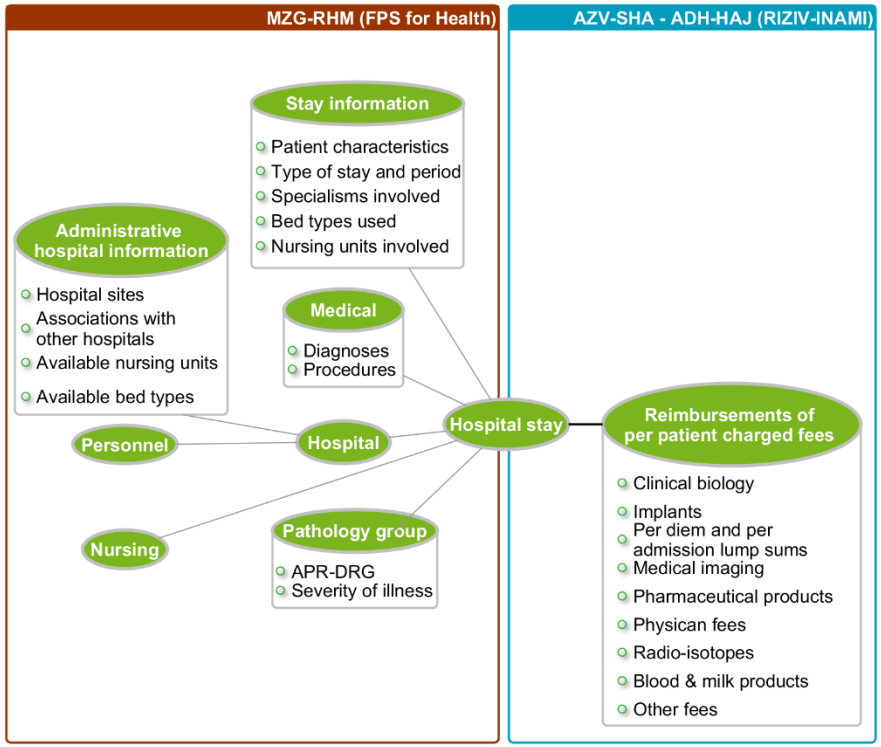
The “Technical Cell – Cellule Technique” (https://tct.fgov.be) created in the Law of 29 April 1996, is a common service of the RIZIV–INAMI and FPS Public Health. Its mission is to collect, link, validate, anonymize data relating to hospitals. The TCT links the Minimal Hospital Data (MZG-RHM) to the Sickness Funds reimbursement data in hospital for the analysis of links between the expenditures of the health care insurance and the treated condition and for the elaboration of financing rules, accreditation standards and quality conditions in the context of an effective health policy.

Access of the KCE to the Technical Cell data is regulated in the same law as the Technical Cell. The data originating from the TCT will be referred to as MZG-RHM (TCT).

Belgian general hospitals are required to provide twice a year, a minimal data set on the administrative, medical and nursing characteristics of both inpatient and day-care stays called MZG-RHM[j]. The data collection serves two general purposes: a) support government health policy on the need, epidemiology, quality, and financing of hospital provisions; b) support the health policy of hospitals by providing individual hospital feedback.

The MZG-RHM data collection contains information per hospital stay on several domains: medical, administrative, nursing and staffing (see Figure 2). It also contains a registration on nursing activity, called VG-MZG – DI-RHM. We describe this latter registration in a separate section below.

Figure 2 – TCT data overview



j MZG: Minimale Ziekenhuisgegevens; RHM: Résumé Hospitalier Minimum.

2.2.1.2 Definition of measures

In the MZG-RHM part of the TCT data (2008 to 2014 and 2016), the following ICD-9-CM procedure and diagnostic codes were used to identify enteral nutrition: 96.6 ("Enteral infusion of concentrated nutritional substances"), 96.35 ("Gastric gavage), V44.1 ("Gastrostomy status"), and V44.4 ("Status of other artificial opening of gastrointestinal tract").

For parenteral feeding, the ICD-9-CM procedure code is 99.15 ("Parenteral infusion of concentrated nutritional substances").

In addition to the MZG-RHM in the TCT data, we received analyses performed by the FPS Public Health on the original MZG-RHM (2003 to 2014 plus 2016[k]). We used the same ICD-9-CM codes for 2003 to 2014. For 2016, we used ICD-10-BE codes in Table 10.

Table 10 – ICD-10-BE diagnostic and procedure codes for enteral and parenteral nutrition

	Code	Description
Enteral nutrition	0DH67UZ	Insertion of Feeding Device into Stomach, Via Natural or Artificial Opening
	0DH68UZ	Insertion of Feeding Device into Stomach, Via Natural or Artificial Opening Endoscopic
	3E0G36Z	Introduction of Nutritional Substance into Upper GI, Percutaneous Approach
	3E0G76Z	Introduction of Nutritional Substance into Upper GI, Via Natural or Artificial Opening
	3E0G86Z	Introduction of Nutritional Substance into Upper GI, Via Natural or Artificial Opening Endoscopic
	Z931	Gastrostomy status
	Z934	Other artificial openings of gastrointestinal tract status
Parenteral nutrition	3E0336Z	Introduction of Nutritional Substance into Peripheral Vein, Percutaneous Approach
	3E0436Z	Introduction of Nutritional Substance into Central Vein, Percutaneous Approach
	3E0536Z	Introduction of Nutritional Substance into Peripheral Artery, Percutaneous Approach
	3E0636Z	Introduction of Nutritional Substance into Central Artery, Percutaneous Approach

Table 11 provides the definitions of the available primary measures in MZG-RHM.

k In 2015, the coding system changed from ICD-9-CM to ICD-10-BE. For this reason, no data are available in 2015 MZG-RHM.

Table 11 – Definitions of primary measures for MZG – RHM

Measure	Definition enteral
Prevalence of stays	$P\ year\ x_{nutrition\ type} = \frac{stays\ year\ x_{nutrition\ type}}{stays\ year\ x_{all}}$ with $stays\ year\ x_{nutrition\ type}$ = number of inpatient stays in year x with at least one ICD-9-CM or ICD-10-BE diagnostic or procedure code of the nutrition type (enteral or parenteral) for patients aged 18 years or older; $stays\ year\ x_{all}$ = number of inpatient stays in year x for patients aged 18 years or older.
Prevalence of patients	Similar to the prevalence of stays, but with patients as the unit of measurement.
Ratio enteral/parenteral	$R_{year\ x} = \frac{P\ year\ x_{enteral}}{P\ year\ x_{parenteral}}$
Duration	Because the ICD-9-CM and ICD-10-BE diagnostic and procedure codes are not coded per day the nutrition was administered, the codes could not be used for an exact calculation of the duration. However, we calculated duration as the difference between the first occurrence of the codes and the end of the stay. This is likely to overestimate the duration in a number of stays.

2.2.2 VG-MZG – DI-RHM

2.2.2.1 Description

In the MZG-RHM registration, a specific dataset exists with registered nursing activity for a number of care items, among which enteral and parenteral nutrition. These activities are registered four times a year for a period of 15 days each. This VG-MZG – DI-RHM dataset is linked to the other datasets in the MZG-RHM registration.

The VG-MZG – DI-RHM is thus a subsample of all hospital stays of on average 23% (SD = 0.5%) of hospital stays per year between 2008 and 2014 (29% (SD = 0.8%) when taking into account only nutrition related stays).

2.2.2.2 Definition of measures

VG-MZG – DI-RHM contains the item D300: “care related to the administration of enteral nutrition by probe”. This item must be scored if a nurse administered enteral nutrition either through a gastro-intestinal probe (score 1) of through artificial route (gastrostomy or jejunostomy; score 2). For our analysis, we do not make a distinction between the two types.

For parenteral nutrition, item D400 is used: care related to the follow-up of total parenteral nutrition. The item is scored 1 if any such care was administered.

Table 12 provides the definitions of the available primary measures in VG-MZG – DI-RHM.

Table 12 – Definitions of primary measures for VG-MZG – DI-RHM

Measure	Definition enteral
Prevalence of stays	$P\ year\ x_{nutrition\ type} = \frac{stays\ year\ x_{nutrition\ type}}{stays\ year\ x_{all}}$ with $stays\ year\ x_{nutrition\ type}$ = number of inpatient stays in year *x* with at least one scored VG-MZG – DI-RHM nutrition item (enteral or parenteral) for patients aged 18 years or older; $stays\ year\ x_{all}$ = number of inpatient stays with VG-MZG – DI-RHM registration in year *x* for patients aged 18 years or older.
Prevalence per registration day	$P\ day\ x_{nutrition\ type} = \frac{stays\ day\ x_{nutrition\ type}}{stays\ day\ x_{all}}$ with $stays\ day\ x_{nutrition\ type}$ = number of inpatient stays on registration day *x* with at least one scored VG-MZG – DI-RHM nutrition item (enteral or parenteral) for patients aged 18 years or older; $stays\ day\ x_{all}$ = number of inpatient stays with VG-MZG – DI-RHM registration on registration day *x* for patients aged 18 years or older.
Ratio enteral/parenteral	$R_{year\ x} = \frac{P\ year\ x_{enteral}}{P\ year\ x_{parenteral}}$
Duration	In VG-MZG – DI-RHM, each item needs to be scored each day of the registration period. However, because VG-MZG – DI-RHM is limited to 15 days per registration period, in longer or already started stays, duration is underestimated. We therefore decided not to use VG-MZG – DI-RHM for calculating duration.

2.2.2.3 Comparison of MZG – RHM and VG-MZG – DI-RHM coding

The FPS Public Health provided us with a comparison of the registration of enteral and parenteral nutrition for the inpatient stays for adults aged 18 years or older both in MZG – RHM and VG-MZG – DI-RHM.

For inpatient stays in 2014, either identified in the MZG – RHM or VG-MZG – DI-RHM with enteral nutrition, about 51% were identified in both registrations (see Figure 3. About 46% had at least one registration for enteral nutrition in VG-MZG – DI-RHM, but no corresponding registration in MZG – RHM. This result strongly suggests an undercoding of enteral nutrition in MZG – RHM.

Vice versa, about 3% of inpatient enteral stays were identified in MZG – RHM but had no registration in VG-MZG – DI-RHM. Almost all of these stays are stays that are longer than the VG-MZG – DI-RHM registration period. In this case, the mismatch is not due to undercoding but due to partial coverage of VG-MZG – DI-RHM registration of the stay.

For parenteral nutrition, inpatient stays in 2014 either identified in the MZG – RHM or VG-MZG – DI-RHM, about 64% had parenteral coding in both registrations (see Figure 4). The undercoding seems to be less strong at 27% compared to enteral nutrition coding. Here also, partial coverage of the VG-MZG – DI-RHM registration of longer stays, accounts almost entirely for about 9% of MZG – RHM inpatient stays without VG-MZG – DI-RHM coding.

Figure 3 – Percentage of enteral stays matched per source by year.

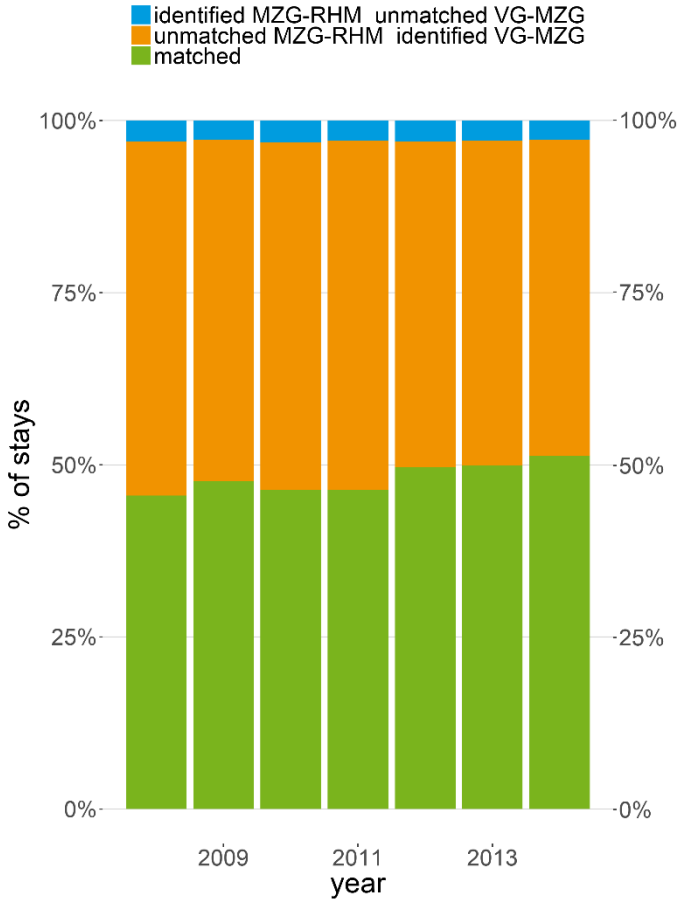
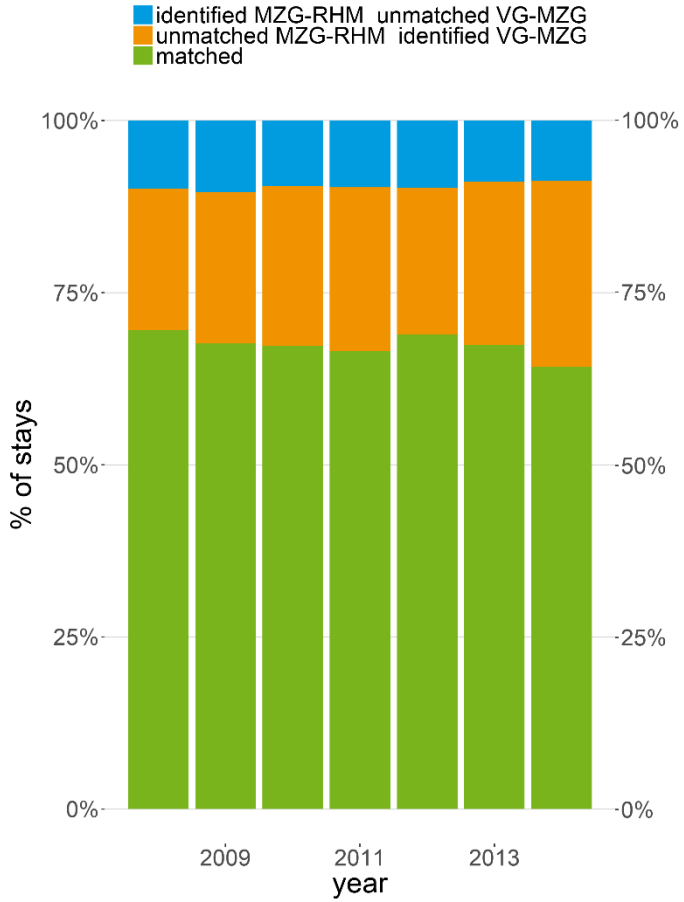


Figure 4 – Percentage of parenteral stays matched per source by year.



The number of unmatched stays differs per hospital (see the appendix to this chapter, section 1.1 for further details).

2.2.3 Nutrition Support Team (NST) registration

2.2.3.1 Description

As part of the financing of NST, hospitals need to report on the nutrition support teams to the FPS Public Health. Although in theory, several measure could be calculated on this registration, we opted not to use the activity registration for calculating prevalence or duration because of the data issues described in Part 1.

2.2.4 nutritionDay

2.2.4.1 Description

nutritionDay worldwide is an international effort to improve knowledge and awareness of malnutrition in health care institutions. Each year, hospitals and nursing homes can submit aggregated data related to nutrition to this initiative collected on one particular day of the year. Overview country reports are available from https://www.nutritionday.org/en/about-nday/national-reports/index.html. For Belgium, data on all patients of participating wards are available from 2011 to 2017, with the exception of 2015 for which only data on oncological patients is published.

2.2.4.2 Definition of measures

Enteral and parenteral nutrition are items in the published country reports. Table 13 defines the primary measures available in nutritionDay.

Table 13 – Definitions of primary for measures for nutritionDay

Measure	Definition enteral
Prevalence of patients	Published percentage of patients by nutrition type

2.2.5 IMA – AIM

2.2.5.1 Description

The IMA-AIM[l] is a non-profit organisation that manages and analyses information on all reimbursements related to the compulsory health insurance, collected by the Belgian sickness funds. These data cover all reimbursed services (consultations, pharmaceuticals, diagnostic and therapeutic procedures) and some patient socio-demographic characteristics as well as social security related data to the extent they influence reimbursement.

2.2.5.2 Definition of measures

For ambulatory nutrition use, adult patients were selected using the RIZIV nomenclature codes for enteral and parenteral nutrition, as described in Table 14. The de facto selection is from 2007 to 2016 as the RIZIV–INAMI reimburses ambulatory enteral and parenteral nutrition at home from 2007 onwards.

[l] IMA: Intermutualistisch Agentschap; AIM: Agence Intermutualiste.

Table 14 – RIZIV nomenclature codes for enteral and parenteral nutrition at home

Description	RIZIV nomen-clature code	Excluded?
Enteral nutrition via tube		
Administration of a polymer product	751251	
Administration of a semi-elemental product	751273	
Use of material without a pump	751295	
Use of material with a pump	751310	
Use of the pump	751332	
Parenteral nutrition		
Bags tailored for adults	751354	
Bags tailored for children up to 17 years	*751376*	*Out of scope*
Industrial pre-mixtures with or without minerals and/or vitamins	751391	
Bags of perdialysis	751413	
Administration of electrolytes on days without parenteral	751951	

For parenteral nutrition in hospitals stays, we used the reimbursement of parenteral pharmaceutical products with ATC code B05BA (solutions for parenteral nutrition) and subcodes to select patients. Since enteral nutrition as a product is not reimbursed in the hospital, we could not identify patients with enteral nutrition in a hospital stay in the IMA – AIM data.

To assess the validity of using the parenteral pharmaceutical products for identifying patients with parenteral nutrition in hospital in the IMA – AIM data, we performed a sensitivity-specificity analysis in the TCT data which includes both the procedure for parenteral nutrition as well as the reimbursement of the parenteral pharmaceutical products (see 2.2.1.1 for details on the TCT data).

For the sensitivity-specificity analysis, we considered the identification of parenteral nutrition based on the ICD-9-CM and ICD-10-BE to be the reference (see 2.2.1.1 and 2.2.2.3 for more details). We calculated sensitivity and specificity of using the parenteral pharmaceutical products compared with this reference. We considered the ATC codes in Table 15.

Table 15 – ATC codes for parenteral nutrition

ATC code	Description
B05BA01	Solutions for parenteral nutrition, amino acids
B05BA02	Solutions for parenteral nutrition, fat emulsions
B05BA03	Solutions for parenteral nutrition, carbohydrates
B05BA10	Solutions for parenteral nutrition, combinations

Figure 5 shows that the using B05BA01, B05BA02, or B05BA10 results in the highest specificity (99.5% for 2016) and the second highest sensitivity (91.4% for 2016). The results for sensitivity and specificity are consistent over the years. We decided to use the occurrence of any of these three ATC codes as indicative of the use of parenteral nutrition in a hospital stay in reimbursement data.

A description of all primary measures for the IMA-AIM data is shown in Table 16.

Figure 5 – Sensitivity and specificity of ATC codes for identifying parenteral nutrition

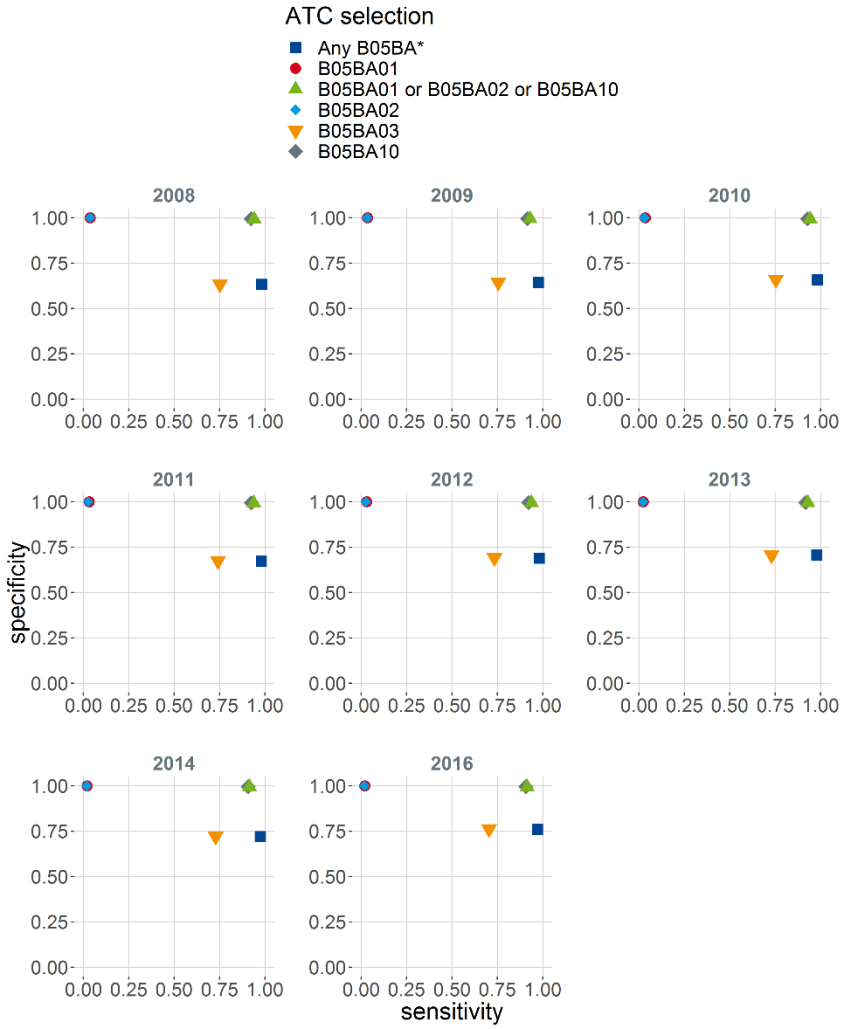


Table 16 – Definitions of primary measures for IMA – AIM

Measure	Definition enteral
Prevalence of patients at home	For enteral and parenteral nutrition at home, prevalence is calculated as the number of patients per year.
Prevalence of patients in hospital for parenteral	$P\ year\ x_{parenteral} = \frac{patients\ year\ x_{parenteral}}{patients\ year\ x_{all}}$ with $patients\ year\ x_{parenteral}$ = number of patients in year x with at least one hospital stay with reimbursement of parenteral pharmaceutical products; $patients\ year\ x_{all}$ = number of patients 18 years or older in year x with at least one hospital stay.
Duration at home	For enteral and parenteral nutrition at home, we used the number of days reimbursed as duration. Patients are attributed to a 'cohort' year: the first year they had a reimbursement of enteral or parenteral nutrition.

2.2.6 Royal Decree parenteral nutrition (RD 2009)

2.2.6.1 Description

The royal decree of 28 January 2009 creates a lump sum covering the costs of a hospital team for their training and follow-up of patients with a benign disease who receive parenteral nutrition at home and the training of their family. Additionally, it covers a lump sum for the costs of this team for treating children with severe dislike of oral nutrition accompanied by or following a period in which this child received ambulant parenteral nutrition.

As part of this financing, the hospital needs to submit a yearly report on the activities to the RIZIV – INAMI.

2.2.6.2 Definition of measures

We received an analysis on the yearly reports from the RIZIV – INAMI on the number of adult patients with parenteral nutrition that are within the scope of the royal decree.

Analysis software

All analyses are conducted in SAS 9.4 M5 (base, stat, and graph modules) and R 3.5.2 (with, aside from standard packages, ggplot2, and the tidyverse packages).

2.3 Results by measure

2.3.1 Prevalence and ratio

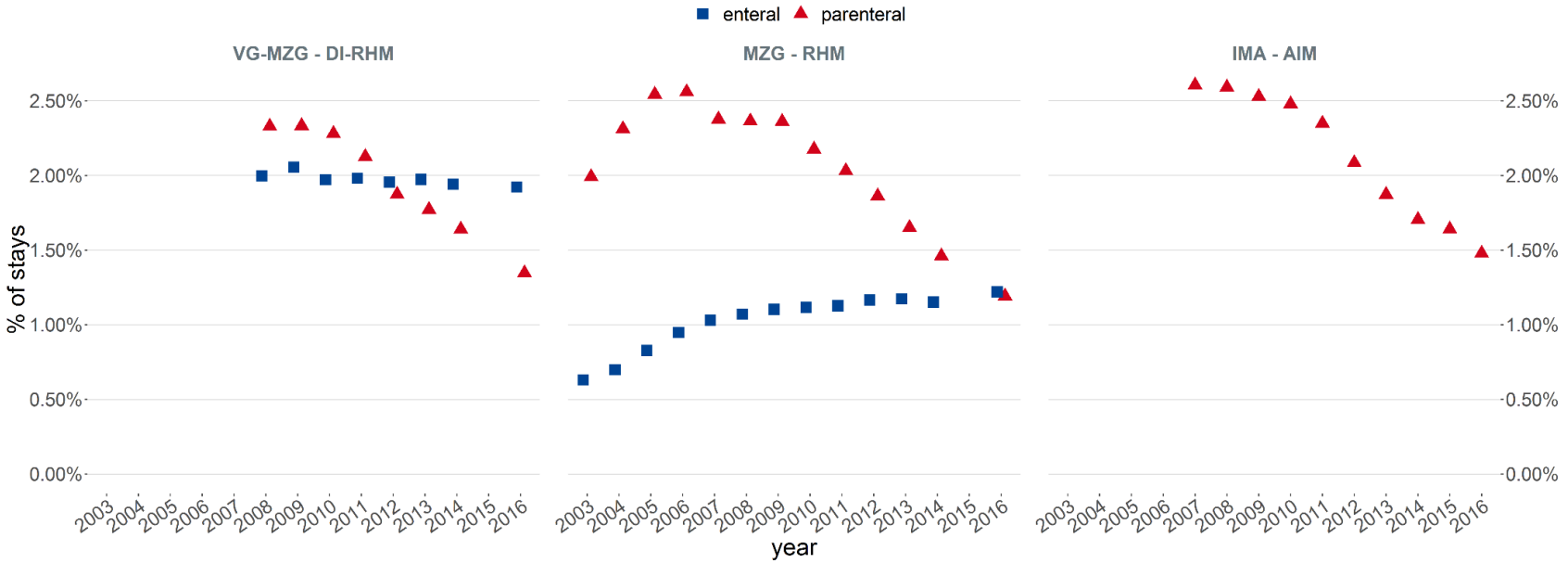
2.3.1.1 Overall in hospital

In hospital, the use of enteral and parenteral nutrition show a similar evolution accros data sources but with large differences in the calculated prevalences (see Figure 6). As discussed in 2.2.2.3 on the comparison of the coding in the VG-MZG – DI-RHM and MZG – RHM data sources, there is a clear undercoding of enteral nutrition in the MZG – RHM data source. The MZG – RHM data source results are shown nevertheless because they provide a longer date range (2003 to 2016) and VG-MZG – DI-RHM is a subsample of all hospital stays.

The undercoding is reflected in the calculated prevalence of enteral nutrition being about twice as high in VG-MZG – DI-RHM. In MZG – RHM, enteral nutrition increases over the years, but stays more or less stable in VG-MZG – DI-RHM.

Parenteral nutrition shows similar results in all data sources. For 2008 to 2016, both VG-MZG – DI-RHM and MZG – RHM show a sharp decline of percentage of stays with parenteral nutrition. The additional 2003 to 2007 date range in MZG – RHM shows an increase which tops out in 2005 and 2006, before decreasing from 2007 onwards. Similarly, the IMA – AIM data show a sharp decline for parenteral nutrition. The estimate of the percentage differs however per data source, ranging for example between 1.2% (MZG-RHM) to almost 1.5% (IMA – AIM) in 2016.

Figure 6 – Percentage of inpatient hospital stays by nutrition type and source.



Looking at prevalence in a different way, we calculated the prevalence of enteral and parenteral nutrition for each of the 60 registration days in VG-MZG – DI-RHM. The decreasing prevalence of parenteral and more or less stable prevalence of enteral nutrition are reproduced (see Figure 7). We do however see variation between registration days, which tend to be in part related to week or weekend day: in general, prevalences are higher on weekend days (triangles in Figure 7).

We also observe a registration period effect: registration periods March and September have higher prevalences than June and December. Looking at the differences between numerator (number of stays with nutrition) and denominator (number of stays), we found that both were lower in the June and December registration periods but at different rates, causing lower prevalences in these registration periods. We have found no explanation as to what could cause this period effect.

Figure 7 – Percentage of inpatient hospital stays per VG-MZG – DI-RHM registration day (symbol = prevalence on a registration day)

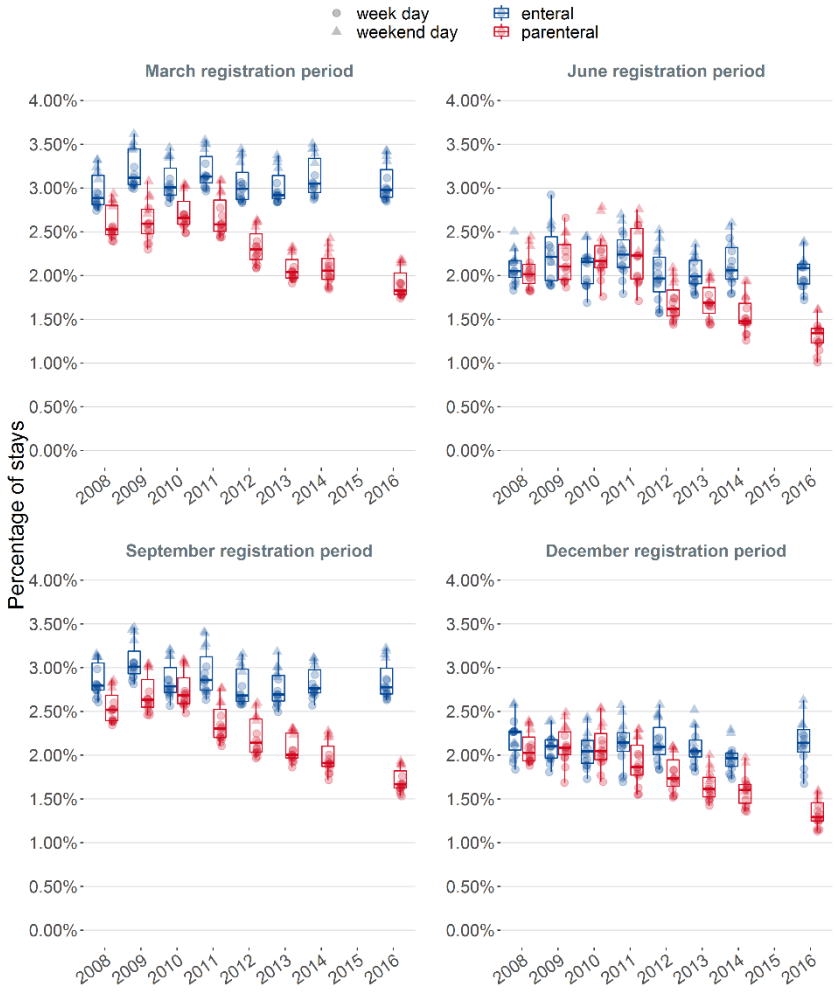
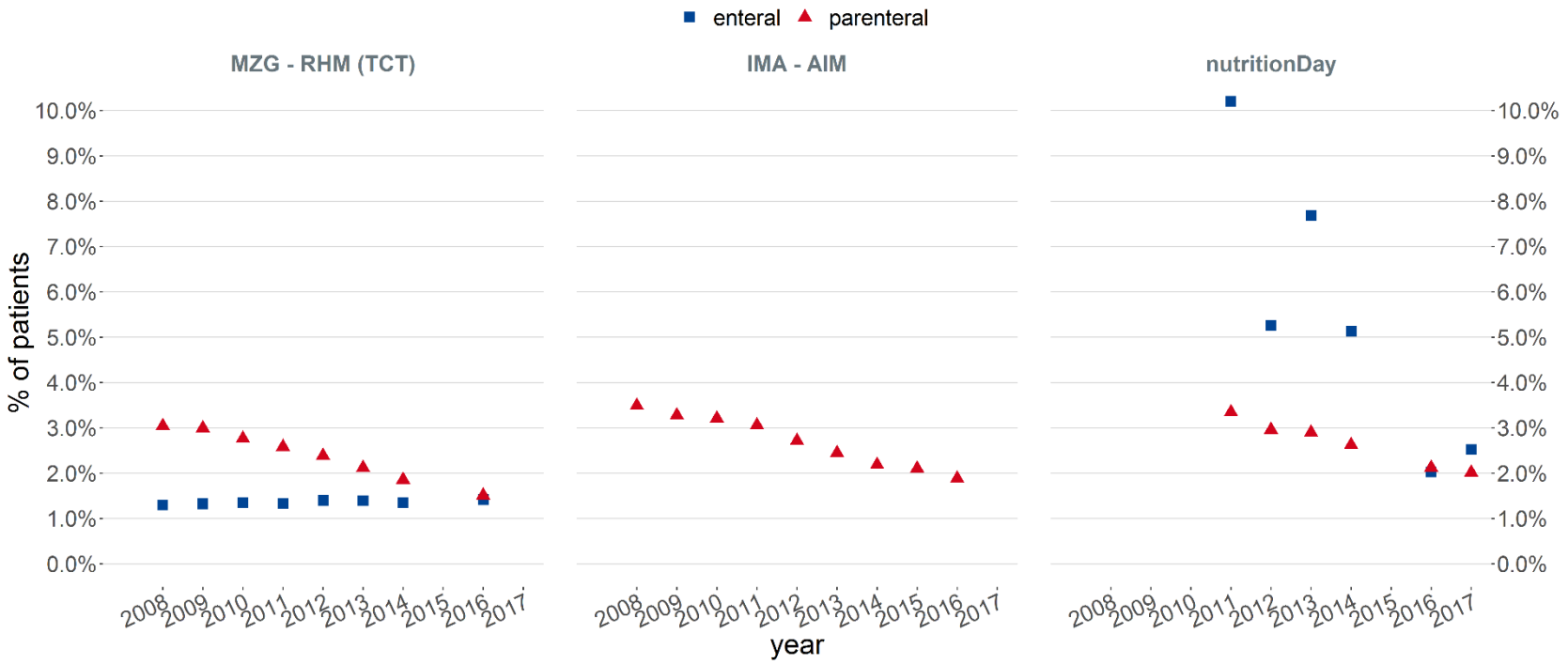


Figure 8 shows the *prevalence of patients* by nutrition type for the available sources. These sources are in part different than those for hospital stays because VG-MZG – DI-RHM does not contain the notion of a unique patient. This is available in MZG – RHM data source coupled to the reimbursement data by the TCT (see 2.2.1.1 for details) for 2008 to 2016. Additionally, nutritionDay reports percentages of patients of participating wards. The prevalences in MZG – RHM (TCT) are very similar to those of the inpatient hospital stays shown in Figure 6 because over 84% of patients had only one stay per year with enteral or parenteral nutrition in the same stay, and there were little differences across nutrition type (see the figure in appendix 1.2 to this chapter). The nutritionDay percentages for parenteral nutrition are within the same range as the MZG – RHM (TCT) percentages. The nutritionDay percentages for enteral nutrition are much higher and more variable.

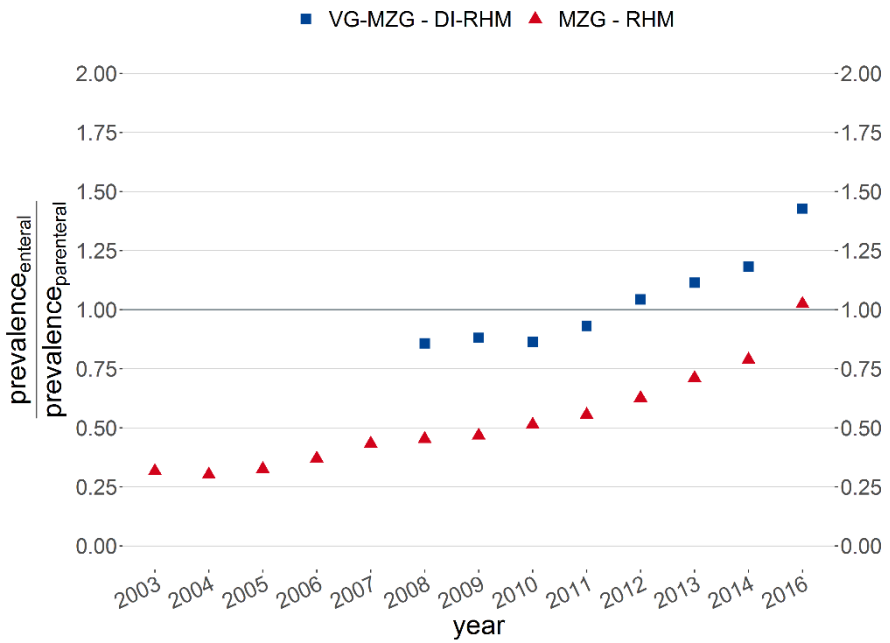
The IMA – AIM percentages for parenteral nutrition are higher than in MZG – RHM, similar to the results for number of stays.

Figure 8 – Percentage of inpatient hospital patients by nutrition type and source.



The ratio between the prevalence of enteral nutrition and parenteral nutrition is another way often used in the literature (see Part 1) to assess the use of nutrition. Figure 9 shows the ratio for inpatient hospital stays. The available sources show a similar trend, but as with the prevalence, VG-MZG – DI-RHM shows a much higher usage of enteral nutrition compared to MZG–RHM.

Figure 9 – Ratio of enteral and parenteral nutrition of inpatient hospital patients by source



2.3.1.2 Subgroup analysis in hospital

For the subgroup analysis of in hospital use of enteral and parenteral nutrition, we only used the VG-MZG – DI-RHM source because from the analysis reported above we consider it to be the most reliable estimate, in particular for enteral nutrition.

The overall prevalence of enteral and parenteral nutrition varies greatly between hospitals. Figure 10 shows that the ratio of enteral and parenteral nutrition ranges from very low (predominantly use of parenteral nutrition) to very high (predominantly use of enteral nutrition) depending on the hospital. There also seems to be no clear evolution in the extent of variation between hospitals across years (IQR ranging from 0.74 to 1.17 depending on the year).

Figure 10 – Ratio enteral and parenteral nutrition per hospital (VG-MZG – DI-RHM)

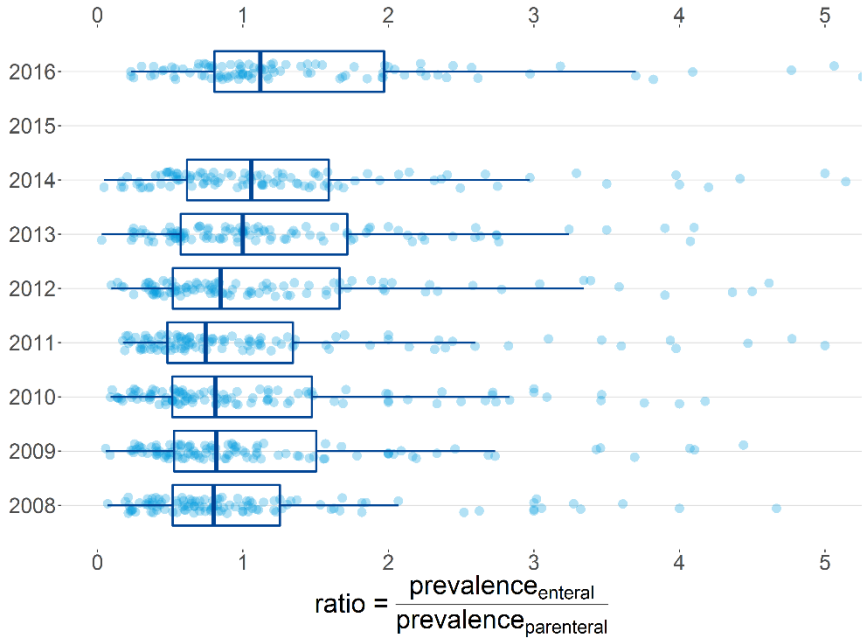
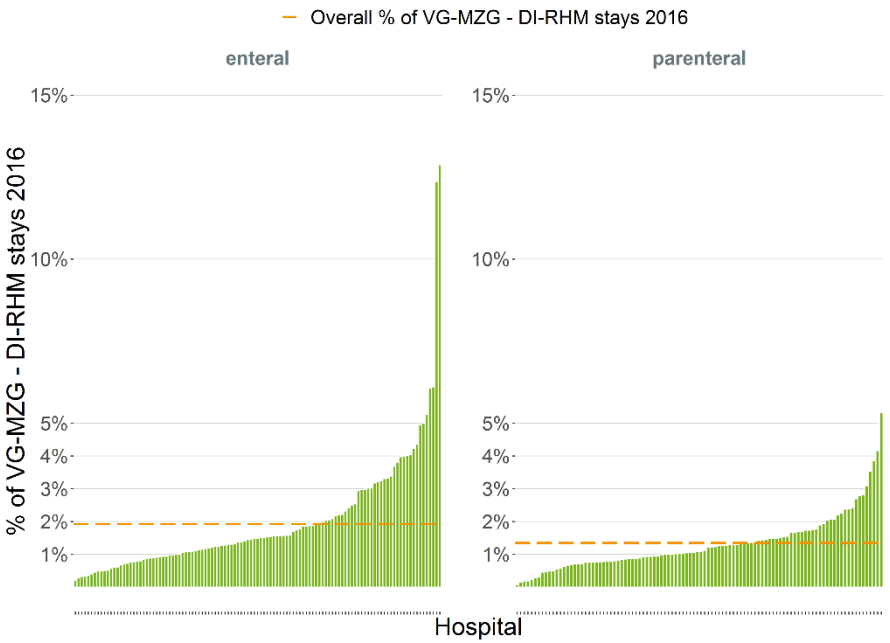


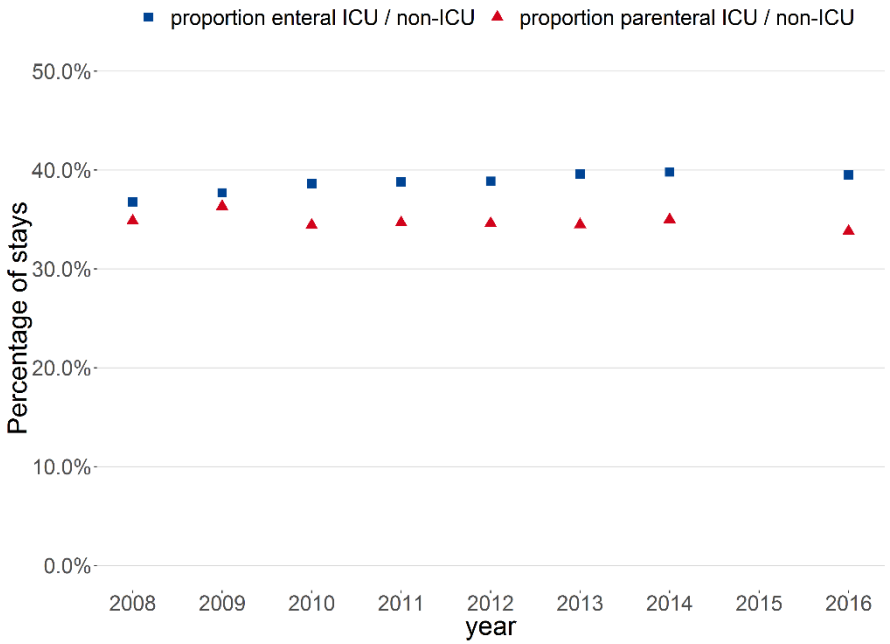
Figure 11 zooms in on the individual prevalences per hospital in 2016, showing large differences between hospitals. The few hospitals with very high prevalences tend to be hospitals with either relatively few stays or rehabilitation hospitals.

Figure 11 – Prevalence of enteral and parenteral nutrition per hospital in 2016 (VG-MZG – DI-RHM)



Since patients in intensive care units (ICU) have a higher probability to receive enteral or parenteral nutrition, we performed a subgroup analysis for this ward. We find that indeed, over a third of stays with enteral or parenteral nutrition are in ICU (see Figure 12).

Figure 12 – Proportion of stays in ICU compared to other wards (VG-MZG – DI-RHM)



We find this also reflected in the percentages of patients on ICU that have enteral or parenteral nutrition in ICU (see Figure 13), which have a substantial higher prevalence compared to the overall prevalence (e.g. 17.8% enteral and 8% parenteral in ICU compared to respectively 1.9% and 1.35% overall). We see a very similar decreasing trend for parenteral nutrition, which seems to be compensated by an increase of the use of enteral nutrition.

Figure 13 – Percentage of inpatient hospital stays in ICU (VG-MZG – DI-RHM)

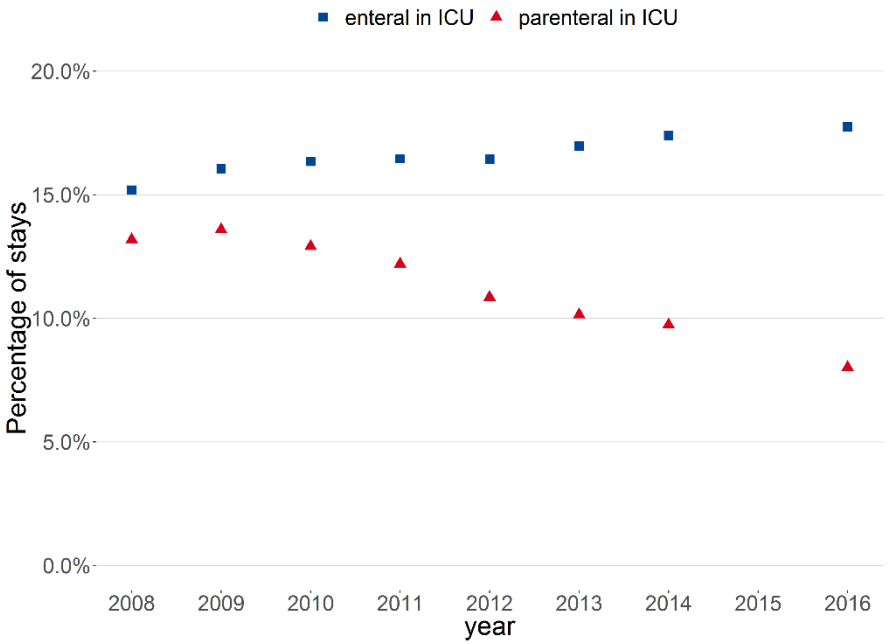
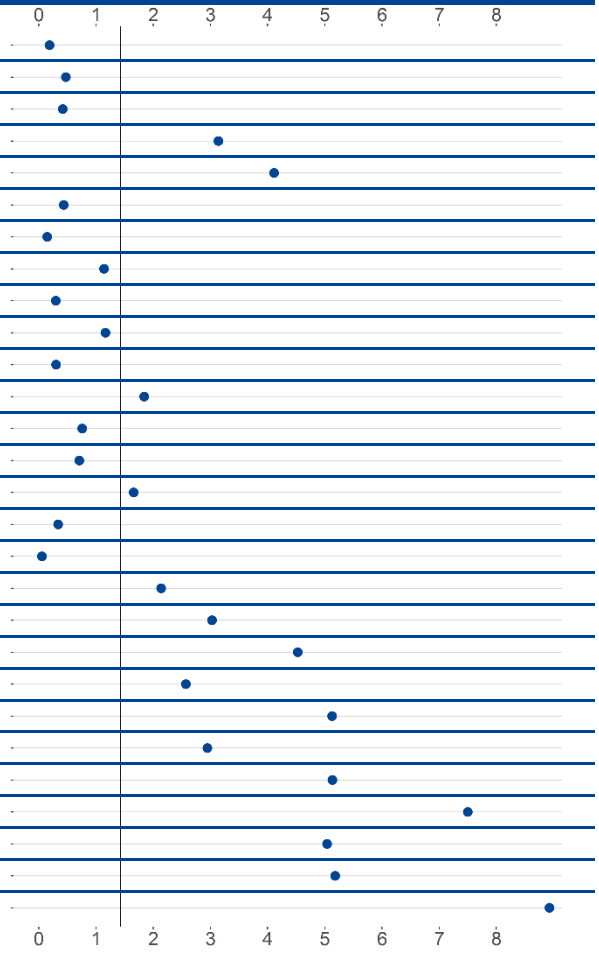


Table 17 shows the prevalence and ratio of enteral and parenteral nutrition per pathology group (APR-DRG[m] version 34) for the largest groups in terms of stays with enteral or parenteral nutrition (details for all APR-DRG can be found in the appendix to this chapter, section 1.3). As can be expected, there is a large variation between pathology groups on the use of enteral or parenteral nutrition.

[m] All Patient Refined – Diagnosis Related Groups: economically, statistically as well as clinically meaningful groups of stays, which are allocated to an APR-DRG on the basis of principal diagnosis, secondary diagnoses and procedures, age and sex of the patient and, for some APR-DRGs (e.g. burns) type of discharge.

Table 17 – Prevalence and ratio enteral and parenteral in 2016 by APR-DRG (covering 50% of VG-MZG – DI-RHM stays of enteral or parenteral)

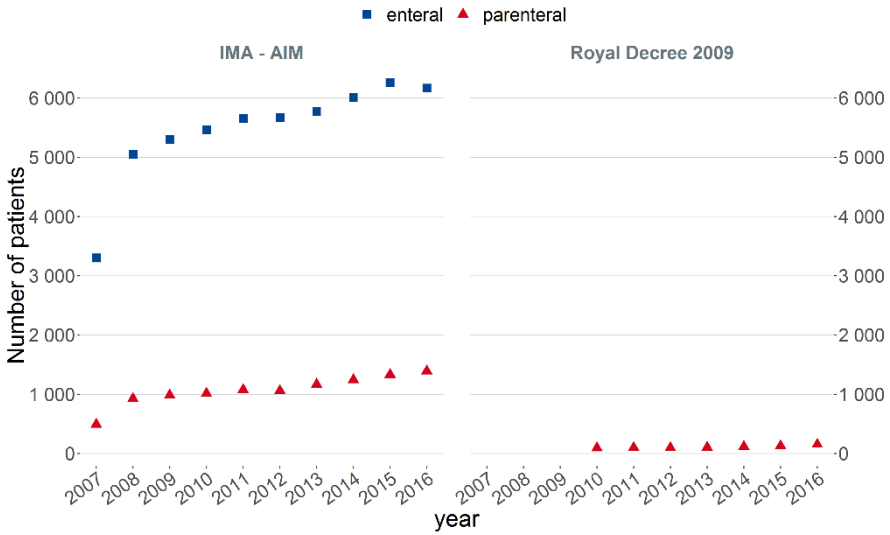
APR-DRG	% of all stays	% enteral	% parenteral	Ratio enteral / parenteral (line = overall ratio)
221 Major Small & Large Bowel Procedures	1.23%	1.51%	11.52%	
220 Major Stomach, Esophageal & Duodenal Procedures	0.29%	1.73%	5.22%	
240 Digestive Malignancy	0.48%	0.89%	3.04%	
004 Tracheostomy W Mv 96+ Hours W Extensive Procedure Or Ecmo	0.20%	6.59%	3.00%	
951 Moderately Extensive Procedure Unrelated To Principal Diagnosis	0.92%	8.20%	2.85%	
260 Major Pancreas, Liver & Shunt Procedures	0.20%	0.72%	2.35%	
003 Bone Marrow Transplant	0.08%	0.23%	2.20%	
950 Extensive Procedure Unrelated To Principal Diagnosis	0.44%	1.73%	2.16%	
247 Intestinal Obstruction	0.43%	0.44%	2.11%	
222 Other Stomach, Esophageal & Duodenal Procedures	0.26%	1.69%	2.07%	
223 Other Small & Large Bowel Procedures	0.28%	0.39%	1.82%	
720 Septicemia & Disseminated Infections	0.81%	2.33%	1.80%	
254 Other Digestive System Diagnoses	0.95%	0.96%	1.80%	
421 Malnutrition, Failure To Thrive & Other Nutritional Disorders	0.31%	0.84%	1.69%	
710 Infectious & Parasitic Diseases Including Hiv W O.R. Procedure	0.23%	1.74%	1.50%	
229 Other Digestive System & Abdominal Procedures	0.20%	0.33%	1.40%	
441 Major Bladder Procedures	0.13%	0.05%	1.39%	
139 Other Pneumonia	1.76%	2.05%	1.37%	
137 Major Respiratory Infections & Inflammations	0.61%	2.86%	1.35%	
045 Cva & Precerebral Occlusion W Infarct	1.18%	3.31%	1.04%	
696 Other Chemotherapy	1.17%	1.67%	0.93%	
130 Respiratory System Diagnosis W Ventilator Support 96+ Hours	0.09%	2.66%	0.74%	
140 Chronic Obstructive Pulmonary Disease	2.00%	1.49%	0.72%	
862 Other Aftercare & Convalescence	1.57%	2.05%	0.57%	
021 Craniotomy Except For Trauma	0.39%	2.59%	0.49%	
005 Tracheostomy W Mv 96+ Hours W/O Extensive Procedure	0.05%	1.67%	0.47%	
110 Ear, Nose, Mouth, Throat, Cranial/Facial Malignancies	0.12%	1.51%	0.42%	
058 Other Disorders Of Nervous System	1.23%	1.66%	0.27%	



2.3.1.3 Overall at home

More patients use enteral nutrition at home than parenteral nutrition (see Figure 14). 2007 was the first year of reimbursement, starting in September, which explains the low number of patients. Since then, the number of patients has slowly increased. In 2016, 6 081 patients were reimbursed for enteral nutrition and 1 308 for parenteral nutrition. Relatively few patients are covered by additional follow-up from the hospital as provided by Royal Decree 2009 (see section 2.2.6 for details on RD 2009). However, it's use has increased from 95 patients in 2010 to 154 in 2016.

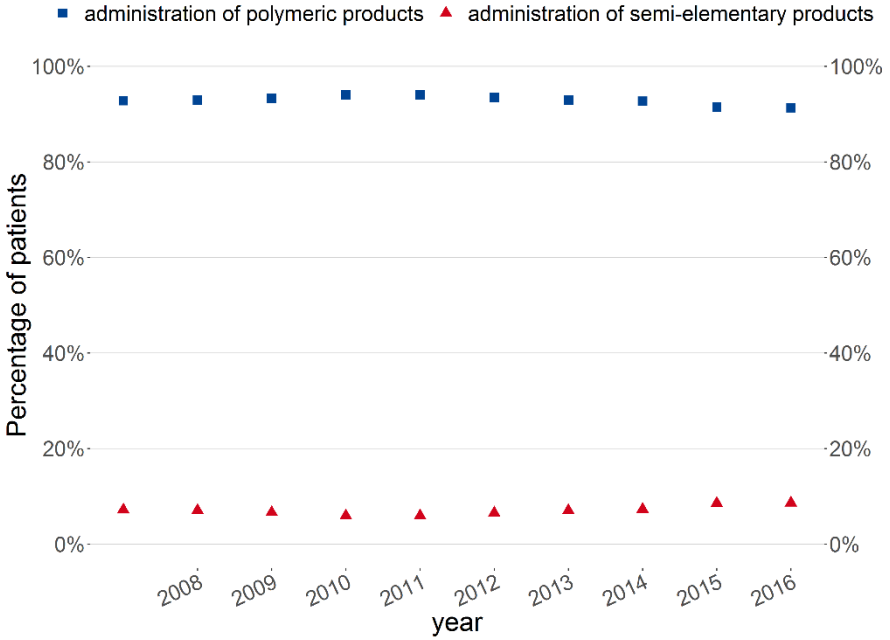
Figure 14 – Number of patients per year by nutrition type at home and by source



2.3.1.4 Subgroup analysis at home

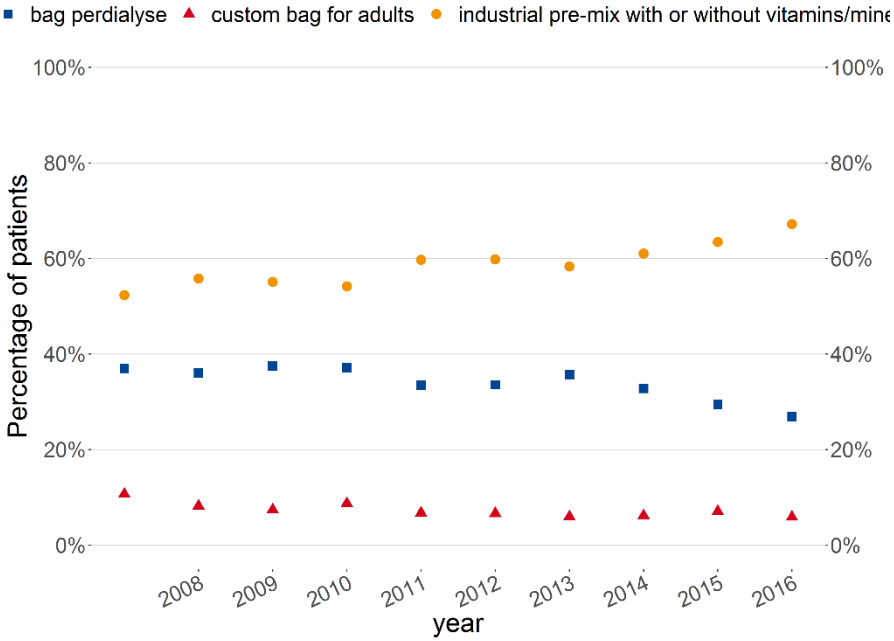
Most patients on enteral nutrition at home, use polymeric products (94.4% in 2016; see Figure 15). Its use has remained stable over the years with a slight tendency to decrease.

Figure 15 – Proportion of patients per enteral product type at home (IMA – AIM)



Parenteral nutrition use at home can be distinguished by patients on perdialyse solutions accounting for 29.6% of patients in 2016 and other patients (see Figure 16). Most of the latter (91.2%) use industrial per-mixture solutions. Both perdialyse and custom solutions for parenteral nutrition are in decline while industrial per-mixture solutions are on the rise.

Figure 16 – Proportion of patients per parenteral product type at home (IMA – AIM)



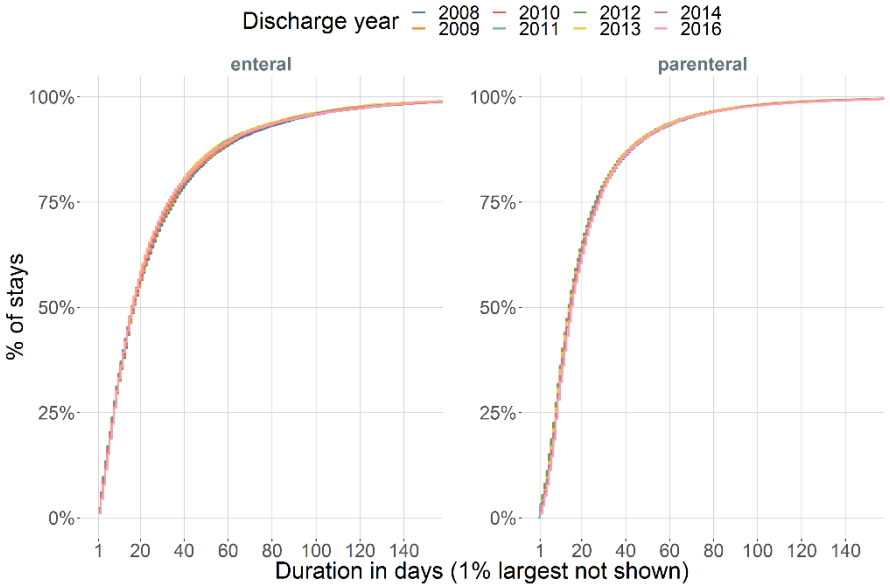
2.3.2 Duration

2.3.2.1 Overall in hospital

The duration of use of enteral and parenteral nutrition in hospital is shown in Figure 17. There is very little variation between years. Patients on enteral nutrition tend to have longer durations (2016: median = 17 days; IQR = 32) than patients on parenteral (2016: median = 15 days; IQR = 19).

Most patients (90% of stays) on enteral have durations of 63 days or less, while most patients on parenteral (90% of stays) have durations of 48 days or less. In 2016, 15.2% of enteral stays and 11.3% of parenteral stays had a duration of five days or less. However, it is important to keep in mind that these durations are most likely overestimated as duration is measured from first occurrence of nutrition to the end of the stay (see 2.2.1.2 for more details).

Figure 17 – Cumulative percentage of stays by duration (from 1st procedure to discharge) in days by nutrition type



Source: MZG-RHM

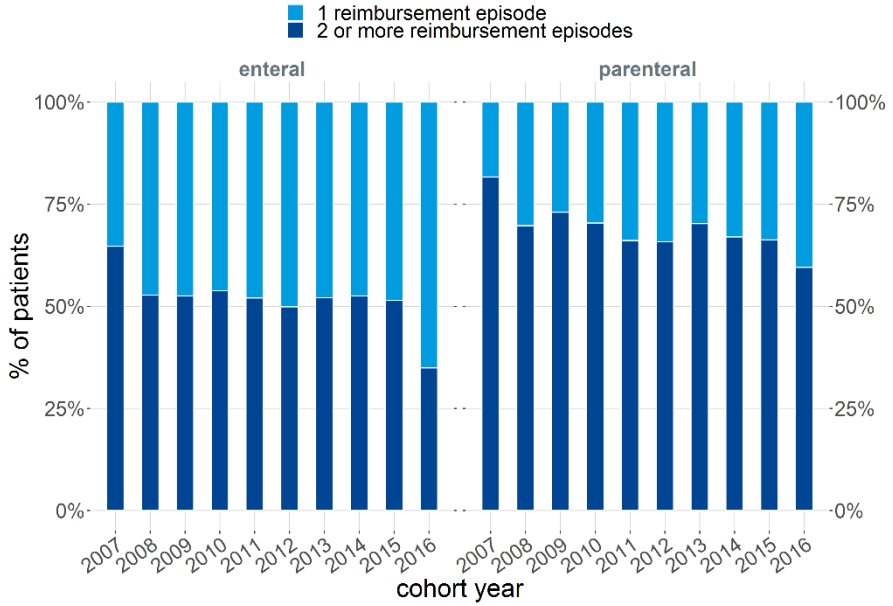
2.3.2.2 Overall at home

The IMA – AIM reimbursement data contain reimbursed health care acts on a certain day, with an associated number of acts. As such, these data do not contain episodes of health care acts, and these need to be constructed. An explanation of the episode algorithm used, can be found in the appendix to this chapter, section 1.4. Summarised, an episode is defined as the consecutive reimbursement of nutrition RIZIV – INAMI nomenclature codes (see Table 14).

As further described in the appendix, we distinguish two cases: patients that have only one episode with all reimbursements corresponding to consecutive days versus patients with 'gaps' between consecutive reimbursements. For the one reimbursement episode patients, the episode is simply the consecutive days. For the patients with two or more reimbursement episodes, a merge has taken place to account for invoicing practices (see appendix section 1.4 for details).

Figure 18 shows the proportion of each type per cohort year (first year of nutrition occurrence). That parenteral has a higher proportion of multiple reimbursement episodes is due to invoicing practices and is dealt with by merging reimbursement episodes. All subsequent analysis described will distinguish these two types of patients after merging reimbursement episodes to estimate clinical episodes of nutrition.

Figure 18 – Proportion of number of reimbursement episodes by cohort year and nutrition type



Duration of enteral nutrition episodes at home is less than a year for most patients (2015: median = 106 days (IQR = 234) for one reimbursement episode patients; median = 89 days (IQR = 156) for multiple reimbursement episode patients; see Figure 19). The graph shows deviant results for cohort years 2007 and 2016. 2007 was the year of introduction of the RIZIV - – INAMI nomenclature and has relatively few patients.

For 2016, this is due to it being the last available year. This right censoring of the data can also be seen for the other years in the 'tree' pattern in the top panel. For 2016, 2.9% of enteral episodes had a duration of 5 days or less.

Figure 19 – Cumulative percent of enteral merged reimbursement episodes at home by duration and cohort year (zoomed bottom panel)

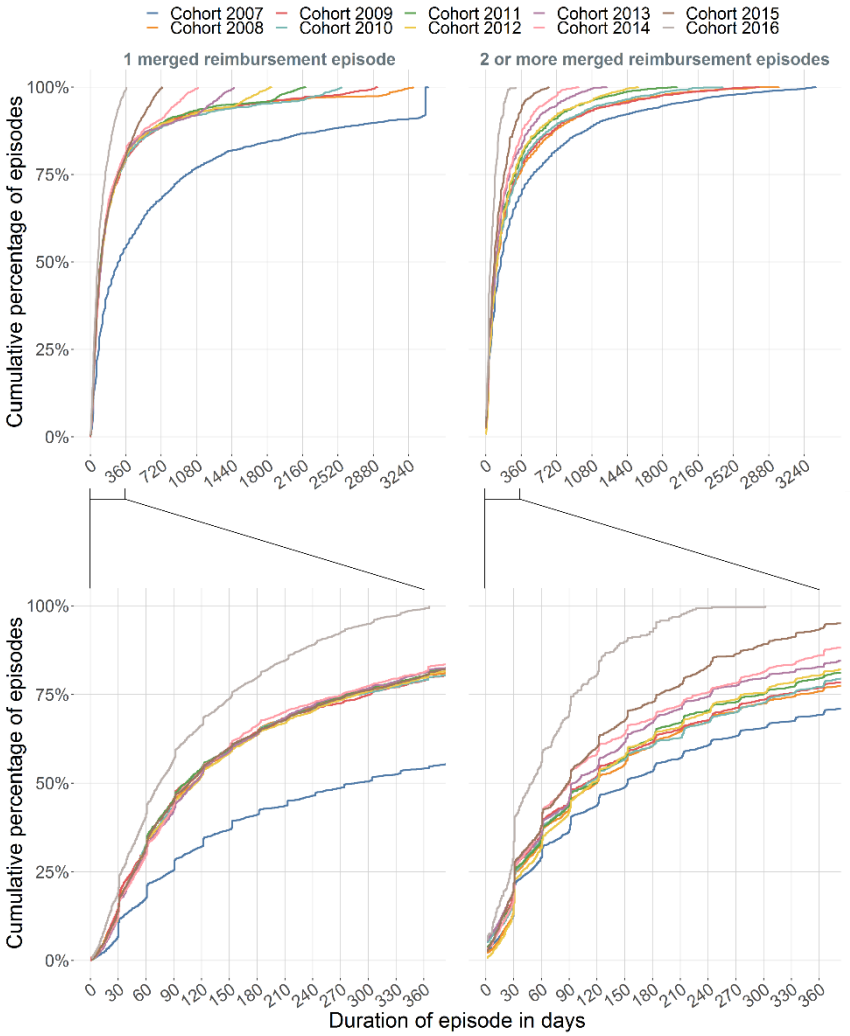
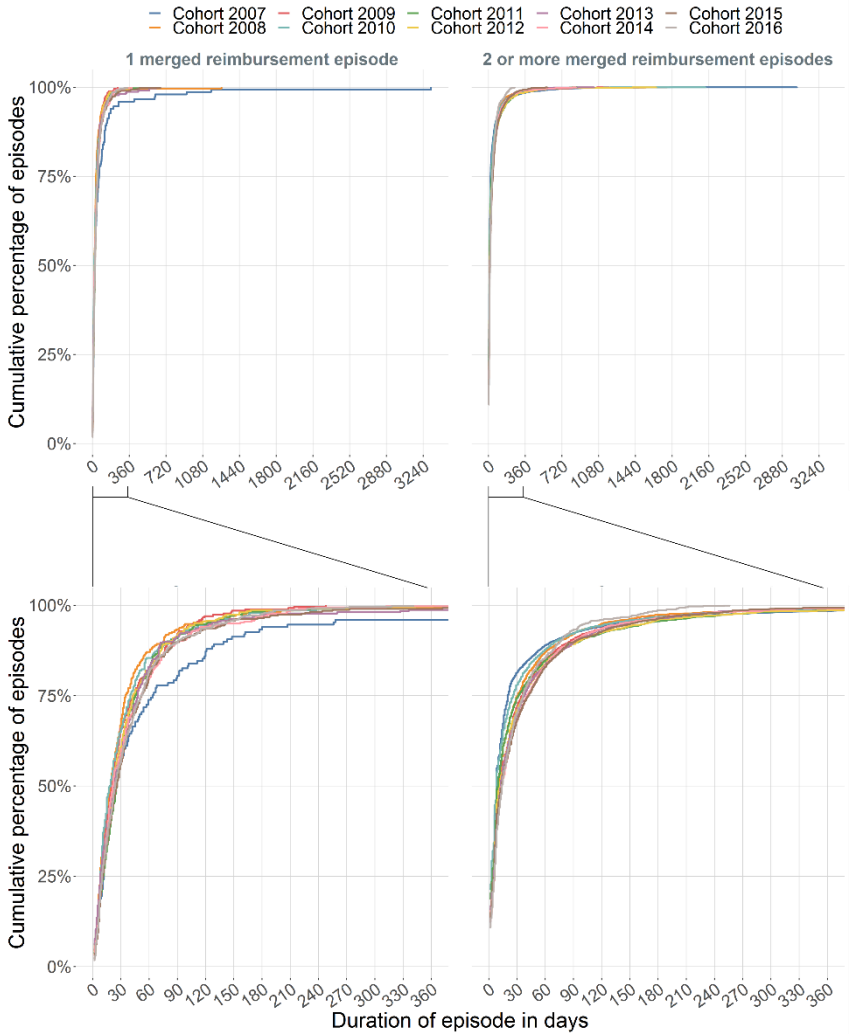


Figure 20 – Cumulative percent of parenteral merged reimbursement episodes at home by duration and cohort year (zoomed bottom panel)



Duration of parenteral nutrition episodes at home are shorter than enteral episodes with most patients having episodes of less than three months (see Figure 20; 2015: median = 26 (IQR = 41) for one reimbursement episode patients; median = 14 days (IQR = 36) for multiple reimbursement episode patients). There are also almost no patients with durations over a year. For 2016, 19.4% of parenteral episodes had a duration of 5 days or less.

For both enteral and parenteral nutrition, a subgroup analysis of duration by product type at home is available in the appendix to this chapter, section 1.5.

2.3.2.3 Preceding hospital stay

About half of the enteral merged reimbursement episodes at home follow a hospital stay, either inpatient or day-care, for patients with one episode and about 40% for patients with multiple episodes (see Figure 21). 2007 deviates most likely due to it being the first year of RIZIV – INAMI reimbursement.

Figure 21 – Percent of enteral merged reimbursement episodes at home immediately following a hospital stay

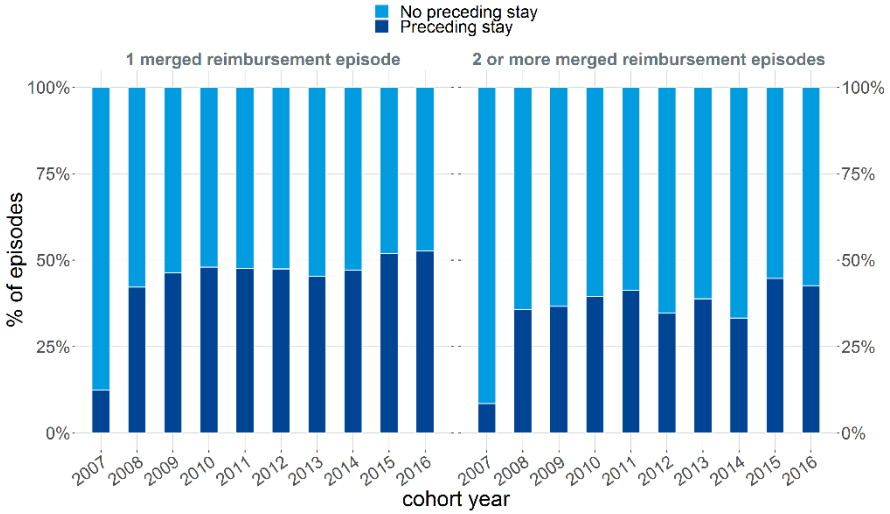
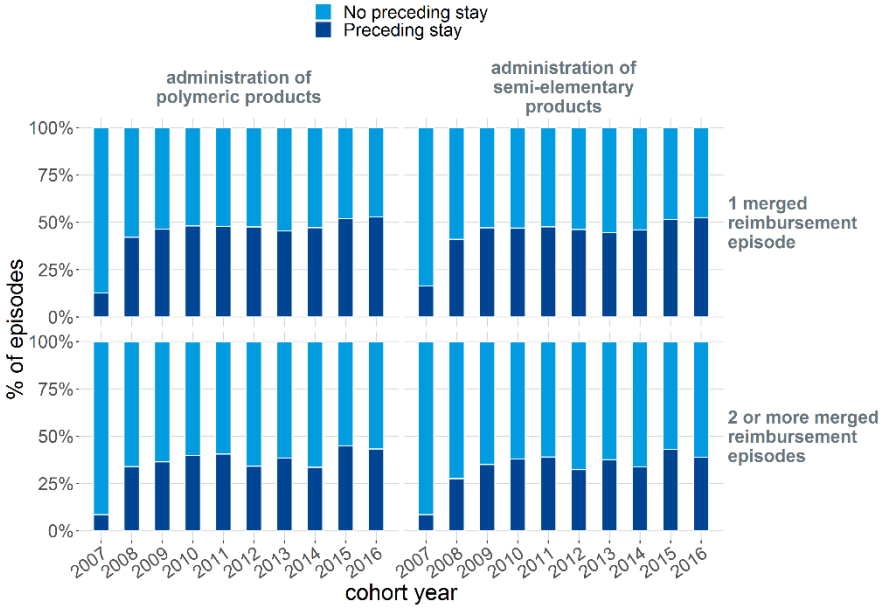


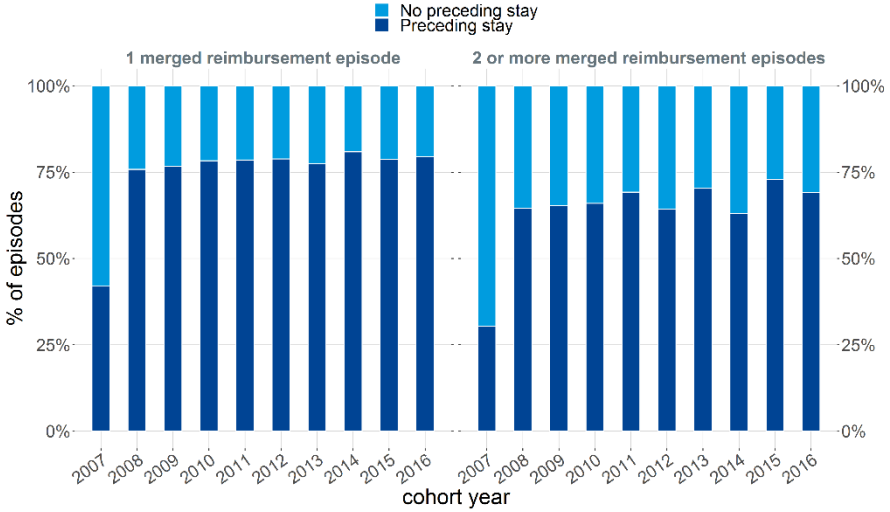
Figure 22 shows the same data by product type for enteral merged reimbursement episodes. Polymeric and semi-elementary enteral nutrition solution follow the same pattern.

Figure 22 – Percent of enteral merged reimbursement episodes at home immediately following a hospital stay by product type



Looking back up to three months before the start of an episode, about three quarter of the episodes is preceded by a hospital stay, inpatient or day-care (see Figure 23).

Figure 23 – Percent of enteral merged reimbursement episodes at home following a hospital stay within 90 days



For parenteral nutrition episodes, a similar result is found for episodes immediately following a hospital stay, inpatient or day-care (see Figure 24). This pattern is also found for custom and industrial pre-mixture bags, but not for perdialyse bags. The percentage of episodes for perdialyse bags immediately following a hospital stay is much lower (see Figure 25).

Over 85% of parenteral merged reimbursement episodes at home follow a hospital stay, inpatient or day-care within three months (see Figure 26).

Figure 24 – Percent of parenteral merged reimbursement episodes at home immediately following a hospital stay

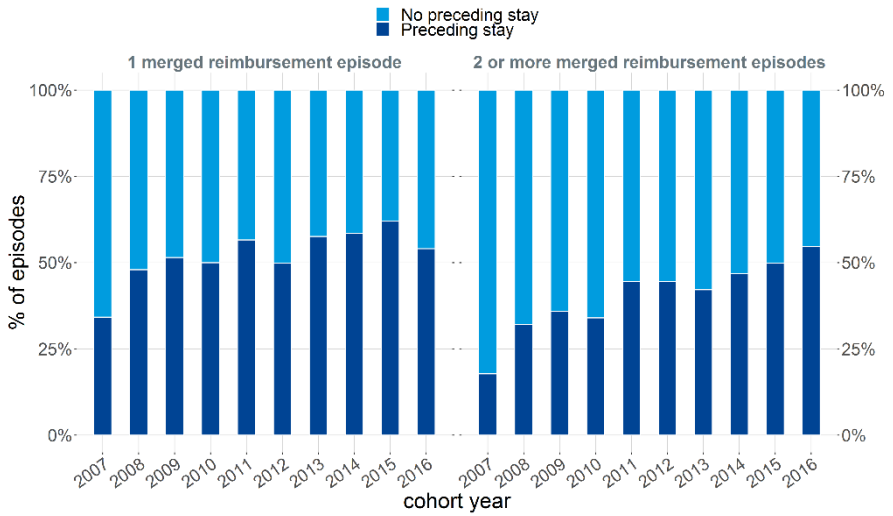


Figure 25 – Percent of parenteral merged reimbursement episodes at home immediately following a hospital stay by product type

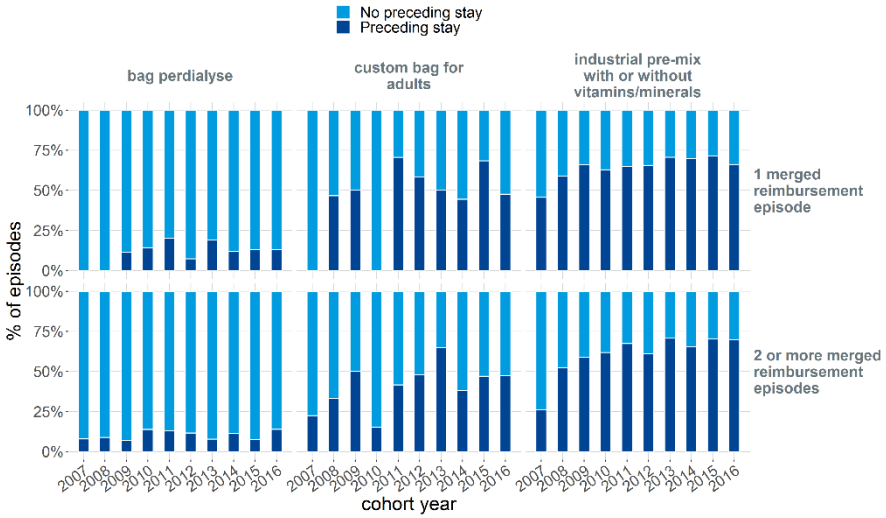
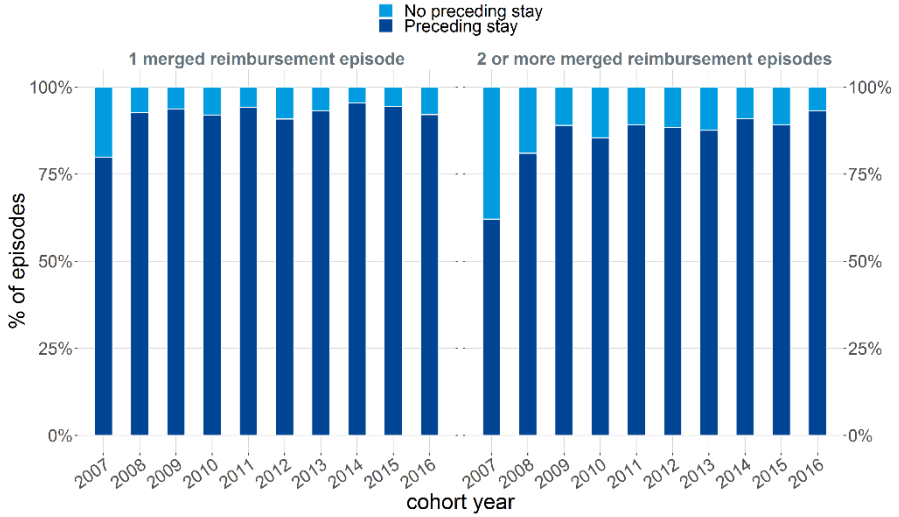


Figure 26 – Percent of parenteral merged reimbursement episodes at home following a hospital stay within 90 days



2.4 Discussion

As Table 9 demonstrates, there are various sources available in Belgium on enteral and parenteral nutrition covering different aspects in different settings. However, our general conclusion is that all of these sources have their merit, but none are without limitations in describing the use of enteral and parenteral nutrition.

2.4.1 Prevalence and ratio

A first conclusion on prevalence in a hospital setting is a clear trend of declining use of parenteral nutrition, confirmed across multiple sources. The concordance between sources both in trend and prevalence suggest confidence in the estimate of prevalence for parenteral nutrition.

For enteral nutrition in a hospital setting, we observe a fairly stable trend of its use in the hospital setting. However, we see some limitations to our estimates. It's measurable in less sources and the disagreement between the MZG – RHM and VG-MZG – DI-RHM coding is striking. We see a strong undercoding in MZG – RHM when comparing directly to VG-MZG – DI-RHM for the same stays. We consider the VG-MZG – DI-RHM coding in this case more accurate. This could be due in part to a different coding procedure: a nurse that registers daily if enteral nutrition was administered versus a post-hoc coding of a medical procedure. For this reason, we used the VG-MZG – DI-RHM for the subgroup analysis in the hospital setting.

Comparing the trends of enteral and parenteral nutrition in the hospital setting, we observe a general decrease of use of these forms of artificial nutrition: the decrease of parenteral nutrition is larger than the increase of enteral nutrition. Unfortunately, the data sources do not allow to explain the reason behind this evolution. Amongst possible explanations are the publication of new guidelines in the last ten years and the introduction of the NST, but we did not dispose of data allowing to test these explanations.

A second conclusion is that there exist much variation in the use of enteral and parenteral nutrition: between hospitals, between hospital wards, and between pathology groups. Exploring this variation and it's reasons require however a different study design and accompanying other data sources, currently not available, like e.g. the reasons for prescribing enteral and parenteral nutrition and the nutritional status and its evolution of the patient.

When considering enteral and parenteral nutrition outside of the hospital setting, its use is more limited, in particular for parenteral nutrition. Although we do observe an increase both of enteral and parenteral nutrition in the nine years available in our data sources. The use of perdialyse bags is decreasing, but made up about one third of patients on parenteral nutrition at home in 2016. Guidelines on the use of nutrition support in dialysis advise against routine use of parenteral nutrition in dialysis patients but to reserve it as a more advanced treatment option (e.g. (Anderson et al. 2019)). However, since we have no information on the clinical profile of the patient, further research is needed to clarify this use.

2.4.2 Duration

Determining the time patients are on enteral and parenteral nutrition proved challenging, both in and outside of the hospital. In the hospital, the MZG – RHM source only records the procedure and repeats if any, resulting in a possible overestimation because we calculated the duration up until the end of the stay. We considered alternative methods, trying to use the VG-MZG – DI-RHM which records daily use but unfortunately only for the registration periods of four times 15 days, resulting in an underestimation of duration. We similarly considered using the reimbursement data in IMA – AIM and TCT data sets of solutions for parenteral nutrition (ATC codes B05BA*). However, the reimbursement is often registered on the date the nutrition started and only the total number of reimbursed bags is available. So for example, on a particular date, the data might contain a record of 20 reimbursed bags of one litre. There is however no further information on what period of use this covered. It might e.g. correspond in one case to daily nutrition for 20 days, and in another case corresponding to two to three bags a day.

Although the duration results need to be interpreted with caution in the hospital setting, we can make some general observations. Patients that were on enteral or parenteral nutrition usually stay longer in the hospital than average patients (7.45 days in 2016, Eurostat). Almost all patients (90%) have a nutrition duration of less than two months.

The duration of enteral and parenteral nutrition episodes at home posed a different challenge due to invoicing practices. Our estimates here are more accurate than those in the hospital setting because the associated RIZIV – INAMI nomenclature codes refer to daily use or activities. We noticed however that there are sometimes small gaps between reimbursed episodes. We considered these to not necessarily correspond to distinct clinical episodes of nutrition support and merged some of these episodes (see section 0 for details).

Keeping these choices in mind, we observe however that patients outside of the hospital on average take enteral nutrition longer than in the hospital. This is not the case for parenteral nutrition which has a distribution of duration more similar to in hospital use.

Trying to infer where enteral or parenteral nutrition was started up, we observed that this is not necessarily in hospital. About 50% of patients had a hospital stay, inpatient or day-care, immediately preceding an episode of enteral or parenteral nutrition. Looking further back increased this to about 75% within three months for enteral and about 85% for parenteral nutrition.

2.4.3 Gaps

To repeat, in Belgium, we dispose of several usable data sources to describe enteral and parenteral nutrition use both in and outside of the hospital. However most of these data sources come with limitations, in particular for estimating duration of use. We also lack good data sources on nutritional support teams, malnutrition and nutritional status of the patient, at least from the perspective of estimating prevalence or duration of use.

Key points

- **There are various sources available in Belgium on enteral and parenteral nutrition covering different aspects in different settings.**
- **Prevalence in a hospital setting:**
  - **There is a clear trend of declining use of parenteral nutrition.**
  - **There is a stable trend of enteral nutrition use, but sources differ.**
- **Prevalence outside of the hospital:**
  - **We observe an increase both of enteral and parenteral nutrition.**
  - **Enteral and parenteral nutrition are not necessarely started up in hospital.**
- **The available data on duration did not allow an accurate estimation of duration due to different limitations. This needs to be kept in mind in interpreting the results:**
  - **We observed that almost all patients (90%) have a nutrition duration of less than two months in a hospital setting.**
  - **Patients on enteral nutrition outside of the hospital, take it on average longer than in the hospital.**

Patients on parenteral nutrition outside of the hospital have more comparable durations to hospitalised patients.

2.5 References part 2

Anderson, J., Peterson, K., Bourne, D. & Boundy, E. (2019) Effectiveness of Intradialytic Parenteral Nutrition in Treating Protein-Energy Wasting in Hemodialysis: A Rapid Systematic Review. *J Ren Nutr*.

3 PART 3: COSTS OF ENTERAL AND PARENTERAL NUTRITION IN BELGIUM

3.1 Cost-effectiveness of Enteral versus PN: A Literature review

As we saw in previous chapters (see Part 2 on data analysis), PN at home continues to be used in indications in which EN could also be considered, despite EN being widely accepted as a more appropriate clinical choice, whenever it is not contraindicated (Centre Hospitalier Universitaire de Liège 2015, NICE 2006). The existing data limitations hamper us to assess the appropriateness of (par)enteral nutrition. Therefore estimations on "inappropriate use" remain out of the project scope.

Nevertheless, in addition to the clinical value of EN, it is important to also evaluate the economic value of these two different medical nutrition types in order to facilitate the drafting of relevant recommendations for Belgian decision makers.

3.1.1 Methods

3.1.1.1 Search strategy

First, to avoid duplication efforts, a systematic literature review of economic reviews in Medline(OVID) and CRD HTA (Centre for Review and Dissemination Health Technology Assessments) was performed. No time restriction was used for this search. Then, our search was completed by searching for primary studies in CRD NHS EED (National Health Service Economic Evaluation Database) and Medline(OVID). No time restriction was used for CRD EED, but in order to limit the number of studies in Medline (OVID), a pragmatic decision was taken to limit the search to the last 10 years. More detail on search strategies and selection criteria, including a flow chart and an overview of included studies can be found in the appendix. Moreover, websites of HTA agencies (e.g. NICE) and networks (i.e. EUnetHTA and INAHTA) were consulted to retrieve systematic reviews of cost-effectiveness studies on this topic. The list of HTA website consulted is provided in an appendix.

3.1.1.2 Selection criteria

Reviews and primary studies were similarly assessed for eligibility against inclusion/exclusion criteria. All retrieved references were assessed against pre-defined selection criteria, in terms of population, intervention, comparator, outcomes and design. For primary studies, the design was restricted to full economic evaluations, i.e. studies comparing at least two alternative treatments in terms of costs and outcomes. Cost-minimization analyses (CMA), cost-utility analyses (CUA, with results expressed as incremental cost per quality-adjusted life year (QALY) gained), cost-effectiveness analyses (CEA, with results expressed as cost per life year (LY) gained) and cost-benefit analyses (CBA, with a monetary valuation of health outcomes) were eligible. Given the likely scarcity of full economic evaluations measuring costs and outcomes on an aggregated manner (ICERs), illustrated by the results of our preliminary search on SRs, it was decided to also include cost-consequence analyses in our review.

Cost comparisons (not considering health outcomes) and non-comparative cost-outcome descriptions were excluded.

The selection of relevant articles was performed by a single reviewer in a two-step procedure: initial assessment on title and abstract, followed by a full-text assessment of the selected references. When no abstract was available and the citation was unclear, consideration of the citation was directly made on the basis of a full-text assessment. If no full-text was found, the study was excluded. Letters, news, conference proceedings, abstracts, posters and editorials were excluded. Studies published in a language other than English, Dutch, French, Italian, Portuguese or Spanish were not included. The flow chart of the selection process can be found in appendix.

Table 18 – Economic evaluation selection criteria

Selection criteria	Inclusion criteria	Exclusion criteria
Population	Patients receiving medical nutrition (EN or PN) at hospital, home or residential care	Patients on mixed nutrition regimes for which a comparison between EN and PN was not possible
Intervention	EN	Oral nutrition or no nutrition support
Comparator	PN	Other nutritional regimes
Outcomes	All	No a priori limitations
Study design	Full economic evaluations: CMA, CUA, CEA, CBA, and Cost consequence analyses.	Cost comparisons (not considering health outcomes) Cost-outcome descriptions (not considering an alternative treatment) Other designs such as cost calculations Narrative reviews
Type of publication	Full article/report	Letters Editorials Notes Abstracts Posters Presentations

Note: Cost-minimization analyses (CMA), cost-utility analyses (CUA), cost-effectiveness analyses (CEA) and cost-benefit analyses (CBA).

3.1.2 Results of the economic search strategy

Our search was performed in February 2018, to identify economic reviews and primary studies regarding parenteral and EN. Medline(OVID), CRD HTA and CRD EED were consulted. The electronic searches returned 787 articles in total (137 in Medline(OVID) for economic reviews, 518 in Medline(OVID) for primary studies, 34 in CRD HTA and 98 in CRD EED). After exclusion of 51 duplicates and removing references published in other language than Dutch, English, French, Italian, Portuguese and Spanish 736 references remained. Two further studies were found via hand search (Patton and Aranda-Michel 2002, Zhang K 2005), given a total of 738 articles. The flow chart of the selection process is presented in the appendix. Based on title and abstract 625 references were excluded. Of the remaining 113 references, 12 references were included based on full-text evaluation. From these, 3 were SRs (Gao et al. 2015, Wheble et al. 2012, Wong et al. 2018) which were only used for checking purposes, in order to ensure no important studies had been missed. The next sections offer an overview of the 9 primary economic evaluations found via our search.

Table 19 – List of selected economic evaluations

References – economic evaluations
Yang S, Guo J, Ni Q, et al. Clinical Nutrition 2017 Dec 20; S0261-5614(17)31428-0. EN improves clinical outcome and reduces costs of acute mesenteric ischaemia after recanalisation in the intensive care unit(Yang et al. 2017)
Modi RM, Mikhail S, Ciombor K, et al. Diseases of the Esophagus 2017; 30(11):1-8. Outcomes of nutritional interventions to treat dysphagia in esophageal cancer: a population-based study(Modi et al. 2017)
Harvey SE, Parrott F, Harrison DA, et al. Health Technology Assessment 2016; 20(28):1-144. A multicentre, randomised controlled trial comparing the clinical effectiveness and cost-effectiveness of early nutritional support via the parenteral versus the enteral route in critically ill patients (CALORIES)(Harvey et al. 2016b)
Li CH, Chen DP and Yang J. Turkish Neurosurgery 2015; 25(6):873-6. ENal Support in Patients with Head Injuries After Craniocerebral Surgery(Li et al. 2015)
Cangelosi MJ, Auerbach HR and Cohen JT. Current Medical Research & Opinion 2011;27(2):413-22. A clinical and economic evaluation of EN(Cangelosi et al. 2011)
Ryu J, Nam BH and Jung YS. Dysphagia 2009; 24(4):378-86. Clinical outcomes comparing parenteral and nasogastric tube nutrition after laryngeal and pharyngeal cancer surgery(Ryu et al. 2009)
Louie BE, Noseworthy T, Hailey D, et al. Can J Surg. 2005 Aug;48(4):298-306. 2004 MacLean-Mueller prize enteral or PN for severe pancreatitis: a randomized controlled trial and health technology assessment(Louie et al. 2005)
Abou-Assi S, Craig K, O'Keefe SJ. Am J Gastroenterol 2002 Sep;97(9):2255-62. Hypocaloric jejunal feeding is better than total PN in acute pancreatitis: results of a randomized comparative study(Abou-Assi et al. 2002)
Braga M, Gianotti L, Gentilini O, et al. Crit Care Med. 2001 Feb;29(2):242-8. Early postoperative EN improves gut oxygenation and reduces costs compared with total PN(Abou-Assi et al. 2002)

3.1.2.1 Overview of economic evaluations

From the nine studies identified:

Four were performed in North America: three in the USA (Abou-Assi et al. 2002, Cangelosi et al. 2011, Modi et al. 2017) and one in Canada (Louie et al. 2005);

Three in Asia: two in China (Li et al. 2015, Yang et al. 2017) and one in Korea (Ryu et al. 2009) and

Two in Europe: one in the UK (Harvey et al. 2016a) and one in Italy (Braga et al. 2001).

No Belgian studies were identified via our search.

Publication dates for the included primary studies ranged from 2001 to 2017, with four evaluations published between 2015 and 2017.

3.1.2.2 Type of economic evaluation

Only two studies performed a cost-effectiveness analysis, taking into consideration different measures of nutritional effectiveness of EN versus that of PN. But, while Louie et al. (Louie et al. 2005) opted for a cost-minimisation approach, Harvey et al. (Harvey et al. 2016a) undertook a cost-utility evaluation. All remaining studies carried out cost-consequences analyses, looking at both costs and outcomes separately. In some cases these analyses lack the necessary detail to fully assess the validity of their results.

3.1.2.3 Time frame of analysis and discounting

Given the fact that most of the identified research carried out an evaluation during the hospitalisation period, costs and outcomes were mainly analysed within a limited time period. The only exception to this was the cost effectiveness evaluation carried out by Harvey et al. in the UK(Harvey et al. 2016a), for which three different time frames were considered: 90 days, one year and patients' lifetime. As a consequence, the time horizon in most other analyses, coincided with the a priori unknown length of hospitalisation, and therefore remained un-predetermined and was, in most cases, analysed as a study outcome (Abou-Assi et al. 2002, Braga et al. 2001, Cangelosi et al. 2011, Li et al. 2015, Modi et al. 2017, Ryu et al. 2009, Yang et al. 2017).

Two studies specified the length of the study period as 7 days (Li et al. 2015) and 6 weeks (Ryu et al. 2009). The short time horizons analysed made discounting unnecessary, with the exception of the UK study by Harvey et al. (Harvey et al. 2016a) which used 3,5% for both costs and outcomes, reflecting current guidelines in that country (NICE 2013).

3.1.2.4 Perspective and population

All but two of the studies evaluated, were carried out from a hospital perspective. The UK study by Harvey et al. (Harvey et al. 2016a) offered a wider Health Services perspective, while the Korean study by Ryu et al. (Ryu et al. 2009) neither specified the perspective used, nor offered a clear view on where the costs were captured from, making it difficult to fully understand the point of view from which the analysis was carried out.

Although all studies here included were limited to adults, they focused on different populations:

Three evaluations covered critically ill patients, with two looking at different indications (Cangelosi et al. 2011, Harvey et al. 2016a) and the remaining specifying acute myocardial infarction patients as being their interest.(Yang et al. 2017)

Two more analyses focused on acute pancreatitis (Abou-Assi et al. 2002, Louie et al. 2005).

The remaining four, studied patients undergoing surgery, most often following a diagnosis of cancer (of the stomach, pancreas, oesophagus, larynges or pharynges) (Braga et al. 2001, Li et al. 2015, Modi et al. 2017, Ryu et al. 2009).

Sample size varied greatly and went from a low of 28 patients (Louie et al. 2005) to a high of 12 205 (Modi et al. 2017), although most studies involved less than 300 patients and only two presented a large sample size. From the latter, Harvey et al. followed 2 400 critically ill patients (Harvey et al. 2016a) and Modi et al. (Modi et al. 2017) analysed a population of 12 205 patients undergoing surgery for oesophageal cancer with dysphagia.

3.1.2.5 Intervention and comparator

All evaluations identified via our search aimed at comparing costs and outcomes of enteral and PN. Small differences were found in the definition of both the intervention (here considered EN) and the comparator (PN). For example, a number of studies, specifically mentioned a focus on "early" EN, compared to "early PN, but the definition of "early" varied from one study to another, with most studies defining "early" as starting medical nutrition within 24 hours (Braga et al. 2001, Li et al. 2015, Louie et al. 2005, Ryu et al. 2009), while on the other extreme, Yang et al. (Yang et al. 2017) described "early" as commencing medical nutrition within 1 week of ICU admission.

There was great consistency across studies regarding an aimed caloric intake for both PN and EN of 25Kcal/kg/day.

3.1.2.6 Cost and outcome inputs

Costs

The estimations included in the evaluations here reviewed, were primarily based on RCT data (Abou-Assi et al. 2002, Braga et al. 2001, Harvey et al. 2016a, Li et al. 2015, Louie et al. 2005, Ryu et al. 2009). Only two studies relied on retrospective patient records (Modi et al. 2017, Yang et al. 2017). Finally, the US study by Cangelosi et al. (Cangelosi et al. 2011) used costs derived from the literature.

Costs quoted in the evaluations referred mainly to hospital accounting costs (Abou-Assi et al. 2002, Braga et al. 2001, Li et al. 2015, Louie et al. 2005, Yang et al. 2017). Two analyses from the USA, made use of national databases, specifying inpatient costs and charges (Cangelosi et al. 2011, Modi et al. 2017). The UK study from 2016(Harvey et al. 2016a), used national reimbursement databases covering both hospitalisation and home care. Finally, a Korean study (Ryu et al. 2009) from 2009 did not specify the source where costs were derived from.

Factors taken into consideration for the costing size of the analysis included in most cases hospitalisation costs other than the cost of the nutrition formulae and other prescribed products (e.g. vitamins and oligoelements). More specifically, they included: central venous catheter costs for PN and nasogastric tube for EN, staff time costs, disposables, length of stay costs (in the ICU and general wards), monitoring costs, and costs of complications (e.g. infections). Two of the studies, mentioned covering nutritional and hospitalisation costs, but did not offer a detailed description on them (Abou-Assi et al. 2002, Modi et al. 2017). A further study from China (Li et al. 2015), did not provide a complete definition of the costs included, although judging from the figures presented, they are likely to simply represent nutrition formulae costs.

Outcomes

Regarding outcomes, the most frequently used included: length of stay (LoS) in hospital, measured in 7/9 studies (Abou-Assi et al. 2002, Braga et al. 2001, Cangelosi et al. 2011, Li et al. 2015, Modi et al. 2017, Ryu et al. 2009, Yang et al. 2017), incidence of AEs or complications, also explored in 7/9 evaluations (Abou-Assi et al. 2002, Braga et al. 2001, Cangelosi et al. 2011, Li et al. 2015, Louie et al. 2005, Ryu et al. 2009, Yang et al. 2017), mortality captured in 5 of the 9 studies (Braga et al. 2001, Harvey et al. 2016a, Louie et al. 2005, Modi et al. 2017, Yang et al. 2017), duration of nutrition therapy, studied in 3 occasions (Abou-Assi et al. 2002, Cangelosi et al. 2011, Ryu et al. 2009). Quality adjusted life years (QALYs) was only explored by Harvey et al. (Harvey et al. 2016a). A full list of all outcomes explored in this review is offered in Table 22.

3.1.2.7 Modelling

Only one of the studies included, made use of modelling in order to extrapolate the cost and outcome data obtained via their RCT over 1 year to a life year time frame. A time horizon of 20 years was chosen as a limit. The available survival data from the trial was used to plot Kaplan–Meier survival curves out to the date of censoring. Data on patients alive at 1 year were then extrapolated by applying parametric extrapolations.

Alternative parametric survival curves were considered, and the parametric extrapolation was combined with all-cause mortality rates to report life expectancy for each patient. Lifetime costs captured via the RCT up to the end of year 1, were considered relative to the initial clinical episode and were applied annually for the number of years (within the time horizon) over which

the parametric survival model predicted excess mortality compared with the age–gender-matched general population

Sensitivity analysis was carried out (see section 3.1.2.9).

All other studies, simply compared their outcomes and costs over the short term and did therefore, not require any modelling.

3.1.2.8 Results

The overall mean incremental costs of PN versus EN varied greatly from one study to another due to differences in the factors considered, indications studied, patient populations, time horizons and local prices/practices (see **Table 21**). Despite these differences, there was consistency in the findings regarding the lower overall costs linked to EN when compared with PN. Most of the potential savings, appeared to come from differences in the cost of the nutrition formulae, which is noticeably cheaper in the case of EN when compared to PN (Abou-Assi et al. 2002, Braga et al. 2001, Harvey et al. 2016a, Louie et al. 2005, Ryu et al. 2009, Yang et al. 2017). Nevertheless, further potential savings linked to other factors such as shorter LOS (Cangelosi et al. 2011), length of nutritional therapy (Abou-Assi et al. 2002), incidence of complications (Cangelosi et al. 2011) or shorter stays in ICU care (Yang et al. 2017) were also shown. This was despite the fact that the studies focussed in different patient populations. Two studies (Li et al. 2015, Modi et al. 2017), calculated only the overall cost savings that could be derived from the use of EN as opposed to PN and did not specify the weight of different cost factors.

Some of the studies included in this review, did find statistically significant differences in some of the outcomes studied, favouring EN as opposed to PN (see for details). Thus, four studies, showed that patients on EN had significantly shorter length of hospital stays than patients on PN (Cangelosi et al. 2011, Li et al. 2015, Modi et al. 2017, Yang et al. 2017). Mean reductions ranged from a minimum of 1,66 days (Cangelosi et al. 2011) to a maximum of 5 days (Yang et al. 2017).

Three out of the seven evaluations identified which considered complications as an outcome highlighted significant differences, favouring patients fed with EN, with Yang et al. describing reductions specifically in infections (Yang et al. 2017), Cangelosi et al., finding significant differences in major infectious and major non-infectious complications (but not in minor complications) (Cangelosi et al. 2011) and Abou-Assi et al. revealing a significant reduction in septic complications (Abou-Assi et al. 2002). All others found no significant differences.

Two out of the five studies that looked at mortality found significant differences favouring EN versus PN (Modi et al. 2017, Yang et al. 2017), while the remaining three did not see significant differences (Braga et al. 2001, Harvey et al. 2016a, Louie et al. 2005).

Only one out of the three studies which looked at length of ICU stay, found a significant difference, of five days, once more in favour of EN versus PN (Yang et al. 2017).

Finally, a US study saw a significant difference in the duration of “medical” nutrition, of 10,8 days with PN versus 6,7 days with EN; (p=0,03).

The UK study which captured ICERs concluded that QALYs were similar at year 1 for EN vs PN nutrition, while costs appeared to be lower for the former, making it a better choice, if not contraindicated. The probability of PN being cost effective was reported to be of less than 20% at a willingness to pay of £20 000 (Harvey et al. 2016a).

3.1.2.9 Sensitivity analysis

Uncertainty is intrinsic to any economic evaluations and should therefore always be accounted for. However, given the fact that the studies included in this review consisted mostly of cost consequences studies, and only one presented a full economic evaluation, it may not be surprising that only the full economic evaluation by Harvey et al.(Harvey et al. 2016a) performed both univariate and probabilistic sensitivity analyses, to assess the robustness of their results.

A further two, carried out simple scenario estimations (conservative versus optimistic) (Cangelosi et al. 2011, Louie et al. 2005). In these very few cases in which the uncertainty was looked at, the results appeared to be robust.

3.1.2.10 Conflict of interest

Three of the nine cost studies included in this review did not provide a declaration of conflict of interest in their manuscript (Braga et al. 2001, Li et al. 2015, Ryu et al. 2009). A further two, declared to have received funding from manufacturers of nutritional products.

The existence of conflicts of interest may introduce a bias which could affect the validity of the study results, although there is, up to date, no hard evidence on this.

Table 20 – Overview of selected economic evaluations

Study	Country	Type of analysis	Setting/Perspective	Intervention/comparator	Time window	Discount rate (%)
Yang et al. 2017	China	Cost-consequences	ICU/Hospital perspective	Early EN /early PN	Hospitalisation period	NA
Modi et al. 2017	USA	Cost-consequences	Hospital/Hospital perspective	EN/PN/esophageal stenting	Hospitalisation period	NA
Harvey et al. 2016	UK	Cost effectiveness	Critical care units /Health services	Early PN/early EN	90 days, 1 yr and lifetime	3,5% for both costs and outcomes
Li et al. 2015	China	Cost-consequences	Hospital/Hospital perspective	Early EN/early PN	7days	NA
Cangelosi et al. 2011	USA	Cost-consequences	Hospital/Hospital perspective	EN/PN	NS	NA
Ryu et al. 2009	Korea	Cost-consequences	Hospital/ Unclear	Early EN/early PN	6 weeks	NA
Louie et al. 2009	Canada	Cost effectiveness	Hospital/ Regional authority or hospital perspective	Early EN/early PN	Hospitalisation period	NA
Abou-Assi et al. 2002	USA	Cost-consequences	Hospital/Hospital perspective	EN/PN	Hospitalisation period	NA
Braga et al. 2001	Italy	Cost-consequences	Hospital (surgical department)/Hospital perspective	Early EN/early PN	Hospitalisation period	NA

NS: Not specified;

Table 21 – Costs of medical nutrition

Study	Costing Yr	Time horizon	Population/ Indication	Costs included	Costing Source	Incremental cost/patient over study period
Yang et al. 2017 China	Taken from a registry. Not updated	Hospitalisation period	183 (95 EN, 88 PN) re-canalised AMI patients	Infusion set; nutrition solutions (inc vit and oligoel); ICU care; monitoring; medical staff	Retrospective patient review	Overall -$339 ($595.8 EN vs $934.8 PN; p<0.01). Nutrition solutions: -$365.19 ($40.51 EN vs $405.7 PN solutions); ICU care -$33.82 ($220,45 EN vs $254,27 PN)
Modi et al. 2917 USA	Taken from a registry. Not updated	Hospitalisation period	12205 hospitalised adults with oesophageal cancer with dysphagia	Hospital costs (no detailed information)	Retrospective inpatient review	Total incremental cost of EN vs PN -$5 510 (95%CI $2 262; $8 759; p=0,004). Using PEG tube only as reference the incremental costs of EN were -$7 638 (95%CI -$4 896; -$10 380; p<0,001)
Harvey et al. 2016 UK	2013–14	90 days, 1 yr and lifetime	2400 critically ill patients	Nutritional intervention, glucose, propofol and insulin, staff time, LoS (in critical care and at the hospital), and readmissions	Open multicentre, parallel group RCT	Overall costs at 90 days: -£1293 (£23 164 EN vs £24 458 PN; p=0,14). Overall costs at 1 yr: -£1580 (£26 775 EN vs £28 354 PN; p=0,19). Overall costs at lifetime: -£2505 (£50 595 EN vs £53 100 PN; p=0,13). Mean cost of nutrition formulae/products at 90 days: -£177 (£51 EN vs £228 PN).
Li et al. 2015 China	NS	7days	272 patients undergoing gastric surgery	Nutritional support costs (no detail or definition offered, although from the figures presented likely to represent "nutrition solutions" only)	RCT	Cost per patient/day: -$14,8 ($71,5 EN vs $86,3 PN; p<0,001)
Cangelosi et al. 2011 USA	NS	NS	Adult critically ill patients.	Cost of complications grouped in different categories: major infectious complications, minor infectious complications, major non-infectious complications and minor non-infectious complications	MA of available literature	Costs/patient of reducing major infections: -$1074 (95%CI: -$199; -$2587); Costs/patient of reducing minor infections: -$161 (95%CI: $28; -$558); Cost/patient of reducing major non-infections AEs: $261 (95%CI:-$34; -$518). Cost/patient of reducing minor non infectious: NA since no good data available and considered very low (almost negligible). Cost/patient of reducing all AEs: -$1496

						(95%CI: -$205; -$3663). Cost/patient of reduction in hospital LoS: -$2473 (95%CI: -$1416; -$3531)
Ryu et al. 2009 Korea	2007 (not updated)	6 weeks	84 adults following surgery after laryngeal and pharyngeal cancer	Cost of PN and EN nutrition products; cost of device: central venous catheter (CVC) for PN and nasogastric tube (NG) for EN; staff costs and disposables (i.e. syringes, infusion lines and pumps)	RCT	Overall costs/ patient/ day: -$11,81 ($19,60 EN vs $31,41 PN). Nutrition solutions: -$9,92 ($19,60 EN vs $31,41 PN); Pump: -$1,68 ($0 EN vs $1,68 PN); Staff: -$0,21 ($1,2 EN vs $1,41 PN); Initial cost of devices (CVC vs NG tube): -$20,70 ($3,51 EN vs $24,21 PN).
Louie et al. 2005 Canada	NS	Hospitalisation period	28 adults with acute pancreatitis; Ranson's score ≥3 and inability to tolerate oral fluids after a maximum of 96 hrs after admission	Nutrition solution costs; Overhead costs; Radiology costs (CT, ultrasonography and insertion of catheters); operation procedures, non-operative complications (Per diem costs for general and intensive care). Costs common to both groups excluded	RCT	Nutritional costs:-$1233 ($1375 EN vs $2608 PN; p=0,08); Other cost categories (radiology, ICU costs and operative costs) were similar.
Abou-Assi et al. 2002 USA	2000 (not updated)	Hospitalisation period	53 adults hospitalised with acute pancreatitis	Nutritional costs and total hospitalisation costs.	RCT	Nutritional costs/patient fed: -$2362 ($394 EN vs $2756 PN; p=0,0004). Nutritional daily costs: -$198,7 ($23,30 EN vs $222 PN). Hospitalisation costs: -$8066 ($26464 EN vs $34530 PN).
Braga et al. 2001 Italy	NS	Hospitalisation period	257 adults with cancer of the stomach, pancreas or oesophagus following a surgical procedure	Infusion set; Test for monitoring; prescriptions; and personnel costs.	RCT	Nutritional costs/patient fed: -$875,92 ($320 EN vs $1195,92 PN). Costs/patient/day: -$65,6 ($25 EN vs $90,60 PN; p<0,001). Nutrition solutions costs/patient/day: -$60,64 ($5,5 EN vs $66,14 PN). Costs of all other variables were similar.

Table 22 – Outcomes of medical nutrition

Study	Time horizon	Outcomes considered	Intervention/comparator	Outcome Source	Incremental Outcomes (as reported)
Yang et al. 2017 China	Hospitalisation period	Rate of bowel schaemia; recurrence, relaparotomy and repeat bowel resection; time to restoration of bowel continuity; LoS at ICU and LoS at hospital; APACHE II score on PRD-7; Incidence of SBS, MODS and PN for =or>6 months; 30 day all cause mortality and 1 yr survival.	Early EN /early PN	Retrospective patient review	Length of ICU stay: -5 days (13 EN vs 18 PN, p<0,001) and length of hospitalisation: - 6 days (20 EN vs 26 PN; <0,001); Infectious complications: -11% (7% EN vs 18% PN; p<0,01); Rate of long term PN requirement (over 6 months): -9% (7% EN vs 16% PN; p=0,027); 1-yr cumulative survival rate 10% (88,4% EN vs 78,4% PN; p=0,031)
Modi et al. 2917 USA	Hospitalisation period	Inpatient all cause mortality (period 2002-2012); LoS at hospital and hospital costs	EN/PN/esophageal stenting	Retrospective patient review	OR mortality PN vs EN: 2,37 (95%CI: 1,22; 4,63; p=0,035); OR mortality PN vs PEG tube only: 3,13 (95%CI: 1,54; 6,37; p=0,007); OR LoS PN vs EN: 2,13 (95% CI: 0,72; 3,54); OR LoS PN vs PEG tube only: 3,26 (95% CI: 1,99; 4,52)
Harvey et al. 2016 UK	90 days, 1 yr and lifetime	All-cause mortality at 30 days after randomisation and incremental net benefit (INB) (at £20,000 per quality-adjusted life-year) at 90 days and 1 year	Early PN/early EN	Open multicentre, parallel group RCT	At 30 days, 33.1% patients on PN and 34.2% on EN had died (p = 0,57); absolute risk reduction 1.15%, (95% CI: -2.65; 4.94); relative risk 0.97 (95%CI: 0.86; 1.08). QALYs at 1 yr: PN vs EN: 0,013 (95% CI: 0,014; 0,040; p=0,35)
Li et al. 2015 China	7days	Body weight (BW), Transferrin (TF), Prealbumin (PA), highly-sensitive C-reactive protein (hs-CRP), LoS, and incidence of complications.	Early EN/early PN	RCT	Differences EN vs PN: Signif. ↑ observed in TF and PA (p<0,01). Signif. ↓ in hs-CRP (p<0,01). Incremental days in anal exhaust time -1,5 (2,2; SD: 0,3 with EN vs 3,7; SD: 0,5 with PN). Incremental LoS (in days) -3,5 (16,2; SD: 3,6 with EN vs 19,7; SD: 4,5 with PN). Incremental incidence of complications -9 (29; SD: 10,6 with EN vs 38; SD 14 with PN)
Cangelosi et al. 2011 USA	NS	Mortality (time dependant on study since MA of different studies), AEs (major infections, minor infections, major non-infectious events and major non-infectious	EN/PN	MA of available lit.	Median relative risk (RR) ↓ (EN vs PN) of death: 0.70 (0.45; 1.09). Median absolute risk (AR) ↓: 2.8% (0.2%; 5.9%). Median RR ↓ of major infections: 0.58 (0.44; 0.77); median AR ↓: 4.3% (1.4%; 7.1%). Median RR ↓ of minor infections: 0.75 (0.52; 1.10); median AR ↓: 1.1% (0.4%, 2.5%). Median RR ↓ of major non-infectious: 0.73

		events, nutritional treatment duration, LoS at hospital and LoS in the ICU			(0.59; 0.91); median AR ↓: 4.1% (0.7%, 7.6%). Median RR ↓ of minor non-infectious: 0.97 (0.61; 1.56); median AR ↓: 0.5% (6.1%; 7.1%). Length of nutritional treatment: Mean ↓ LOS (in days): 1.66 (0.95 to 2.37).
Ryu et al. 2009 Korea	6 weeks	Time to commencement of oral feeding, LoS at hospital?, complications (e.g. fistula).	Early EN/early PN	RCT	No statistically sig difference in clinical outcomes (time to oral commencement, LoS or complications). One case of catheter related sepsis was seen in the PN group, while aspiration pneumonia was present in 4 patients in the EN group. Nasal or pharyngeal pain and discomfort were stat sig more severe in the EN group during the first week although became similar after that.
Louie et al. 2005 Canada	Hospitalisation period	Reduction in inflammation (C-reactive protein and Lipase); Effective nutrition (body mass index, ideal body weight, albumin, prealbumin and 24-hrs urinary nitrogen levels. Mortality and morbidity (secondary to pancreatitis and secondary to nutritional therapy) over the hospitalisation period.	Early EN/early PN	RCT	No stat sig differences in outcomes. A trend in quicker reduction of inflammation for C-reactive protein was seen.
Abou-Assi et al. 2002 USA	Hospitalisation period	LoS at hospital, duration of nutritional therapy, incidence of nutritional complications (including death) and tolerance to starting oral diet.	EN/PN	RCT	Duration of feeding EN vs PN: -4,1 days (6,7 EN vs 10,8 PN; p=0,03). EN less effective in meeting nutritional requirements (54% with EN vs 88% with PN; p<0,0001). Significantly less metabolic complications with EN (hyperglycemia requiring insulin in 4 EN patients vs 14 PN patients; p=0,03) and less septic complications in the EN group (catheter related infections requiring removal of catheter and antibiotic use in 1 EN patient vs 9 PN patients; p=0,01). No significant differences were seen in the other outcomes studies.
Braga et al. 2001 Italy	Hospitalisation period	Morbidity, mortality over hospitalisation period and LoS at hospital.	Early EN/early PN	RCT	No statistically significant differences were found for infectious or non-infectious complications, LoS or mortality between the two groups.

3.1.3 Conclusions and limitations

Our review is not exempt of limitations. It is important to highlight that the purpose of this review was to offer a comprehensive overview of the cost effectiveness and/or economic value that EN may offer when compared to PN, in indications where the former is not contraindicated.

Given the scarcity of full cost effectiveness evaluations, the authors of this review made a decision to be as inclusive as possible on this regard and to add cost consequences studies looking at both costs and outcomes, even when these were not analysed together, in order to enrich the informative value of the chapter. This meant that some of the considered evidence lacked the quantitative detail to draw clear conclusions on the cost effectiveness of EN versus PN nutrition.

No Belgian studies were identified, and only two European studies were included (Braga et al. 2001, Harvey et al. 2016a), while three were undertaken in Asian countries (Li et al. 2015, Ryu et al. 2009, Yang et al. 2017), where not just costs, but also standard practices could differ greatly from those followed in this country.

Nevertheless, the consistency in the overall results supports an incremental economic value of EN, which complements the well accepted clinical preference for this type of medical nutrition, compared to PN, for as long as the former is not contraindicated.

The following chapter looks at the Belgian context and in particular at the current reimbursement and costs surrounding medical nutrition in Belgium.

Key points

- **Very limited evidence on cost effectiveness in this field**
- **No Belgian evaluations published**
- **Low quality studies in general**
- **High consistency in the results**
- **Studies favour the economic value of EN versus PN, which appears to be mainly (but not exclusively) driven by the lower prices of EN nutrition solutions.**

3.2 Reimbursement and funding of enteral (EN) and parenteral (PN) nutrition in Belgium

This section summarises the (complex) situation surrounding the reimbursement rules and coverage of enteral (EN) and parenteral (PN) nutrition in this country.

3.2.1 Methods

The description of coverage and reimbursement rules and practices presented below draws mainly from information publicly available from the RIZIV-INAMI[n], but also from face to face discussions with stakeholders and, to a lesser extent, from the grey literature. When the information is derived from the grey literature, an explicit mention and references or footnotes are provided.

It is important to highlight that “home” is used for both “home care and residential home care”, since the same reimbursement rules apply for patients on medical nutrition, whether they live at home or in a residence.

[n] http://www.inami.fgov.be/fr/themes/cout-remboursement/par-mutualite/produits-sante/nutrition/Pages/default.aspx#.WuGTFJexWUk

http://www.inami.fgov.be/nl/themas/kost-terugbetaling/door-ziekenfonds/gezondheidsproducten/voeding/Paginas/default.aspx#.WuGTQpexWUk

Official list prices for nutrition bags and vitamins/oligoelements were obtained via consultation of six online Belgian pharmacies[o], discussions with "at home" services providers and, to a lesser extent, consultation of administrative databases (IMA-AIM reimbursement data[p]) or the Belgian Centre of Pharmaco-therapeutic Information[q] . The cost of material and pump used at home was primarily based on a "Kom op tegen Kanker" report (Rommel et al. 2017)[r] for EN, and from stakeholders for PN. All list prices and material and equipment costs are "final" costs and therefore inclusive of value added tax (VAT): The relevant rates (reduced: 6% or normal: 21%)[s] were taken directly from the sources consulted.

It is important to note that the prices here quoted reflect mean public prices and, for the hospital setting, they do not take into consideration discounts. They may, therefore, offer an overestimation of the "real costs".

3.2.2 Background information on reimbursement decisions for EN and PN at home

3.2.2.1 Advisory bodies and committees involved in reimbursement decisions for medical nutrition at home

The reimbursement of specific dietetic products is regulated in the Royal Decree of 24 October 2002[t]. Since then, small modifications or adaptations have been introduced in the law, the latest via a Royal Decree from 25 March 2018.[u]

At present reimbursement decisions on nutrition involve an important number of bodies at RIZIV/INAMI, for which some overlap exists. These include:

- The Medical nutrition working group[v] (Werkgroep Medische Voeding/ Groupe de travail Nutrition médicale):
  This is composed by members of the OCA (see below), dietitians, nurses and other medical nutrition experts.
- OCA - Contract committee for pharmacists-insurance institutions[w] (Overeenkomstencommissie apothekers-verzekeringsinstellingen / Convention entre les pharmaciens et les organismes assureurs): Mainly composed by community and hospital pharmacists.
- Committee on Budgetary Control (Commissie voor begrotingscontrole/ La Commission de contrôle budgétaire):

o Farmaline.be, medibib.be, newpharma.be, multipharma.be, pharma-online.be and sorgente.be.

p http://aim-ima.be/L-Echantillon-Permanent-EPS?lang_ok=oui

q Belgisch centrum voor farmacopeutische informatie: http://www.bcfi.be; Centre Belge d' Information Pharmacothérapeutique: http://www.cbip.be.

r https://www.komoptegenkanker.be/sites/default/files/media/2018-10/de_kosten_van_implantaten_def_pdf_0.pdf

s https://www.departementwvg.be/sites/default/files/media/documenten/KB%2020%20BTW-Tarieven.pdf

t http://www.etaamb.be/fr/arrete-royal-du-24-octobre-2002_n2002022792.html

u https://legalnews.be/wp-content/uploads/2018/05/30_1.pdf

v https://www.riziv.fgov.be/fr/inami/organes/Pages/soins-sante-organes.aspx#Le_Comité_de_l'assurance_soins_de_santé

w https://www.riziv.fgov.be/nl/professionals/individuelezorgverleners/apothekers/Paginas/overeenkomst-apothekers-verzekeringsinstellingen.aspx

Formed by representatives of insurance institutions, doctors and dentists, pharmacists, care institutions, paramedics (physiotherapists, nurses, speech therapists, ...), the Minister of Social Affairs and Public Health, of Budget, of Security and Home Affairs and of Employment, Economy and Consumer Affairs.

- Committee for Health Care Insurance (Comité van de verzekering voor geneeskundige verzorging/ le Comité de l'assurance soins de santé): Composed by physicians and dentists, pharmacists, care institutions and services, paramedics, Ministers of Social Affairs and Public Health, Budget and Social Security (Self-employed) and the social partners (advisory voice).
- Council for Health Care Insurance (de Algemene raad van de verzekering voor geneeskundige verzorging / le Conseil général de l'assurance soins de santé)
- Board of medical directors (College van artsen- directeurs /: Le Collège des médecins-directeurs).

Decision-making power is shared between the financial contributors to the system (government, employers, salaried employees and self-employed workers) and the sickness funds. Representatives of health care providers have an advisory role. The General Council decides on general policy matters concerning health insurance.

Since the OCA does not have a special focus on nutrition, the medical nutrition working group was set up in order to review all dossiers related to nutrition. The tasks of the working group largely correspond to those of the Technical Councils at the RIZIV/INAMI.

The main task of the OCA, is to prioritize the files. Once prioritized, these files go to the Committee on Budgetary Control, in charge of assessing whether the proposal for reimbursement fits within the planned budget.

Finally, the file passes by the Committee for Health Care Insurance, where a final advice to the General Council for Health Care Insurance is offered, from the point of view of all care providers, taking into consideration the recommendations of the OCA and the Committee on Budgetary Control.

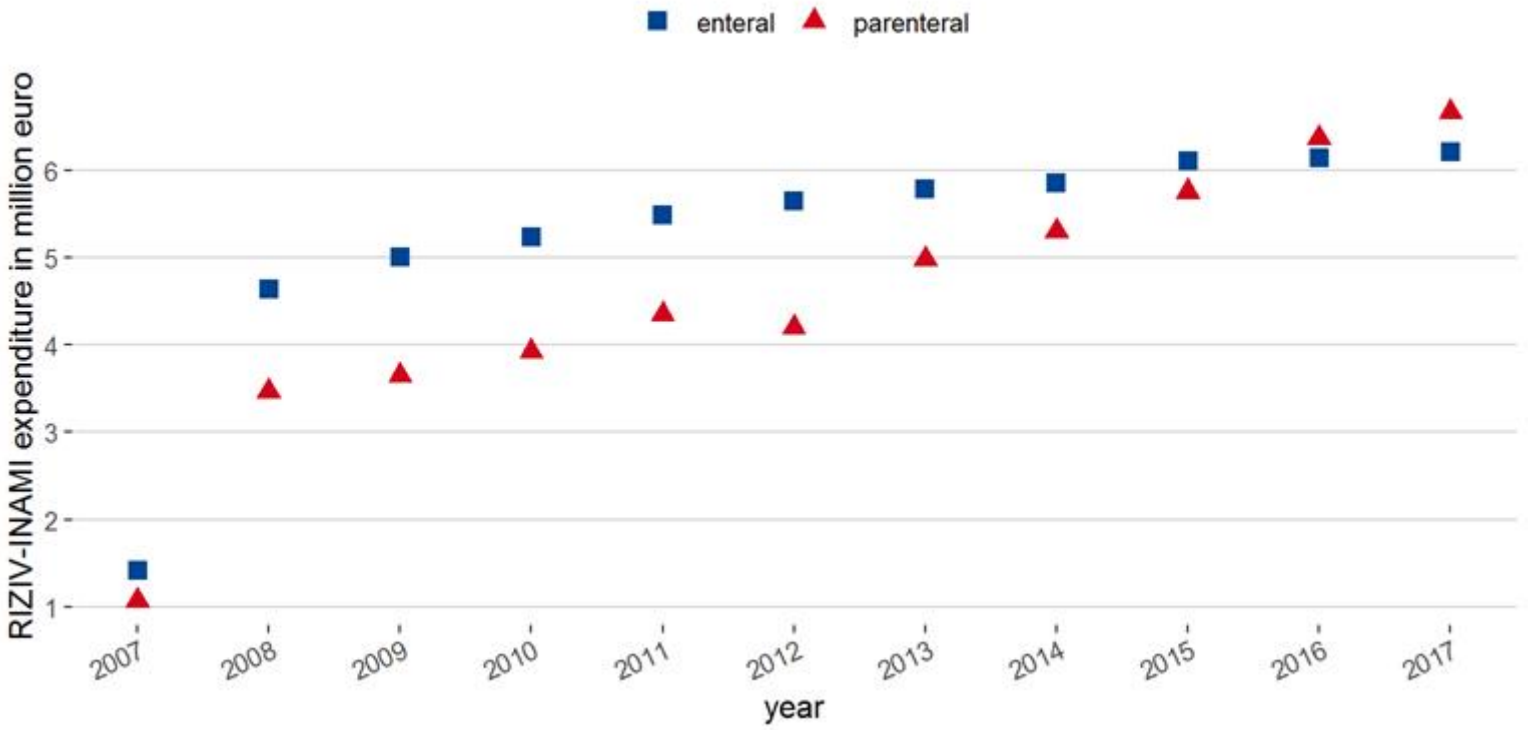
The Board of medical directors can propose modifications to the system (e.g. changes in the indications covered or in the insurance benefits).

3.2.2.2 Maximum budget allowance for EN and PN (solutions, pumps and materials) at home

According to figures from the RIZIV/INAMI, their overall expenses in 2017 for EN nutrition (i.e solutions, pumps and materials) were 6,246,000€, representing an actual growth of 1,6% from the previous year. Expenses in PN (solutions with or without vitamins and trace elements) on the other hand, were slightly over those for EN, reaching 6,825,000€ in 2017, up by 10,3% from the previous year. Expenses appear to be in line with the "maximum" budget figures estimated for 2017 in the case of EN, while PN showed a growth slightly above (+0,5% over budget).

Figure 27 shows the growth in expenditure from a health insurance perspective in the last 10 years for both EN and PN nutrition at home.

Figure 27 – Health Insurance expenditure in parenteral and enteral nutrition (i.e. bags, pump and materials) - home use 2007-2017



It is important to note, that the overall expenditure for medical nutrition products was 25,761,000€ for the year 2017, with a growth of 5,4% in comparison to the previous year, and well within the established budgetary limits.

This budget includes in addition to EN and PN products, other types of foods such as special diet foods or foods for celiac or gluten allergies. It is therefore, split into categories covering different types of nutrition for which “maximum” annual growth rates are set.

Although currently the overall budget does not leave room for expansion (over the estimated accepted annual growth rate), compensations within the different categories are possible (e.g. if savings were made in PN use, these could be used to increase the budget allowance for EN).

Therefore, if additional reimbursement is needed, a first option could be to look for compensation/coverage coming from another “medical food” category. An alternative would be to request an overall budget increase via a “needs request”. Such requests need to be introduced by the medical

nutrition working groups to the OCA with a detailed description of the need/situation, proposition, annual budgetary impact and suggestions regarding possible compensation measures. Likelihood of acceptance depends on the size of the budget and other existing, competing priorities.

Finally, a limited budget was agreed as part of action 12 of the plan for "rare illnesses"[x], published in 2014, that could potentially be used for a limited number of patients with rare chronic conditions, such as metabolic diseases and chronic renal insufficiency.

3.2.3 Enteral and parenteral nutrition in hospital

Most often, parenteral or enteral nutrition is started during a hospitalization episode. Already in this setting, different funding rules apply for the two nutrition types.

Hospital perspective

On the one hand, EN is included in the hospital Budget of Financial Means (BFM), and therefore financed through a prospective closed-end budget. This BFM, covers mainly the hotel function and nursing activities. EN is considered part of the "hotel function" in the same way as oral nutrition, since it is considered "food", despite the complexities linked to the careful administration it requires.

PN, on the other hand, is considered a pharmaceutical and therefore part of the pharmaceutical hospital budget which also consist mainly on a prospective payment[y]. Since 2006, 75% of medicine expenditure is financed through a lump sum, and the remaining 25% is reimbursed per product (Gerkens et al. 2010).

In this context, the amount of use/administration of medical nutrition in the hospital is to a large extent, independent from its main funding mechanism, and as such, the lower the use of these types of nutrition, or the cheapest the products used are, the better it would be for the hospital budget.

The official "list/public" price for PN (pre mixed) solutions[z] vary depending on the size of the bag, with a mean price of around €56.82 per 2000 Kcal (assuming complete dependency on PN). The most frequently used EN solutions (polymeric) on the other hand, have official "list/public" prices mostly ranging from €10-16 per 2000 Kcal, with a mean price of €13.88[aa]. This is below the price of semi-elemental EN solutions[bb] (≈€41,01 per 2000 Kcal). EN is therefore a significantly cheaper alternative from a hospital perspective (assuming similar workload/human resources involvement).

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x Available at: https://www.health.belgium.be/sites/default/files/uploads/fields/fpshealth_theme_file/plan_belge_maladies_rares.pdf

y The prospective budget is calculated based on its case mix and the national average cost per APR-DRG, taking into account the severity of illness.

z Based on mean of list prices for Smofkabiven 16Gr N, from 6 Belgian online pharmacies consulted (only 2 online pharmacies referred prices) and the evaluation report by RIZIV-INAMI (https://www.inami.fgov.be/SiteCollectionDocuments/smofkabiven_j60.pdf).

aa Based on mean list prices from 6 Belgian online pharmacies (for the following polymeric solution: novasource GI control, nutrison MF, nutrison energy MF, nutrison protein plus MF and Fresubin HP Energy Fibre), as well as on prices quoted in a report by Kom op tegen Kanker from 2017, available at: https://www.komoptegenkanker.be/sites/default/files/media/2018-10/de_kosten_van_implantaten_def_pdf_0.pdf

bb Based on mean list prices of Peptamen af (0.5L) from 6 Belgian online pharmacies as well as on prices quoted in the report by Kom op tegen Kanker from 2017, available at: https://www.komoptegenkanker.be/sites/default/files/media/2018-10/de_kosten_van_implantaten_def_pdf_0.pdf

Patient perspective

EN is also less expensive from a patient perspective when hospitalized, since it is covered by the hospital budget BFM. As such, the patient is exempt from any financial contribution on that regard.

Although PN bags[cc] are covered by the hospital's pharmaceutical budget and are fully reimbursed by RIZIV-INAMI, most often, they require the addition of vitamins, and trace elements(Centre Hospitalier Universitaire de Liège 2015, NICE 2006), which are not reimbursed[dd] and thus, represent out of pocket expenses for the patient. The official, "list/public" price of commonly used intravenous vitamins and trace elements is of €7.09[ee] and €3-4[ff] (mean €3.61) per day respectively, which translates into mean out of pocket expenses for the patient of around €10.70 per day.

Table 23, summarizes the information regarding coverage and patient out of pocket expenses in hospitals in Belgium for medical nutrition solutions. To keep the illustration simple, only the most frequently used nutritions are represented. Thus, in the case of EN, the figures reflect costs and coverage of polymeric solutions, while for PN, only industrial pre-mixed bags are considered. Furthermore, the costs of materials and pumps are not included in the table, first because of the difficulties that exist in identifying adequate, representative estimates for prices of both disposable and reusable materials within the hospital setting, and second, because in this setting, all materials required for the administration of medical nutrition (PN or EN) are covered by the hospital budget and in no case, represent out of pocket expenses for the patient, which makes such costs less relevant for the purpose of our analysis.

Table 23 – Daily hospital patient out of pocket expenses for medical nutrition solutions in Belgium

Type of Nutrition	Mean cost/day	Patient out of pocket expenses/day
ENTERAL - Polymeric solution	€13.88*	Fully covered (no out of pocket payment)
PARENTERAL - (a+b)	€67.52	€10.70
Nutrition solution - pre-mixed bags (a)	€56.82**	Fully covered (no out of pocket payment)
Vitamins/oligoelements (b)	€10.70***	€10.70

*Note: *Based on mean list prices from 6 online pharmacies in Belgium and, for EN, also on prices quoted in a report by Kom op tegen Kanker from 2017. Available at "https://www.komoptegenkanker.be/sites/default/files/media/2018-10/de_kosten_van_implantaten_def_pdf_0.pdf, for an intake of 2000Kcal/day.*
***Based on mean of list prices for Smofkabiven 16Gr N, from 6 Belgian online pharmacies consulted (only 2 online pharmacies referred prices) and the evaluation report by RIZIV-INAMI (https://www.inami.fgov.be/SiteCollectionDocuments/smofkabiven_j60.pdf).*
****Based on mean list prices of Cernevit(R) and Addamel(R).*

[cc] PN bags are classified as A – 100% reimbursed by RIZIV-INAMI.

[dd] Classified as D – non-reimbursed medicines.

[ee] Based on price of Cernevit (10 units), available at http://www.bcfi.be/nl/chapters/15?frag=13730

[ff] Based on mean list price from 6 online pharmacies in Belgium for Addamel 10ml (20 units).

3.2.4 Reimbursement for EN and PN use at home in Belgium

Reimbursement for EN or PN at home is subject to a prescription by a medical specialist, or other medical doctor (MD) in case of EN, working in collaboration with a hospital medical team with experience in nutrition, who must fill in a specific form aimed at obtaining an agreement from the sickness funds[gg].

The authorization from the sickness funds, once obtained, is valid for 1 year but can be renewed, for periods of maximum 12 months for each request in case of EN, and periods of up to five years for each request in case of PN. Data from IMA – AIM for the period 2007-2016, show that more than half of patients on EN (between 60% and 82% depending on number of episodes) and almost all patients on PN received their treatment for less than 6 months (see section on duration in the data analysis chapter for more details). Nevertheless, a small number of patients on EN (less than 10%) and even less on PN, had treatment periods longer than one year.

The necessary services required to facilitate the administration of EN or PN at home, are currently, under most circumstances (despite some variation in practice), outsourced to a limited number of companies (2-4) who are directly paid by the hospital (in case of PN) or by patients themselves (in case of EN) and become responsible for multiple aspects related to the care of patients requiring these special nutrition arrangements: such as the logistics linked to the delivery and maintenance of the necessary medical equipment (e.g. pump) and the training or education of home nurses, patients and/or family carers. In addition to this, they also ensure the same information reaches all interested parties and remain in contact with the treating physician, dietician and GP.

The hospital remains responsible for any special “custom made” product preparation (when this is required).

3.2.4.1 PN at home

General reimbursement rules for all patients receiving PN at home

PN at home, should only be pursued for specific conditions (KB 20-07-2007), under which benign and malignant patients are unable to achieve a sufficient nutritional intake to meet their metabolic needs via oral or EN. The possible conditions are summarised below:

1. Temporary or permanent intestinal insufficiency as a result of:

- idiopathic inflammatory diseases of the intestine (Crohn's disease, ulcerative hemorrhagic ulcerative colitis), which are drug resistant and affect extensive segments of the intestine
- extensive intestinal resections
- very severe intestinal malabsorption
- Radiation enteritis
- Total villous atrophy (celiac disease) or equivalent conditions that do not respond to standard treatment
- Intestinal lymphomas
- Chronic pancreatitis for which oral or EN are not possible
- Cystic fibrosis
- Peritoneal carcinomatosis with bowel obstruction.
    - secondary infection of the digestive tract in patients with the "acquired immunodeficiency syndrome"
    - recurrent diarrhea of the child, (congenital or acquired)
    - recurrent chylous ascites.

[gg] Reimbursement documents for EN: https://www.riziv.fgov.be/SiteCollectionDocuments/formulaire_nutrition_medicale_alimentation_enterale_sonde.pdf Reimbursement documents for PN: https://www.riziv.fgov.be/SiteCollectionDocuments/formulaire_nutrition_medicale_parenterale_demande.pdf

2. Intestinal resting for therapeutic reasons for fistulas, or complications linked to any of the conditions mentioned in point 1.
3. Protein-calorie malnutrition demonstrated by:
    - a decrease in body weight of 10 points or more over one year,
    - a pre-albumin level of < 0,3 g / L
    - in hemodialysis recipients (when dialysis prescription is adequate by one of the Kt / V evaluation methods).
4. Severe functional disorder of the gastrointestinal system with a significant impact on nutritional status that could not be corrected by oral or EN.

Hospitals cover most costs and claim reimbursement directly to the health insurance. Coverage by health insurers for adults depends on whether the composition of the bag requires preparation or not. Thus, the hospital can claim €60hh per day in case of industrial pre-mixed bags (reimbursed for 67.2% of patients in 2016), with or without vitamins and minerals. If bags require some preparation "custom-made" (5.9% of patients in 2016), then the hospital can claim €75ii per day. For perdialytic bags, 26.9% of patients in 2016) the hospital can claim €35 per dayjj. These amounts cover the composition of the bags (excluding any separately reimbursed pharmaceuticals), vitamins, oligoelements, the cost of preparation as well as the material required for its administration with the only exception of the pump and the drip stand, which are excluded from reimbursement (although the use of a pump is recommended in international guidelines (Ayers et al. 2014, Durfee et al. 2014, Gorski 2017, Kirby et al. 2017, Pironi et al. 2016)). Most often, hospitals pay service companies to manage home care nutrition.

It is important for hospitals to successfully negotiate their PN bags prices in order to avoid bearing the weight of any cost differences between total costs (PN bags, materials required for the administration of the PN and company services) and the received reimbursement (i.e. daily lump sums). A further element to bear in mind is the pump (and drip stand). Given that these are specifically excluded from reimbursement, hospitals and/or patients have to bear their cost.

From a patient perspective, home based PN is almost fully reimbursed, with a limited patient copayment of €0,62 per day. However, as already mentioned, the cost of the pump and drip stand is not captured in this co-payment[kk], and remains therefore, unclear if part, or all of these costs, could in some cases be shifted to patients, or if decisions on whether to use or not a pump could be influenced by the financial implications this choice poses. Table 24 summarizes the mean costs and the general coverage situation in Belgium for home PN and reflects the situation for industrial pre-mixed solutions. Nevertheless, the price of per dialytic bags was consulted based on the cost Smofkabiven EF 8Gr N; 1L, and the mean list price found (€58,71), appear to be very similar to that here quoted for pre-mixed bags. The list prices of PN bags in general, do not appear to vary greatly on the basis of their volume.

A difference in terms of out of pocket expenses for patients when comparing PN use within or outside of hospital (i.e. at home) in addition to the lack of coverage of the pump and drip stand when at home, is that intravenous vitamin and mineral supplements required to be administrated with PN, cost patients around €10,70 per day[ll], while hospitalised, but these are mostly covered (patient copayment limited to €0.62 per day) if patients receive PN at home (included in the €60-75 per diem payment for the nutrition bags). It is important to highlight that both vitamins and minerals are recognised by the Belgian Centre of Pharmaco-therapeutic Information as an essential part of PN[mm].

hh RIZIV-INAMI pseudo-code 751391

ii RIZIV-INAMI pseudo-code 751354

jj RIZIV-INAMI pseudo-code 751413

kk https://www.inami.fgov.be/fr/themes/cout-remboursement/par-mutualite/produits-sante/nutrition/Pages/nutrition-parenterale.aspx

ll Based on the mean daily cost of Cernevit+Addamel.

mm http://www.bcfi.be/nl/chapters/15?frag=20941

Table 24 – Daily patient out of pocket expenses for home PN in Belgium - industrial pre-mixed bags

	Mean cost/day* Data source 1	Mean cost per day* Data source 2	Covered by Health Insurance	Patient out of pocket expenses/day
PARENTERAL – (a+b+c+d)	€95,52	€98,52	Everything but pump and drip stand	General co-payment of €0,62/day for all but the pump and drip stand
Nutrition solution (a)**	€56,82	€56,82	Yes	NA
Vitamins/trace elements* (b)**	€10,70	€10,70	Yes	NA
Materials+services** (c)**	€25	€16	Yes	NA
Pump+drip stand** (d)**	€3	€15	No	Unclear if patients cover in some cases part (or all) of the pump+ drip stand costs

*Note: * Based on an intake of 2000Kcal/day and full dependency on PN.*
***Based on mean of list prices for Smofkabiven 16Gr N, from 6 Belgian online pharmacies consulted (only 2 online pharmacies referred prices) and the evaluation report by RIZIV-INAMI (https://www.inami.fgov.be/SiteCollectionDocuments/smofkabiven_j60.pdf).*
****Based public prices of on Cernevit and Addamel;*
***** Estimates for materials, services and pump based on information from two sources: one Belgian hospital and a service provider. The estimates for the cost of the pump represents the difference between daily charges for the kit with a pump versus daily charges for kit without a pump (i.e.gravity kit).*

Additional reimbursement available for "benign" patients receiving PN at home

A convention exists since 2009, offering additional funding for "benign" patients suffering from chronic, non-malignant illnesses requiring home PN (KB 13-02-2009). It is important to note that these represent a minority compared to the overall malignant disease patient volume. The convention was set up to ensure good quality training/education, an effective patient follow-up, the possibility of (phone) consultations 24/24 every day of the week, or a quick response to complications. General hospitals signing this convention (6 among 102 hospitals[nn] in 2016), commit to writing an annual report including parameters such as the number of patients on PN at home (both adults and children), the indications for the PN, the number and type of complications and/or hospitalisations.

The additional funding for adults received by the hospital via this convention (over the €60-€75 received for the nutrition bags under regular reimbursement) is as follows:

- During the first 3 months: €300 per month per patient on home PN.
- From the 4th month: €200 per month, per patient on home PN.

The difference of funding between the first three months and the period after that, reflects the additional resources required for training and education of the patient and/or carers on those first months. In 2016, this convention

[nn] https://www.health.belgium.be/sites/default/files/uploads/fields/fpshealth_theme_file/vue_densemble_donnees_generales_hopitaux_2018.pdf

covered overall 191 patients of which 35 were children (internal data RIZIV – INAMI).

The administrative weight for this convention, as well as for the reimbursement standards set for any “non benign” patients, falls mainly on hospitals.

Other reimbursement linked to the administration of PN at home

A review in the EPS[oo] database of the most common reimbursement codes, registered on the same date as the nutrition, did not reveal a common pattern regarding pharmaceuticals or other treatments/services offered in combination with PN care. The only exception being codes linked to “nursing care at home” which were, registered regularly.

The RIZIV – INAMI nomenclature for nursing care covers many different aspects, some more directly related to nutrition, while others cover more general activities. However, there are no nursing care related codes covering only parenteral nutrition. The most specific are nomenclature for a lump sum for either placing and / or monitoring of (intravenous or subcutaneous) perfusion, or the administration and / or supervision of parenteral nutrition (codes 425375, 425773, 426171, 429155). But since these still cover other acts, we do not include them in our reimbursement calculations.

3.2.4.2 EN at home

Unlike PN, patients on EN at home, have to pay in advance all their treatment costs and then, claim reimbursement from health insurers. The reimbursement of EN at home is somehow more fragmented with different amounts depending on the type of product to be administered (polymeric versus semi-elementary), as well as on the need, or not, of a pump. Regarding the type of product, it is important to highlight that the use of semi-elementary products remains very limited (8.6% of patients using enteral nutrition in 2016). Regarding the evolution of the use of the pump in EN, data shows an increase in reimbursement of pump use from 26.3% in 2007 to 57.1% in 2016 (see chapter on data analysis for more details); while materials with pump use (a separate nomenclature number) are reimbursed from 34.3% in 2007 up to 75.4% in 2016.

The list of conditions under which reimbursement is envisaged for adults in Belgium (KB 10-11-1996) is summarized below:

1. A pathology from one of the following groups:

- Severe neurological pathologies with absence or lack of coordination of the swallowing reflex.
- Sequelae of surgery and / or oral or pharyngeal or laryngeal radiotherapy.
- Obstruction of the oropharynx, esophagus, or stomach.
- Hereditary metabolic diseases.

2. Temporary or permanent intestinal insufficiency, as a result of:

- Idiopathic inflammatory diseases of the intestine (Crohn's disease, ulcerative colitis) drug-resistant and having reached large segments of the intestine.
- Extensive intestinal resections.
- Very severe intestinal malabsorption following:
    - radio-enteritis;
    - villous total atrophy;
    - intestinal lymphomas;
    - recurrent chronic pancreatitis;
    - cystic fibrosis;
- secondary infection of the digestive tract in patients with the "acquired immunodeficiency syndrome"

[oo] http://aim-ima.be/L-Echantillon-Permanent-EPS?lang_ok=oui

3. Children and adolescents up to 17 years of age included in growth phase with a condition leading to a severe nutritional deficit with repercussions on development.

The amounts currently reimbursed are as follows:

For the product/nutrition bag:

- €4,10 per day in case of a polymeric nutrition solution[pp] (considered as previously mentioned, the standard in EN).
- €15 per day in case of a semi-elemental nutrition solution [qq].

For the material (other than the pump):

- €0,71 per day, if no pump is used[rr].
- €1,15 per day, if a pump is used[ss].

For the use of a pump (if required):

- €0,41 per day[tt].

Therefore, the overall reimbursement for a patient receiving EN at home in Belgium varies at present from a minimum of €4,81 (without a pump) to a maximum of €5.66 per day (with a pump), when the most common polymeric solutions are used.

It is important to note that, even when we consider the maximum reimbursement for a patient per day of €5,66 for polymeric solutions, the mean price for that type of EN solution in Belgium is higher (≈€13,88 per day), with an additional €3.63 per day for materials and pump, if a pump is used for the administration of the EN, or ≈€1,37 just for materials, if a pump is not required.(Rommel et al. 2017) This large difference between the amount reimbursed and the mean cost of EN at home, means that the patient often faces daily out of pocket expenses of ≈ €11.85 if using a pump, or of ≈€10.44 if a pump is not required, in case of polymeric solutions and of ≈€28,08 if using a pump or ≈€26,67 if no pump is used, in case of semi-elemental solutions. The limited reimbursement currently in place in Belgium is paid by the insurer on a per calendar month basis, after presentation by the patient, of invoices paid for both the food administered and / or the materials used. Table 25 summarises these figures.

Table 25 – Daily patient out of pocket expenses for home EN (bags, materials and pump) in Belgium

Type of nutrition	Mean cost/day*	Patient out of pocket expenses/day
ENTERAL – Polymeric (a+b)	€17.51	€11.85
Nutrition solution (polymeric) (a)	€13.88	€9.78
Pump+materials (b)**	€3.63	€2.07
ENTERAL - Semi-elemental (c+d)	€44.64	€28.08
Nutrition solution (semi-elemental) (c)	€41.01	€26.01
Pump+materials (d)**	€3.63	€2.07

*Note: *Based on an intake of 2000Kcal/day and public prices from 6 Belgian online pharmacies. Assumes a pump is used.*
*** The estimate represents the average costs from two company offering services and information from Kom op tegen Kanker (available at https://www.komoptegenkanker.be/sites/default/files/media/2018-10/de_kosten_van_implantaten_def_pdf_0.pdf.)*

[pp] RIZIV-INAMI pseudo-code 751251

[qq] RIZIV-INAMI pseudo-code 751273

[rr] RIZIV-INAMI pseudo-code 751295

[ss] RIZIV-INAMI pseudo-code 751310

[tt] RIZIV-INAMI pseudo-code 751332

Special arrangements for patient specific-groups

During stakeholder consultations, the Belgian association for cystic fibrosis informed us of their involvement and active participation in the costs of home EN for patients suffering from cystic fibrosis. They currently not only cover their out of pocket expenses, but they also advance the full cost for the EN (and necessary equipment) and then claim reimbursement directly to the health insurance funds, in order to release patients from the administrative burden they face.
Overall, the reimbursement this association obtains appears to cover approximately half their actual expenses on EN at home.

It is important to note that this type of arrangement is possible in the case of cystic fibrosis patients, a limited population with around 50 patients requiring EN at home on a yearly basis. Nevertheless, the mean out of pocket expenses the association has covered in the last 4 years is of around €1500 per patient, per year with a range between €900 and €2100.

Although this is the only example we have come cross during the course of this research, we cannot exclude an involvement of other patient organizations at present in Belgium.

Other reimbursement linked to the administration of EN at home

Similar to parenteral nutrition, the RIZIV – INAMI nomenclature has no nursing care related codes covering only EN. The most specific are nomenclature for one of several specific acts: manual removal of faecalomas; enema and / or administration of medicinal solutions via rectal probe; gastrointestinal tube and drain; intestinal rinsing; enteral nutrition via gastric probe, gastro or enterostomy probe (codes 426016, 425213, 425611, 426414, 429074). But since these still cover other acts, they are excluded from our reimbursement calculations.

3.2.5 Summary of reimbursement/funding and out of pocket patient expenses for EN and PN in Belgium

Table 26 offers a summary of the situation in order to illustrate the inconsistencies seen in this field. It uses daily mean costs and third party reimbursement levels (i.e the part of the costs covered by a third party – hospital or insurance – and not by the patient). It is important to note, that the inputs used here, represent the best available data but may differ from "real" cost. Nevertheless, given that the same sources were consulted for both types of nutrition, the differences seen between EN and PN should still offer a good overview of the current challenges and inconsistencies in medical nutrition.

A further important point to highlight is that, at present, adults' patient contributions for EN at home, do not count for the maximum invoice (limited to patients younger than 19 years)[uu], despite the important amounts these could represent, especially in cases in which home EN is required over an important time period.

Daily mean cost

- At the hospital or at home (home or residential care)

The daily mean cost of PN, and the materials required for its administration, appear to be over 5 times more expensive than EN (respectively ≈€95,52-€98,52 versus ≈€17.51). These estimations are purely based on mean (list/official) prices for the solutions (hospital negotiated discounts not considered), and from charges shared by stakeholders, for the materials and equipment required for PN and EN administration. Price differences exist also between EN using polymeric solutions and semi-elementary solutions, although the latter are used in few cases. Medical nutrition is more expensive when a pump is required for its administration.

[uu] http://www.riziv.fgov.be/nl/themas/kost-terugbetaling/financiele-toegankelijkheid/Paginas/maximumfactuur-(maf)-houdt-medische-kosten-binnen perken.aspx#Welke_kosten_tellen_mee

Patient perspective

- At hospital

On the one hand, patients on EN at hospital, regardless of the type of solution they receive, appear to be well covered with no out of pocket expenses to their charge. On the other hand, hospitalised patients on PN need to pay out of pocket expenses of around €10,70 per day, for the vitamins and trace elements required and used by most (if not all) of them.

- At home (home or residential care)

Patients on home PN need to pay a limited co-payment of €0.62 per day. However, given the current exclusion of the pump and drip stand from reimbursement, the extent to which some of these costs could be shifted in some cases to the patient, remains unknown. The charges for the pump were estimated for the purpose of this exercise, based on differences in daily charges for a "pump kit" versus a "gravity kit", provided by one Belgian hospital and one service provider. However, specific rental or purchasing pump costs could not be obtained, given the "service kit" costing approach currently used by service providers, which does not separate the charges for the pump from charges for materials and services.

As seen in Table 26 patients on EN, face out-of-pocket payments of almost €12 per day for the most commonly used polymeric solutions (see table for more details).

Table 26 – Summary of daily hospital and home patient out of pocket expenses for most frequent medical nutrition types in Belgium

Type of Nutrition	Mean cost/day	Mean cost/day	Patient out of pocket expenses/day	
	Data source 1	Data source 2	Hospital	Home/residential
ENTERAL – Polymeric solution (a+b)	€ 17,51	NA	Fully covered (no out of pocket payment)	€ 11,85
Nutrition solution (a)	€ 13,88	NA		
Pump+materials (b)	€ 3,63	NA		
PARENTERAL – Pre-mixed (c+d+e+f)	€ 95,52	€ 98,52	€ 10,70	€0,62/day + Part (or all?) of the €3-€15/day for pump and drip stand?
Nutrition solution (c)	€ 56,82	€ 56,82		
Vitamins/trace elements (d)	€ 10,70	€ 10,70		
Materials+ services (e)	€ 25	€ 16		
Pump+drip stand (f)	€ 3	€ 15		

3.2.6 Other funding related to nutrition

This section aims at offering an overview of other types of funding currently available in Belgium that could have an impact on EN and/or PN in this country.

Special dispositions for patients with cancer

Since the 2011, (KB 26-11-2011) a specific budget is dedicated to strengthening nutritional support in cancer patients. A dedicated budget of €7.544.871 is distributed among hospitals accredited for offering basic care in oncology or a full oncology care program in order to finance dieticians. The missions of these dieticians, defined by the Royal Decree of 29th November 2011, read as follows:

- To develop a specific nutrition policy for oncology patients in order to increase awareness of the importance of nutrition among health professionals and facilitate earlier detection of nutritional problems by means of screening methods.
- To ensure the link between provider of meals, communication with partners outside the hospital and the education of cancer patients about nutrition.

The same Royal Decree describes also the requirements that dieticians must meet (e.g. be part of the oncology team). Dieticians will have to collect and send yearly data to the FPS Health, Food Chain Safety and Environment (SPF-FOD) in order to support the supervision and evaluation of this project.

In 2011, the budget (i.e. €7.544.871) was allocated according to the number of multidisciplinary oncology consultations reimbursed by the National Institute for Health and Disability Insurance (RIZIV-INAMI) in 2008. An amount of €46.146 per full-time equivalent (FTE) dietician was assigned[vv]. Funding may be adjusted annually.

Dieticians for the non-malignant patients

In Belgium, dieticians, as a profession, are not reimbursed and the price of their consultations are therefore not regulated by law. In general, for a consultation of one hour, prices can vary between €35 and €60[ww]. However, under some special circumstances (e.g patients suffering from diabetes, renal failure or cystic fibrosis), the sickness funds or private insurance may cover some of these fees.[xx]

Flemish Health Insurance funds

A further potential source for additional funding which could count towards the cost of renting the pump and the drip stand as well as other materials required for the administration of medical nutrition, is via a request to the Flemish health insurance (Vlaamse zorgverzekering). The additional funding is not specifically linked to a patient's need for medical nutrition but depends instead on the need for care and the level of dependence of the patient. Typically, these are elderly people in residential care or patients who need a lot of support at home. The maximum amount would be of 130 € per month.

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vv 1 FTE dietician up to 500 consultations, 1.5 FTE dietician between 501 and 750 consultations, 2 FTE dietician between 751 and 1 000 consultations, 2.5 FTE dietician between 1 001 and 1 250 consultations, 3 FTE dietician between 1 251 and 1 500 consultations, 3.5 FTE dietician between 1 501 and 1 999 consultations and 4 FTE dieticians from 2 000 consultations.

ww https://updlf-asbl.be/pages/tarif-des-consultations-et-remboursement

xx Dispositions for diabetes or renal insufficiency: http://www.zorgtraject.be/NL/Professioneel/Dietist/default.aspx;
For rehabilitation: https://www.riziv.fgov.be/SiteCollectionDocuments/tarief_revalidatie_verstrekkingen_20190101.pdf;
For cystic fibrosis: https://www.riziv.fgov.be/nl/themas/kost-terugbetaling/ziekten/endocriene-metabole/Paginas/mucoviscidose-tegemoetkoming-kosten-behandeling-gespecialiseerde-centra.aspx

Key points

- **The current rules for reimbursement in Belgium are complex and inconsistent across settings**
- **Patients out of pocket expenses remain high both in hospital, when a patient is on PN, and in the community, when a patient is on EN.**
- **From a patient's perspective, the existing reimbursement conditions appear to favour (financially) the choice of PN at home over that of EN despite enteral being the "prefered" clinical choice whenever it is not contraindicated. From a insurer's perspective, EN remains less expensive than PN.**
- **Not all aspects of nutrition are considered in the reimbursement rules (e.g .vitamins and trace elements in hospital or the use of a pump and drip stand at home for patients on PN).**
- **No link made between the daily reimbursement amounts by the sickness funds and the volume of EN or PN nutrition required for patients being cared for at home. This penalises those more dependent on one of these types of nutrition.**
- **No out of pocket ceiling for patients on chronic, long-term EN treatment at home, despite the high financial contributions it could pose on them.**
- **The administrative burden for home PN is mainly a responsibility of the hospital, while this is picked up by patients in the case of home EN.**
- **The use of a pump and the drip stand for PN at home is currently excluded from reimbursement and the financial and clinical consequences to the patient of such an exclusion lacks transparency. Thus, the extent to which clinical decisions on whether to use or not a pump for PN at home, may be influenced by the higher cost of the pump versus gravity, remains unknown. Similarly, the posibility for some (or all) costs related to the pump being shifted to the patient in some cases, cannot be excluded.**

3.3 Costs in Belgium

This section aims at estimating global costs of medical nutrition from a health care payer perspective (i.e. heath insurer or patient), by setting (i.e. hospital and home). These calculations should facilitate a better understanding of the financial burden currently faced by the affected patient populations, as well as by the healthcare system.

Calculations are based on limited data and their interpretation deserves careful consideration. They are aimed at offering an overview of the situation at present in Belgium.

The main data sources are the VG MZG and MZG for the period 2008-2016 for the hospital setting and, IMA-AIM for the period 2008-2016, for community use (see chapter on data analysis for more details on the two sources).

3.3.1 Total costs for bags at hospital

According to VG MZG and MZG data for the year 2016, the overall number of hospital stays on PN were 20 241 (around 1,35% of all hospital stays), while those on EN were 28 902 (≈1,92% of all hospital stays). The mean duration of these hospital stays for PN was of 22,1 days (median 15), while the duration for patients hospitalized and on EN appear to be slightly above with a mean of 27,3 days (median 17) (see chapter on data analysis for details on these statistics).

Given the uncertainties surrounding the length of nutritional treatment at hospital, primarily linked to data limitations, (see chapter on data analysis for more details), the number of days on medical nutrition registered during the year 2016 were extrapolated from VG-MZG – DI_RHM: all days registered with either EN or PN were extrapolated from 60 registration days to 365 (total days in registration periods multiplied by 365/60). Thus, the overall registered days for PN amounted in 2016 to 194 928 in Belgian hospitals, while registered days on EN were 314 474. Multiplying these overall medical nutrition days at hospital, by the estimated mean costs of nutrition solutions (solution bags, vitamins and trace elements) already presented in the reimbursement chapter, we observe that PN solutions cost on average €13,2 million to the hospital, while EN solution bags fall well

below that, with an approximate cost of around €4,4 million (see Table 27). It is important to bear in mind that these calculations are likely to offer an overestimation of the costs due to a lack of information regarding hospital discounts and that given the current funding systems linked to medical nutrition in the hospital setting, (EN part of the BFM and PN included in the pharmaceutical budget - see chapter on reimbursement and funding for details), they do not represent health care budget expenses but rather an approximation to costs.

While no out-of-pocket payments are required for EN, patients on PN therapy will most often require vitamins and trace elements (priced at around €10,70 per day). These would add a total cost of € 2,1 million, to PN. Amount which is currently paid in full by patients. This is a direct consequence of the lack of coverage of vitamins and minerals for patients on PN in Belgian hospitals. It should be noted that estimations are based on the most common types of solutions (polymeric for EN and pre-mixed for PN), given that the VG-MZG data does not allow for separating EN or PN by type of solution. Nevertheless, given that polymeric EN and pre-mixed PN solutions appear to be the most common choice (based on data on home use), the figures here presented should still provide a valuable approximation to the total cost of nutrition solutions. For PN, an assumption was made that per dialytic bags would be primarily used in the ambulatory setting and that their cost would therefore be very limited in the hospital setting.

As we can see, hospital costs linked to nutrition solutions remain, despite their slightly shorter length of stay, and the significantly lower number of registered days, higher for PN nutrition. This is driven by the higher costs of PN solutions already discussed in previous sections of this report.

No attempt was done to measure the overall costs linked to each type of nutrition (e.g. cost of disposables, equipment, complications, hospitalization, medical staff time, etc), since it was not possible to link hospital data on that regard, to the nutrition therapy.

Table 27 – Total hospital costs per year for PN and EN solutions (bags and vitamins/trace elements)

Setting: Hospital	Prevalence	Number of days*	Mean list price**	Estimated total costs for hospital	Estimated total out-of-pocket payment for patients
EN	1.92% (2016)	314 474	€13,88	€4 364 899	€0
PN	1.35% (2016)	194 928	€67,52	€13 161 538	€2 085 730

*Source: * VG MZG and MZG 2016.*
*** Negotiated hospital discounts not considered*

3.3.2 Home care costs

Data for the years 2015 and 2016 were extracted from IMA-AIM, which allowed for the separation of the different types of EN and PN.

Data from 2016 show that the use of EN solutions is much higher at home than that of PN (see Table 28 for details), with 6 019 patients on EN at home (mostly on polymeric solutions) versus 1 411 on PN (948 of them on industrial pre-mixed solutions). Looking at the total number of days on home medical nutrition for the same year, the difference becomes even more noticeable, with 1 043 838 days registered on home EN (953 100 for polymeric solutions only), versus 101 731 on PN (76 651 on industrial pre-mixed solutions).

Regarding treatment duration, the mean for EN was also much higher than that of PN, with a mean of 100.8 days (median 71,5), for the most frequently used polymeric solutions, while the mean treatment duration for patients on home PN was of 33,1 days (median 19) for industrial pre-mixed solutions.

For calculating the total mean costs, the total number of days registered for each type of nutrition were multiplied by the mean costs (solution, pump and materials) estimated and presented in the reimbursement chapter.

The combination of higher use and longer episodes of EN at home, explains the differences in terms of costs from a health care payer perspective (i.e. health insurance or patient costs), despite the lower prices of EN solutions (€13,88 for polymeric solutions, excluding pump and materials) when compared to those of PN solutions (€67,52 for industrial pre-mixed solutions including vitamins and trace elements). Thus, PN appears to have lower costs when used at home, when compared to EN.

When focusing purely on global patient out of pocket expenses, it appears that the financial burden is, in their case, also greater in the case of EN. This is a direct consequence of the high use, longer episodes and the partial reimbursement current available in Belgium for this type of nutrition at home.

Table 28 shows the existing discrepancies. Nevertheless, it should be noted that the assumption for home PN is that the pump (together with the drip stand) is currently covered in all cases by the hospital and not by patients themselves. If such costs were shifted in some cases to patients, this would results in additional out of pocket expenses between €3 and €15 per day, per patient. For example, if we bear in mind the median treatment duration in 2016 for the most frequently used pre-mixed solutions, this could translate into per patient costs between €57 and €285 per episode.

It is also important to highlight that there are some differences between the health insurance costs here presented (derived from IMA-AIM data) and the overall health insurance expenses presented in section 3.2.2.2 (from RIZIV/INAMI data). These differences are explained by a number of factors:

- global estimates from INAMI/RIZIV include data on children, while the table here presented focuses in the adult population (18+);
- different accounting periods can cause small deviations between the two sources, even if all other factors are kept constant.
- Table 28 assumes that all patients would use a pump, which in the case of EN is partly reimbursed by the health insurance.

We know from the data analysis section, that although a majority of patients on EN do use a pump, and pump users appear to be growing on a yearly basis, there are some patients who do not use it, so the table here presented would, in this case, offer a slight overestimation of the health insurance costs for EN at home.

Table 28 – Costs for medical nutrition (i.e. solution, pump and materials) at home

Community care (home or residential)	Prevalence (N. of patients)	Duration (2016)	Total days	Total mean cost (solution, pump, materials)	Total costs	Estimated costs for health insurance	Estimated payment for patients
EN polymeric	5 637(2015) 5 499 (2016)	Mean: 100.8 days (SD:87.5) Median: 71.5 days (IQR:115)	953 710 (2015) 953 100 (2016)	€17,51	€16 699 462 (2015) €16 688 781 (2016)	€5 397 999 (2015) €5 394 546 (2016)	€11 301 464 (2015) €11 294 235 (2016)
EN semi-elemental	526 (2015) 520 (2016)	Mean: 95.5 (SD: 85.6) Median: 65 (IQR: 105)	90 058 (2015) 90 738 (2016)	€44.64	€4 020 189 (2015) €4 050 544 (2016)	€1 491 360 (2015) €1 502 621 (2016)	€2 528 829 (2015) €2 547 923 (2016)
PN (pre-mixture)	871 (2015) 948 (2016)	Mean: 33.1 days (SD:39.5) Median: 19 days (IQR:35)	66 320 (2015) 76 651 (2016)	€95,52-€98,52	€6 334 886- €6 533 846 (2015) €7 321 704- €7 551 657 (2016)	€3 979 200 (2015) €4 599 060 (2016)	€41 118 (2015) €47 524 (2016)
PN per-dialytic	405 (2015) 380 (2016)	Mean: 29.5 days (SD: 43.1) Median: 15 days (IQR: 31.3)	19 150 (2015) 16 791 (2016)	€58,71	€1 124 297 (2015) €985 800 (2016)	€670 250 (2015) €587 685 (2016)	€11 873 (2015) €10 410 (2016)
PN custom made	97 (2015) 83 (2016	Mean: 37.1 days (SD: 56.2) Median: 17 days (IQR: 47.8)	8 931 (2015) 8 289 (2016)	NA	NA	€ 669 825 (2015) €621 675 (2016)	NA

Finally, it is worthwhile highlighting that for PN, the table shows total costs that do not seem to be covered by adding the costs picked up by the health insurance and the patient out of pocket costs. However, the calculations here presented are based on list “public” prices which do not consider hospital negotiated discounts. As already mentioned in the reimbursement chapter, it is important for hospitals to successfully negotiate their PN bags prices in order to avoid bearing the weight of any cost differences between their expenditure in PN and the lump sum they receive from health insurers.

3.3.3 Incremental Budgetary estimations

As already mentioned in this report, two of the main inconsistencies in the current reimbursement system for medical nutrition are:

- The coverage of vitamins and trace elements necessary for the administration of PN are reimbursed at home, but paid in full by the patient when PN is administered in the hospital setting.
- EN is only partially covered by the health insurance when administered at home. PN solutions, vitamins and trace elements on the other hand are well covered (with a limited out of pocket expense of €0,62/day per patient). Less clear is the situation with the pump and drip stand for patients on PN at home. Due to the lack of transparency on this regard, the costs of the pump have been left out from the estimations, but it is important to highlight that in some situations, part of the costs could, at least in theory, be transferred to the patient.

The purpose of this section is to provide an approximation to the budgetary impact, from a health insurance perspective, that would result from extending the current reimbursement system in order to:

- cover both vitamins and trace elements for PN in the hospital setting (scenario 1),
- offer full reimbursement of EN at home (scenario 2).

It should be noted that although estimations are presented separately, both scenarios could co-exist and do not represent mutually exclusive approaches.

Estimates presented in this section were extracted from different data sources, which are clearly stated throughout this section, to ensure transparency and facilitate reproducibility. In order to account for the uncertainty that surrounds all estimates here presented, minimum and maximum values were used in a sensitivity analysis (see Table 29 and Table 30 for more details).

3.3.3.1 Scenario 1: Full coverage of vitamins and trace elements for PN in hospital

Prevalence and patient numbers:

MZG data from the year 2016 show that on that year, 17 474 patients hospitalized required PN. PN has seen a continuous decrease from 2008 to 2016, moving from 3% of all hospitalised patients in 2008 to 1,5% in 2016. An assumption was made that the minimum value would represent a decrease of 11,10%, since in the last two years for which data were available, the annual decrease appeared to be just above 11%. For the maximum value, given the continuous decrease from 2010-2016, the assumption was that there would be no growth (or decrease), implying that the number of hospitalised patients on PN would remain constant.

Regarding the length of the nutrition episodes, MZG-RHM data shows that the mean length of an episode lasted 23.1 days in 2016, with a median of 15 days. Quartiles 1 (duration of 9 days) and 3 (duration of 28 days) were used as the minimum and maximum values in our sensitivity analysis.

The mean number of episodes per patient was in the year 2016 1,145, and remained rather stable over the period 2008-2016, ranging from a maximum of 1,145 in 2016 to a minimum of 1,132 in 2013.

Data on patient days on PN per year were also extracted from the VG-MZG database. These days were considered to be the best estimate to be used for an approximation to the costs, as the VG-MZG – DI-RHM was considered the most accurate source for in-hospital nutrition use (see chapter on data-analysis). Minimum and maximum values were, in this case, based in the maximum (absolute) growth and decrease in the number of days on PN over the period 2008-2016. Nevertheless data on prevalence and treatment episodes as well as their duration were left in the tables for information purposes.

Price of vitamins/trace elements

In order to calculate the budget impact, estimates needed to be made with regard to the price of vitamins and trace-elements required for the administration of PN. As previously explained, official "list/public" prices for vitamins and trace-elements were obtained via consultation of six online Belgian pharmacies. It is important to note that these prices do not necessarily reflect the real prices, since discounts for hospital pharmacies are common. However, given the lack of information on them, and the existing variations between one hospital and another, list prices represent a good approximation that will nevertheless, be tested in the sensitivity analysis (+25%/- 25% values used for maximum and minimum prices).

The official, "list/public" price of commonly used intravenous vitamins and trace elements is of around €7.09[yy] and €3-4[zz] (mean €3.61) per day respectively, which translates into mean out of pocket expenses for the patient of around €10.70 per day.

Results

Table 29 shows the mean budgetary impact expected from the perspective of the public payer, (i.e. RIZIV –INAMI), of a full coverage of vitamins and trace elements for patients requiring PN in the hospital setting. Looking first as the estimations obtained by using the number of registered days, this appears to be of €2,1 million. However, the sensitivity analysis showed a possible variation of between €1,3 to €2,8 millions that should be brought to attention.

[yy] Based on price of Cernevit (10 units), available at http://www.bcfi.be/nl/chapters/15?frag=13730

[zz] Based on mean list price from 6 online pharmacies in Belgium for Addamel 10ml (20 units).

Table 29 – Budget impact estimations – full coverage of vitamins and trace elements necessary for the administration of PN in hospital

	Base value	SA - Lower bound	SA – Upper bound
N. of patients per year - 2016 (a)	17 474	15 534	**17 474**
Median episode duration in days – 2016 (b)	15	9 (Q1)	**28 (Q3)**
Mean N. of episodes per patient – 2016 (c)	1,15	1,13	**1,15**
N. of patient-days on PN per year – 2016 - (d)	194 928	167 924	**207 474**
Mean cost per day of vitamins (e)	€7,09	€5,32	**€8,86**
Mean cost per day of trace elements (f)	€3,61	€2,71	**€4,51**
Total mean cost per day of vitamins + trace elements (g=e+f)	€10,70	€8,03	**€13,37**
Budget impact (health insurance) of full coverage (d*g) using the number of patient-days on PN per year	**€2 085 730**	**€1 348 430**	**€2 773 927**

3.3.3.2 Scenario 2 – full coverage for EN at home

Prevalence and patient numbers:

IMA-AIM reimbursement data show that, approximately 6 019 patients were on EN at home in 2016. The large majority of these patients were on polymeric solutions (n=5 499), while the remaining were on semi-elemental (n=520). Sixty nine patients that had both polymeric and semi elemental nutrition solutions in the same year had to be excluded from these calculations to avoid double counting and simplify the estimations. The maximum value assumed for the sensitivity analysis reflects the maximum yearly growth seen over the period 2008-2016 (+5%), while the minimum value reflects the highest decrease experienced over the same time period (1,75%).

The mean duration of treatment for patients in 2016 was 100,8 (median 71,5 days) for polymeric EN and of 95,5 (median 65 days) for semi-elemental EN.

The mean number of episodes per patient was in the year 2016 1,05 for polymeric solutions (range from a high of 1,77 in 2007 to a low of 1,05 in 2016). The same mean was found for patients on semi-elemental solutions in that year (i.e.) 1,05, although the range seen over the period analysed 2007-2016 was slightly narrower in this case (range from a high of 1,62 in 2007 to a low of 1,05 in 2016).

Cost estimations were, once more, based on registered patient days per year. In this case, these extracted from the IMA-AIM database, since such source was considered to be the most accurate from those available. The minimum and maximum annual growth in the number of days on EN over the period 2008-2016 was used in our sensitivity analysis. No approximation to the costs was done by means of the prevalence, number of episodes and median length of episodes, given the limitations linked to those estimates, which are nevertheless presented in the table for information purposes.

Price of EN solution and patient out of pocket expenses

Current reimbursement values were subtracted from list public prices in order to estimate patient out of pocket expenses. A similar exercise was completed for the pump and materials. These estimated out of pocket expenses were multiplied by the relevant patient population (i.e. patients receiving polymeric EN or on semi-elemental EN at home) and the mean duration of treatment in order to calculate an approximate potential budget impact from a health insurance perspective, of a full coverage scenario. The overall results were tested in a sensitivity analysis by applying minimum and maximum values for each input: (+/-25% applied for list prices).

Results

As seen in Table 30, the overall potential budget impact would be of approximately €13 842 158, from a low of € 8 257 142 to a high of € 19 721 710.

Nursing care and other aspects of medical nutrition at home appear to be well covered independently of the type of nutrition received. Therefore, only factors for which there was a difference in coverage (eg the solution, the pump and the materials) were considered in our incremental budget estimations.

Table 30 – Budget impact calculations – full coverage of EN at home

	Value	SA - Lower bound	SA – Upper bound
POLYMERIC			
N. of patients per year on home EN - Polymeric (a; 2016)	5 499	5403	**5774**
Median enteral episode duration in days (b; 2016)	72	31 (Q1)	**146 (Q3)**
Mean N. of episodes per patient (c; 2016)	1,05	1,05	**1,77**
Total number of patient-days on home EN per year – Polymeric (d; 2016)	953 100	909 067	**987 888**
Mean daily* list price for EN polymeric solution (e)	€13,88	€10,41	**€17,35**
Daily reimbursement for EN polymeric solution (f)	€4,10	€4,10	**€4,10**
Daily patient out of pocket expenses for EN polymeric solution (g=e-f)	€9,78	€6,31	**€13,25**
Mean daily cost of pump and materials (h)**	€3,63	€2,72	**€4,54**
Daily reimbursement for pump and materials* (i)**	€1,56	€1,56	**€1,56**
Daily patient out of pocket expenses for pump and materials (j=h-i)	€2,07	€1,16	**€2,98**
Total annual patient out of pocket expenses for EN – Polymeric k=((g+j)*d) using total N. of patient days	€11 294 235	€6 790 730	**€16 033 422**
SEMI-ELEMENTAL			
N. of patients per year on home EN – semi-elemental (l; 2016)	520	511	**546**
Median enteral episode duration in days (m)	65	31 (Q1)	**136 (Q2)**
Mean N. of episodes per patient (n)	1,05	1,05	**1,62**
Total number of patient-days on home EN per year – semi-elemental (o)	90 738	86 546	**94 050**

Mean daily* list price for EN semi-elemental solution (p)	€41,01	€30,76	**€51,26**
Daily reimbursement for EN semi-elemental solution (q)	€15,00	€15,00	**€15,00**
Daily patient out of pocket expenses for EN semi-elemental solution (r=p-q)	€26,01	€15,76	**€36,26**
Mean daily cost of pump and materials (h)**	€3,63	€2,72	**€4,54**
Daily reimbursement for pump and materials (i)	€1,56	€1,56	**€1,56**
Daily patient out of pocket expenses for pump and materials (j=h-i)	€2,07	€1,16	**€2,98**
Total annual patient out of pocket expenses for EN - semi-elemental s=((r+j)*o) using total N. of patient days	€2 547 923	€1 464 358	**€3 690 522**
Budget impact (health insurance) of full coverage - home EN (k+s) using total N. of patient days	**€13 842 158**	**€8 255 088**	**€19 723 944**

**Based on a mean intake of 2000 Kcal;*
*** Based on Mean costs per day of pump from KOTK report: https://www.komoptegenkanker.be/sites/default/files/media/2018-10/de_kosten_van_implantaten_def_pdf_0.pdf)*
**** Assumes a pump is used*

Key points

- **PN solution bags cost on average €13,2 million to the hospital, while EN solution bags cost around €4,4 million**
- **No out-of-pocket payments are required for EN in hospital, but patients on PN therapy will need vitamins and trace elements for a total annual cost of € 2,1 million.**
- **The costs for EN at home in 2016 were around €20 739 325 (€16 688 781 for polymeric EN), while those for PN at home (industrial pre-mixed) ranged from 7 321 704 to €7 475 006, with an additional €985 800 spent on per-dialytic bags (no data available on the cost of custom made bags). From these costs, patients pay out of pocket expenses of €13 842 158 for EN and €47 524 for PN in the case of industrial pre-mixed and around €10 410 for per-dialytic PN bags.**
- **Offering coverage for vitamins and trace elements at hospital would have a budgetary impact of around €2,1 million**
- **The overall potential budget impact of extending the current reimbursement of EN at home to eliminate the current out of pocket expenses would be of be of approximately €13 842 158 (including solutions, pump and materials).**

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4 GENERAL CONCLUSIONS

In Part 1 we learned that nutrition support teams exist in almost all acute care hospitals in Belgium. However, it remained unclear how they function and what they attain and if there are differences between teams. Also it became apparent from the systematic review that effectivity of nutrition support teams is general viewed positively but hard evidence is lacking. Therefore it seems necessary that good performance indicators for nutrition support teams need to be developed and measured in a systematic way, so further research and quality improvement could be done. Also the creation of a knowledge platform in which nutrition support teams can share their expertise and discuss with each other, could be a nice way to advance a better performance of good nutritional care.

In Part 2 we learned that there are several sources/databases from which prevalence rates of patients with enteral and parenteral nutrition in hospital or at home could be derived. However, all databases had their limitations in doing so and some were even not usable at all due to unstructured format of data gathering. Moreover, prevalence rates in a same patient population could differ from database to database. So, more adequate rules for registering nutritional interventions are needed. Moreover, there is a need to set up a data system that is routinely collected (e.g. integration in existing administrative data systems) and link it to electronic patient files. An easy to use and performant registration is needed to monitor nutritional interventions and for inter-hospital benchmark initiatives.

Nevertheless, the different analyses clearly showed that the prevalence of patients with parenteral nutrition in the hospital is declining across the past ten years, dropping from almost 2.5% in 2006 to 1.35% in 2016. Enteral nutrition use in hospital remained quit stable. We also observed a large variation between hospitals for both enteral and parenteral nutrition use.

Regarding the home situation, we found that the use of parenteral nutrition is increasing across years, but remains rather limited to about 1300 patients a year in 2016, among which approximately 300 patients receiving intradialytic parenteral nutrition. The number of patients receiving enteral nutrition at home is slowly increasing across years and counts to approximately 6000 patients per year in 2016.

Duration of enteral and parenteral nutrition use in hospitals was difficult to calculate, due to lacking information on start- or/and stop-day in the data sources we used.

We haven't studied the appropriateness of enteral and parenteral nutrition use and therefore we cannot interpret if e.g. the decline in parenteral nutrition use in the hospital or the number of patients receiving intradialytic parenteral nutrition at home is something 'good' or not.

Also we did not study other more first step nutritional interventions as dietary advice or nutritional supplements compared to (par)enteral nutrition.

In Part 3 we learned from a systematic review that enteral nutrition is more cost-effective than parenteral nutrition and is therefore preferred from an economic point of view; this is above in line with the general clinical preference for enteral nutrition if possible.

Further, regulations about funding and reimbursement were presented and it became clear that there is a wide diversity of rules depending on e.g. type of nutrition and type of setting. Current regulations lead to financial inequalities and out-of-pocket payments for patients depending on setting where they are and the type of nutrition they receive.

Cost calculations were difficult due to lack of transparency on prices of nutrition products, necessary equipment and services. Nevertheless, the cost-calculations made clear that the differences in amount of out-of-pocket expenses, induced by inconsistencies in reimbursement regulations, are substantial. It would be good if the different regulations are harmonized and changed in such a way that financial reasons would no longer have to play a role in the clinical decisions surrounding the most appropriate nutrition and most safe way of administration. Also it is important that future reimbursement regulations consider/comprehend all nutritional interventions such as dietary advice or oral nutritional supplements and not only focus to the most advanced interventions as (par)enteral nutrition. Also the (European) regulations on 'Food for Special Medical Purposes' needs to be

taken into account, as was advised by the Belgian Superior Health Council (Hoge Gezondheidsraad, 2017)[aaa].

Finally, we like to thank all experts and stakeholders that we met during initial orientation visits, and in expert and stakeholders meetings during the project. Their comments were invaluable to interpret results and to formulate relevant recommendations. The list of involved experts and stakeholders can be found in the colophon.

Recommendations from this study are presented in the Dutch and French syntheses, which are published separately from this scientific report.

aaa https://www.health.belgium.be/sites/default/files/uploads/fields/fpshealth_theme_file/hgr_9371_advies_fsmp_a5.pdf

APPENDICES

APPENDIX 1. EXCLUDED STUDIES NST REVIEW

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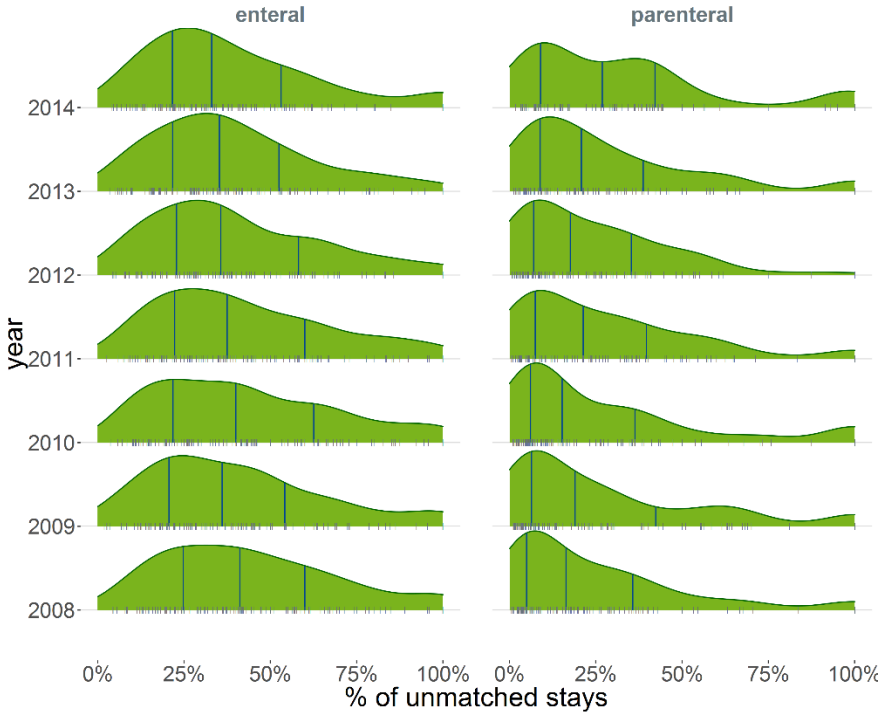
APPENDIX 2. PATIENTS ON ENTERAL OR PARENTERAL NUTRITION IN BELGIUM

Appendix 2.1. Comparison of MZG – RHM and VG-MZG – DI-RHM coding

Figure 28 shows the distribution of the hospitals given their proportion of unmatched MZG – RHM stays by nutrition type. For 2014, for example, 25% of hospitals have less than about a quarter of their enteral MZG – RHM stays unmatched, while 25% have more than 53% of their enteral MZG – RHM stays unmatched. Similarly but with overall lower proportions of unmatched stays, 25% of hospitals have less than 9% of their parenteral MZG – RHM stays unmatched. And 25% of hospitals have more than 42% of their parenteral MZG – RHM stays unmatched. Both for enteral and parenteral, for about 7% of hospitals in 2014 all MZG – RHM stays were unmatched.

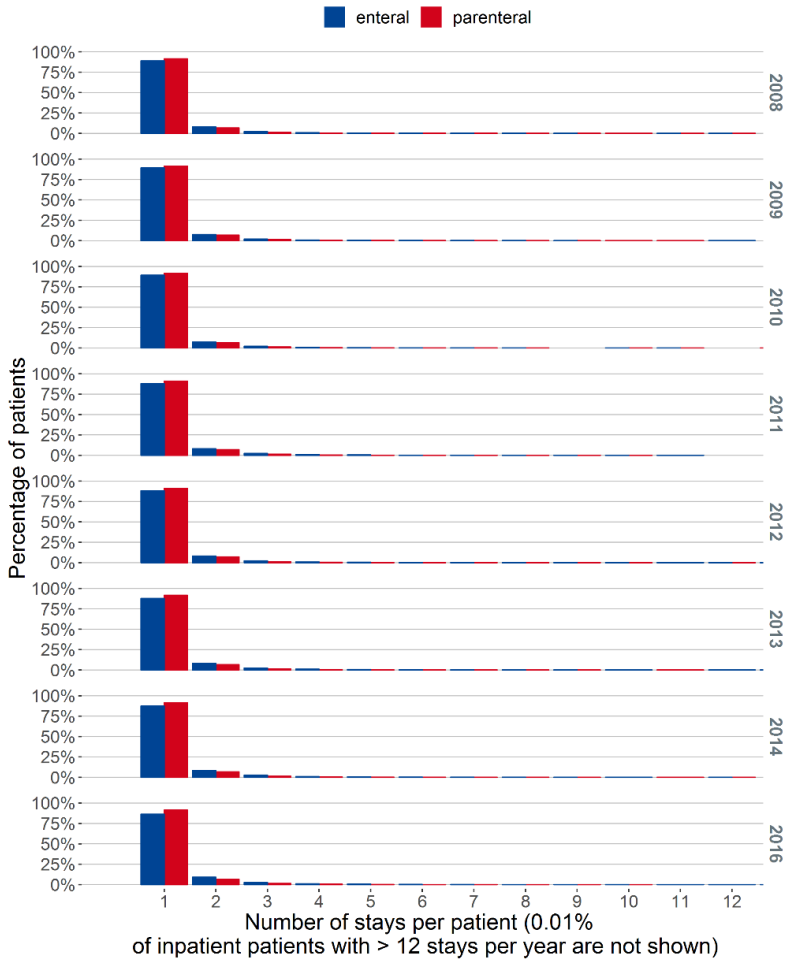
Figure 28 – Percentage of unmatched MZG – RHM stays per hospital by nutrition type



Blue lines represent respectively the 25th, the 50th, and the 75th percentile. The black strips beneath each graph represent individual data points.

Appendix 2.2. Prevalence overall

Figure 29 – Number of inpatient stays per patient per year in MZG – RHM



Appendix 2.3. Prevalence and ratio enteral and parenteral in 2016 by APR-DRG

APR-DRG	% of all stays	% enteral	% parenteral	Ratio enteral / parenteral
221 Major Small & Large Bowel Procedures	1.23%	1.51%	11.52%	0.19
220 Major Stomach, Esophageal & Duodenal Procedures	0.29%	1.73%	5.22%	0.47
240 Digestive Malignancy	0.48%	0.89%	3.04%	0.42
004 Tracheostomy W Mv 96+ Hours W Extensive Procedure Or Ecmo	0.20%	6.59%	3.00%	3.14
951 Moderately Extensive Procedure Unrelated To Principal Diagnosis	0.92%	8.20%	2.85%	4.11
260 Major Pancreas, Liver & Shunt Procedures	0.20%	0.72%	2.35%	0.44
003 Bone Marrow Transplant	0.08%	0.23%	2.20%	0.15
950 Extensive Procedure Unrelated To Principal Diagnosis	0.44%	1.73%	2.16%	1.14
247 Intestinal Obstruction	0.43%	0.44%	2.11%	0.30
222 Other Stomach, Esophageal & Duodenal Procedures	0.26%	1.69%	2.07%	1.17
223 Other Small & Large Bowel Procedures	0.28%	0.39%	1.82%	0.30
720 Septicemia & Disseminated Infections	0.81%	2.33%	1.80%	1.84
254 Other Digestive System Diagnoses	0.95%	0.96%	1.80%	0.76
421 Malnutrition, Failure To Thrive & Other Nutritional Disorders	0.31%	0.84%	1.69%	0.71
710 Infectious & Parasitic Diseases Including Hiv W O.R. Procedure	0.23%	1.74%	1.50%	1.66
229 Other Digestive System & Abdominal Procedures	0.20%	0.33%	1.40%	0.34
441 Major Bladder Procedures	0.13%	0.05%	1.39%	0.05
139 Other Pneumonia	1.76%	2.05%	1.37%	2.14
137 Major Respiratory Infections & Inflammations	0.61%	2.86%	1.35%	3.03
249 Other Gastroenteritis, Nausa & Vomiting	0.90%	0.45%	1.33%	0.49
136 Respiratory Malignancy	0.59%	0.40%	1.08%	0.53
282 Disorders Of Pancreas Except Malignancy	0.39%	0.35%	1.08%	0.46
252 Malfunction, Reaction & Complication Of Gi Device Or Procedure	0.14%	0.76%	1.06%	1.02

APR-DRG	% of all stays	% enteral	% parenteral	Ratio enteral / parenteral
045 Cva & Precerebral Occlusion W Infarct	1.18%	3.31%	1.04%	4.53
264 Other Hepatobiliary, Pancreas & Abdominal Procedures	0.20%	0.41%	1.01%	0.58
696 Other Chemotherapy	1.17%	1.67%	0.93%	2.57
711 Post-Op, Post-Trauma, Other Device Infections W O.R. Procedure	0.16%	0.27%	0.87%	0.43
245 Inflammatory Bowel Disease	0.19%	0.08%	0.85%	0.13
660 Major Hematologic/Immunologic Diag Exc Sickle Cell Crisis & Coagul	0.22%	0.31%	0.82%	0.53
861 Signs, Symptoms & Other Factors Influencing Health Status	1.58%	0.41%	0.78%	0.76
681 Other O.R. Procedures For Lymphatic/Hematopoietic/Other Neoplasms	0.23%	0.45%	0.76%	0.85
130 Respiratory System Diagnosis W Ventilator Support 96+ Hours	0.09%	2.66%	0.74%	5.13
281 Malignancy Of Hepatobiliary System & Pancreas	0.31%	0.16%	0.74%	0.31
140 Chronic Obstructive Pulmonary Disease	2.00%	1.49%	0.72%	2.95
243 Other Esophageal Disorders	0.27%	0.49%	0.72%	0.97
791 O.R. Procedure For Other Complications Of Treatment	0.23%	0.32%	0.72%	0.63
690 Acute Leukemia	0.08%	0.05%	0.70%	0.11
248 Major Gastrointestinal & Peritoneal Infections	0.22%	0.19%	0.68%	0.39
169 Major Abdominal Vascular Procedures	0.19%	0.36%	0.65%	0.79
224 Peritoneal Adhesiolysis	0.10%	0.11%	0.65%	0.24
121 Other Respiratory & Chest Procedures	0.29%	1.20%	0.63%	2.73
862 Other Aftercare & Convalescence	1.57%	2.05%	0.57%	5.13
850 Procedure W Diag Of Rehab, Aftercare Or Oth Contact W Health Service	0.65%	0.84%	0.57%	2.10
301 Hip Joint Replacement	2.24%	0.44%	0.57%	1.10
721 Post-Operative, Post-Traumatic, Other Device Infections	0.21%	0.15%	0.57%	0.37
244 Diverticulitis & Diverticulosis	0.56%	0.05%	0.55%	0.14
691 Lymphoma, Myeloma & Non-Acute Leukemia	0.23%	0.23%	0.53%	0.61

APR-DRG	% of all stays	% enteral	% parenteral	Ratio enteral / parenteral
680 Major O.R. Procedures For Lymphatic/Hematopoietic/Other Neoplasms	0.07%	0.13%	0.53%	0.36
952 Nonextensive Procedure Unrelated To Principal Diagnosis	0.41%	0.43%	0.51%	1.19
021 Craniotomy Except For Trauma	0.39%	2.59%	0.49%	7.50
181 Lower Extremity Arterial Procedures	1.22%	0.43%	0.49%	1.23
261 Major Biliary Tract Procedures	0.10%	0.11%	0.49%	0.31
005 Tracheostomy W Mv 96+ Hours W/O Extensive Procedure	0.05%	1.67%	0.47%	5.04
422 Hypovolemia & Related Electrolyte Disorders	0.21%	0.36%	0.47%	1.08
284 Disorders Of Gallbladder & Biliary Tract	0.58%	0.19%	0.47%	0.56
241 Peptic Ulcer & Gastritis	0.40%	0.16%	0.47%	0.48
194 Heart Failure	1.63%	0.92%	0.46%	2.88
110 Ear, Nose, Mouth, Throat, Cranial/Facial Malignancies	0.12%	1.51%	0.42%	5.18
041 Nervous System Malignancy	0.22%	0.16%	0.42%	0.55
443 Kidney & Urinary Tract Procedures For Nonmalignancy	0.45%	0.16%	0.42%	0.55
403 Procedures For Obesity	0.87%	0.09%	0.42%	0.32
280 Alcoholic Liver Disease	0.27%	0.40%	0.40%	1.43
114 Dental & Oral Diseases & Injuries	0.14%	0.29%	0.40%	1.05
530 Female Reproductive System Malignancy	0.09%	0.01%	0.36%	0.05
098 Other Ear, Nose, Mouth & Throat Procedures	0.68%	0.98%	0.34%	4.11
463 Kidney & Urinary Tract Infections	1.10%	0.84%	0.34%	3.50
694 Lymphatic & Other Malignancies & Neoplasms Of Uncertain Behavior	0.18%	0.16%	0.34%	0.67
511 Uterine & Adnexa Procedures For Ovarian & Adnexal Malignancy	0.05%		0.34%	
468 Other Kidney & Urinary Tract Diagnoses, Signs & Symptoms	0.59%	0.29%	0.30%	1.38
308 Hip And Femur Fracture Repair	0.91%	0.28%	0.30%	1.31
911 Extensive Abdominal/Thoracic Procedures For Mult Significant Trauma	0.02%	0.15%	0.30%	0.69
813 Other Complications Of Treatment	0.25%	0.12%	0.30%	0.56

APR-DRG	% of all stays	% enteral	% parenteral	Ratio enteral / parenteral
442 Kidney & Urinary Tract Procedures For Malignancy	0.15%	0.09%	0.30%	0.44
163 Cardiac Valve Procedures W/O Ami Or Complex Pdx	0.30%	0.85%	0.28%	4.27
469 Acute Kidney Injury	0.22%	0.25%	0.28%	1.27
182 Other Peripheral Vascular Procedures	0.26%	0.20%	0.28%	1.00
663 Other Anemia & Disorders Of Blood & Blood-Forming Organs	0.57%	0.20%	0.28%	1.00
263 Laparoscopic Cholecystectomy	1.08%	0.16%	0.28%	0.80
695 Chemotherapy For Acute Leukemia	0.06%		0.28%	
058 Other Disorders Of Nervous System	1.23%	1.66%	0.27%	8.93
042 Degenerative Nervous System Disorders Exc Mult Sclerosis	1.11%	1.41%	0.27%	7.57
044 Intracranial Hemorrhage	0.25%	1.13%	0.27%	6.07
120 Major Respiratory & Chest Procedures	0.23%	0.92%	0.27%	4.93
053 Seizure	0.60%	0.86%	0.27%	4.64
425 Electrolyte Disorders Except Hypovolemia Related	0.25%	0.37%	0.27%	2.00
347 Other Back & Neck Disorders, Fractures & Injuries	1.29%	0.25%	0.27%	1.36
351 Other Musculoskeletal System & Connective Tissue Diagnoses	0.88%	0.16%	0.27%	0.86
206 Malfunction,reaction,complication Of Cardiac/Vasc Device Or Procedure	0.07%	0.05%	0.27%	0.29
343 Musculoskeletal Malignancy & Pathol Fracture D/T Muscskel Malig	0.17%	0.05%	0.27%	0.29
167 Other Cardiothoracic & Thoracic Vascular Procedures	0.22%	0.23%	0.25%	1.31
279 Hepatic Coma & Other Major Acute Liver Disorders	0.08%	0.08%	0.25%	0.46
227 Hernia Procedures Except Inguinal, Femoral & Umbilical	0.47%	0.07%	0.25%	0.38
144 Respiratory Signs, Symptoms & Minor Diagnoses	0.95%	0.65%	0.23%	4.08
201 Cardiac Arrhythmia & Conduction Disorders	1.08%	0.28%	0.23%	1.75
461 Kidney & Urinary Tract Malignancy	0.12%	0.04%	0.23%	0.25
246 Gastrointestinal Vascular Insufficiency	0.10%	0.03%	0.23%	0.17

APR-DRG	% of all stays	% enteral	% parenteral	Ratio enteral / parenteral
510 Pelvic Evisceration, Radical Hysterectomy & Other Radical Gyn Procs	0.07%	0.03%	0.23%	0.17
020 Craniotomy For Trauma	0.07%	0.96%	0.21%	6.55
424 Other Endocrine Disorders	0.19%	0.16%	0.21%	1.09
383 Cellulitis & Other Skin Infections	0.68%	0.05%	0.21%	0.36
447 Other Kidney, Urinary Tract & Related Procedures	0.04%	0.08%	0.19%	0.60
382 Malignant Breast Disorders	0.08%	0.04%	0.19%	0.30
225 Appendectomy	0.48%	0.01%	0.19%	0.10
090 Major Larynx & Trachea Procedures	0.03%	0.97%	0.17%	8.11
024 Extracranial Vascular Procedures	0.35%	0.76%	0.17%	6.33
052 Nontraumatic Stupor & Coma	0.15%	0.49%	0.17%	4.11
566 Other Antepartum Diagnoses	0.62%	0.03%	0.17%	0.22
166 Coronary Bypass W/O Ami Or Complex Pdx	0.36%	0.44%	0.15%	4.13
002 Heart &/Or Lung Transplant	0.02%	0.35%	0.15%	3.25
420 Diabetes	0.63%	0.23%	0.15%	2.13
134 Pulmonary Embolism	0.36%	0.05%	0.15%	0.50
860 Rehabilitation	1.17%	1.34%	0.13%	14.43
812 Poisoning Of Medicinal Agents	0.33%	0.70%	0.13%	7.57
910 Craniotomy For Multiple Significant Trauma	0.02%	0.49%	0.13%	5.29
190 Acute Myocardial Infarction	0.41%	0.44%	0.13%	4.71
912 Musculoskeletal & Other Procedures For Multiple Significant Trauma	0.12%	0.40%	0.13%	4.29
305 Amputation Of Lower Limb Except Toes	0.14%	0.19%	0.13%	2.00
048 Peripheral, Cranial & Autonomic Nerve Disorders	0.27%	0.16%	0.13%	1.71
342 Fractures & Dislocations Except Femur, Pelvis & Back	0.45%	0.09%	0.13%	1.00
180 Other Circulatory System Procedures	0.18%	0.08%	0.13%	0.86
816 Toxic Effects Of Non-Medicinal Substances	0.05%	0.05%	0.13%	0.57

APR-DRG	% of all stays	% enteral	% parenteral	Ratio enteral / parenteral
226 Anal Procedures	0.35%		0.13%	
055 Head Trauma W Coma >1 Hr Or Hemorrhage	0.19%	0.40%	0.11%	5.00
175 Percutaneous Coronary Intervention W/O Ami	1.38%	0.29%	0.11%	3.67
775 Alcohol Abuse & Dependence	0.29%	0.23%	0.11%	2.83
001 Liver Transplant &/Or Intestinal Transplant	0.03%	0.16%	0.11%	2.00
097 Tonsil & Adenoid Procedures	0.28%	0.16%	0.11%	2.00
142 Interstitial & Alveolar Lung Diseases	0.13%	0.12%	0.11%	1.50
759 Eating Disorders	0.01%	0.12%	0.11%	1.50
113 Infections Of Upper Respiratory Tract	0.33%	0.09%	0.11%	1.17
315 Shoulder, Upper Arm & Forearm Procedures Except Joint Replacement	1.82%	0.09%	0.11%	1.17
283 Other Disorders Of The Liver	0.14%	0.07%	0.11%	0.83
302 Knee Joint Replacement	1.80%	0.05%	0.11%	0.67
513 Uterine & Adnexa Procedures For Non-Malignancy Except Leiomyoma	0.80%	0.05%	0.11%	0.67
518 Other Female Reproductive System & Related Procedures	0.12%		0.11%	
089 Major Cranial/Facial Bone Procedures	0.10%	0.76%	0.09%	11.40
091 Other Major Head & Neck Procedures	0.04%	0.66%	0.09%	10.00
143 Other Respiratory Diagnoses Except Signs, Symptoms & Minor Diagnoses	0.32%	0.50%	0.09%	7.60
380 Skin Ulcers	0.16%	0.24%	0.09%	3.60
026 Other Nervous System & Related Procedures	0.20%	0.21%	0.09%	3.20
321 Cervical Spinal Fusion & Other Back/Neck Proc Exc Disc Excis/Decomp	0.42%	0.13%	0.09%	2.00
171 Perm Cardiac Pacemaker Implant W/O Ami, Heart Failure Or Shock	0.38%	0.11%	0.09%	1.60
384 Contusion, Open Wound & Other Trauma To Skin & Subcutaneous Tissue	0.37%	0.11%	0.09%	1.60
309 Other Significant Hip And Femur Surgery	0.24%	0.07%	0.09%	1.00

APR-DRG	% of all stays	% enteral	% parenteral	Ratio enteral / parenteral
253 Other & Unspecified Gastrointestinal Hemorrhage	0.15%	0.01%	0.09%	0.20
344 Osteomyelitis, Septic Arthritis & Other Musculoskeletal Infections	0.10%	0.01%	0.09%	0.20
512 Uterine & Adnexa Procedures For Non-Ovarian & Non-Adnexal Malig	0.07%		0.09%	
723 Viral Illness	0.15%		0.09%	
174 Percutaneous Coronary Intervention W Ami	0.50%	0.72%	0.08%	13.50
023 Spinal Procedures	0.10%	0.29%	0.08%	5.50
165 Coronary Bypass W Ami Or Complex Pdx	0.09%	0.29%	0.08%	5.50
192 Cardiac Catheterization For Other Non-Coronary Conditions	0.83%	0.28%	0.08%	5.25
049 Bacterial & Tuberculous Infections Of Nervous System	0.05%	0.23%	0.08%	4.25
131 Cystic Fibrosis - Pulmonary Disease	0.04%	0.16%	0.08%	3.00
757 Organic Mental Health Disturbances	0.42%	0.16%	0.08%	3.00
207 Other Circulatory System Diagnoses	0.32%	0.15%	0.08%	2.75
815 Other Injury, Poisoning & Toxic Effect Diagnoses	0.07%	0.15%	0.08%	2.75
722 Fever	0.10%	0.13%	0.08%	2.50
724 Other Infectious & Parasitic Diseases	0.13%	0.12%	0.08%	2.25
262 Cholecystectomy Except Laparoscopic	0.05%	0.09%	0.08%	1.75
385 Other Skin, Subcutaneous Tissue & Breast Disorders	0.23%	0.08%	0.08%	1.50
135 Major Chest & Respiratory Trauma	0.23%	0.05%	0.08%	1.00
361 Skin Graft For Skin & Subcutaneous Tissue Diagnoses	0.32%	0.05%	0.08%	1.00
341 Fracture Of Pelvis Or Dislocation Of Hip	0.28%	0.03%	0.08%	0.50
760 Other Mental Health Disorders	0.18%	0.03%	0.08%	0.50
401 Pituitary & Adrenal Procedures	0.04%	0.01%	0.08%	0.25
480 Major Male Pelvic Procedures	0.25%	0.01%	0.08%	0.25
651 Other Procedures Of Blood & Blood-Forming Organs	0.05%	0.01%	0.08%	0.25
006 Pancreas Transplant	0.00%		0.08%	

APR-DRG	% of all stays	% enteral	% parenteral	Ratio enteral / parenteral
930 Multiple Significant Trauma W/O O.R. Procedure	0.10%	0.28%	0.06%	7.00
364 Other Skin, Subcutaneous Tissue & Related Procedures	0.44%	0.20%	0.06%	5.00
115 Other Ear, Nose, Mouth,throat & Cranial/Facial Diagnoses	2.57%	0.17%	0.06%	4.33
317 Tendon, Muscle & Other Soft Tissue Procedures	0.52%	0.11%	0.06%	2.67
050 Non-Bacterial Infections Of Nervous System Exc Viral Meningitis	0.05%	0.08%	0.06%	2.00
466 Malfunction, Reaction, Complic Of Genitourinary Device Or Proc	0.14%	0.07%	0.06%	1.67
320 Other Musculoskeletal System & Connective Tissue Procedures	0.54%	0.05%	0.06%	1.33
242 Major Esophageal Disorders	0.03%	0.04%	0.06%	1.00
381 Major Skin Disorders	0.05%	0.04%	0.06%	1.00
661 Coagulation & Platelet Disorders	0.05%	0.04%	0.06%	1.00
751 Major Depressive Disorders & Other/Unspecified Psychoses	0.17%	0.04%	0.06%	1.00
844 Partial Thickness Burns Without Skin Graft	0.03%	0.03%	0.06%	0.67
560 Vaginal Delivery	4.64%	0.01%	0.06%	0.33
892 Hiv W Major Hiv Related Condition	0.02%		0.06%	
162 Cardiac Valve Procedures W Ami Or Complex Pdx	0.05%	0.32%	0.04%	12.00
133 Respiratory Failure	0.08%	0.28%	0.04%	10.50
740 Mental Illness Diagnosis W O.R. Procedure	0.06%	0.27%	0.04%	10.00
161 Cardiac Defibrillator & Heart Assist Implant	0.10%	0.15%	0.04%	5.50
197 Peripheral & Other Vascular Disorders	0.34%	0.12%	0.04%	4.50
470 Chronic Kidney Disease	0.19%	0.12%	0.04%	4.50
310 Intervertebral Disc Excision & Decompression	1.14%	0.11%	0.04%	4.00
405 Other Procedures For Endocrine, Nutritional & Metabolic Disorders	0.03%	0.11%	0.04%	4.00
313 Knee & Lower Leg Procedures Except Foot	1.03%	0.09%	0.04%	3.50
312 Skin Graft, Except Hand, For Musculoskeletal & Connective Tissue Diagnoses	0.05%	0.07%	0.04%	2.50

APR-DRG	% of all stays	% enteral	% parenteral	Ratio enteral / parenteral
314 Foot & Toe Procedures	0.88%	0.07%	0.04%	2.50
446 Urethral & Transurethral Procedures	0.77%	0.05%	0.04%	2.00
754 Depression Except Major Depressive Disorder	0.15%	0.05%	0.04%	2.00
047 Transient Ischemia	0.47%	0.04%	0.04%	1.50
340 Fracture Of Femur	0.11%	0.04%	0.04%	1.50
073 Eye Procedures Except Orbit	0.57%	0.03%	0.04%	1.00
199 Hypertension	0.13%	0.01%	0.04%	0.50
228 Inguinal, Femoral & Umbilical Hernia Procedures	0.81%	0.01%	0.04%	0.50
251 Abdominal Pain	0.25%	0.01%	0.04%	0.50
303 Dorsal & Lumbar Fusion Proc For Curvature Of Back	0.02%	0.01%	0.04%	0.50
776 Other Drug Abuse & Dependence	0.04%	0.01%	0.04%	0.50
316 Hand & Wrist Procedures	0.26%		0.04%	
462 Nephritis & Nephrosis	0.04%		0.04%	
500 Malignancy, Male Reproductive System	0.09%		0.04%	
519 Uterine & Adnexa Procedures For Leiomyoma	0.30%		0.04%	
196 Cardiac Arrest And Shock	0.04%	0.44%	0.02%	33.00
043 Multiple Sclerosis & Other Demyelinating Diseases	0.27%	0.33%	0.02%	25.00
092 Facial Bone Procedures Except Major Cranial/Facial Bone Procedures	0.18%	0.28%	0.02%	21.00
346 Connective Tissue Disorders	0.20%	0.13%	0.02%	10.00
842 Burns With Skin Graft Except Extensive 3rd Degree Burns	0.02%	0.11%	0.02%	8.00
040 Spinal Disorders & Injuries	0.06%	0.09%	0.02%	7.00
204 Syncope & Collapse	0.55%	0.09%	0.02%	7.00
198 Angina Pectoris & Coronary Atherosclerosis	0.25%	0.08%	0.02%	6.00
200 Cardiac Structural & Valvular Disorders	0.07%	0.08%	0.02%	6.00
193 Acute & Subacute Endocarditis	0.02%	0.05%	0.02%	4.00

APR-DRG	% of all stays	% enteral	% parenteral	Ratio enteral / parenteral
304 Dorsal & Lumbar Fusion Proc Except For Curvature Of Back	0.62%	0.05%	0.02%	4.00
753 Bipolar Disorders	0.07%	0.05%	0.02%	4.00
890 Hiv W Multiple Major Hiv Related Conditions	0.01%	0.05%	0.02%	4.00
082 Eye Disorders Except Major Infections	0.14%	0.04%	0.02%	3.00
160 Major Cardiothoracic Repair Of Heart Anomaly	0.00%	0.03%	0.02%	2.00
349 Malfunction, Reaction, Complic Of Orthopedic Device Or Procedure	0.16%	0.03%	0.02%	2.00
423 Inborn Errors Of Metabolism	0.02%	0.03%	0.02%	2.00
540 Cesarean Delivery	1.39%	0.03%	0.02%	2.00
755 Adjustment Disorders & Neuroses Except Depressive Diagnoses	0.11%	0.03%	0.02%	2.00
756 Acute Anxiety & Delirium States	0.17%	0.03%	0.02%	2.00
772 Alcohol & Drug Dependence W Rehab Or Rehab/Detox Therapy	0.10%	0.03%	0.02%	2.00
138 Bronchiolitis & Rsv Pneumonia	0.01%	0.01%	0.02%	1.00
177 Cardiac Pacemaker & Defibrillator Revision Except Device Replacement	0.05%	0.01%	0.02%	1.00
544 D&c, Aspiration Curettage Or Hysterotomy For Obstetric Diagnoses	0.07%	0.01%	0.02%	1.00
545 Ectopic Pregnancy Procedure	0.06%	0.01%	0.02%	1.00
650 Splenectomy	0.01%	0.01%	0.02%	1.00
054 Migraine & Other Headaches	0.28%		0.02%	
170 Permanent Cardiac Pacemaker Implant W Ami, Heart Failure Or Shock	0.03%		0.02%	
444 Renal Dialysis Access Device Procedure Only	0.06%		0.02%	
514 Female Reproductive System Reconstructive Procedures	0.23%		0.02%	
517 Dilation & Curettage For Non-Obstetric Diagnoses	0.04%		0.02%	
531 Female Reproductive System Infections	0.05%		0.02%	
Uaa Urgency In Psychiatrie	0.04%		0.02%	
022 Ventricular Shunt Procedures	0.04%	0.17%		

APR-DRG	% of all stays	% enteral	% parenteral	Ratio enteral / parenteral
692 Radiotherapy	0.05%	0.13%		
404 Thyroid, Parathyroid & Thyroglossal Procedures	0.40%	0.09%		
465 Urinary Stones & Acquired Upper Urinary Tract Obstruction	0.54%	0.07%		
841 Extensive 3rd Degree Burns W Skin Graft	0.00%	0.07%		
046 Nonspecific Cva & Precerebral Occlusion W/O Infarct	0.04%	0.05%		
057 Concussion, Closed Skull Fx Nos,uncomplicated Intracranial Injury, Coma < 1 Hr Or No Coma	0.19%	0.05%		
191 Cardiac Catheterization For Coronary Artery Disease	0.80%	0.05%		
363 Breast Procedures Except Mastectomy	0.86%	0.05%		
482 Transurethral Prostatectomy	0.49%	0.04%		
501 Male Reproductive System Diagnoses Except Malignancy	0.25%	0.04%		
056 Brain Contusion/Laceration & Complicated Skull Fx, Coma < 1 Hr Or No Coma	0.02%	0.03%		
141 Asthma	0.20%	0.03%		
176 Cardiac Pacemaker & Defibrillator Device Replacement	0.16%	0.03%		
750 Schizophrenia	0.02%	0.03%		
811 Allergic Reactions	0.03%	0.03%		
894 Hiv W One Signif Hiv Cond Or W/O Signif Related Cond	0.02%	0.03%		
051 Viral Meningitis	0.04%	0.01%		
070 Orbital Procedures	0.03%	0.01%		
080 Acute Major Eye Infections	0.03%	0.01%		
093 Sinus & Mastoid Procedures	0.29%	0.01%		
205 Cardiomyopathy	0.03%	0.01%		
440 Kidney Transplant	0.04%	0.01%		
445 Other Bladder Procedures	0.08%	0.01%		

APR-DRG	% of all stays	% enteral	% parenteral	Ratio enteral / parenteral
484 Other Male Reproductive System & Related Procedures	0.12%	0.01%		
561 Postpartum & Post Abortion Diagnoses W/O Procedure	0.08%	0.01%		
770 Drug & Alcohol Abuse Or Dependence, Left Against Medical Advice	0.03%	0.01%		
774 Cocaine Abuse & Dependence	0.01%	0.01%		
956 Ungroupable	0.00%	0.01%		
Aaa Psychiatrie (A, K, T)	0.02%	0.01%		

Appendix 2.4. Merging of reimbursement episodes

Figure 30 shows a schematic theoretical overview of how the reimbursement episodes are determined in the data. Summarised, consecutive dates of reimbursement are taken to be part of the same reimbursement episode. New episodes are started if the dates no longer follow consecutively.

Figure 30 – Schematic overview of constructing reimbursement episodes

RIZIV-INAMI code	Date	Number of days		End		First episode	Last episode	Episode	Start episode date	End episode date	Merged episode	Start merged episode	End merged episode
751310	01 jan 2013	31		01 feb 2013		01 jan 2013	01 feb 2013	1	01 jan 2013		1	01 jan 2013	01 jul 2013
751251	01 jan 2013	31		01 feb 2013	First episode date$_1$ = Date$_1$	01 jan 2013	01 feb 2013	1		01 jul 2013			
751310	01 feb 2013	4		05 feb 2013	Last episode date$_1$ = End$_1$	01 jan 2013	05 feb 2013	1					
751251	01 feb 2013	4		05 feb 2013		01 jan 2013	05 feb 2013	1					
751310	05 feb 2013	24		01 mrt 2013	--- new episode ---	01 jan 2013	01 mrt 2013	1					
751251	05 feb 2013	24		01 mrt 2013	if Date$_i$ > Last episode$_{k-1}$ then	01 jan 2013	01 mrt 2013	1					
751310	01 mrt 2013	31	Date + Number of days = End	01 apr 2013	episode$_k$ = episode$_{k-1}$ + 1	01 jan 2013	01 apr 2013	1					
751251	01 mrt 2013	31		01 apr 2013	First episode$_k$ = Date$_k$	01 jan 2013	01 apr 2013	1					
751310	01 apr 2013	30		01 mei 2013	Last episode$_k$ = End$_k$	01 jan 2013	01 mei 2013	1					
751251	01 apr 2013	30		01 mei 2013	--- episode continues ---	01 jan 2013	01 mei 2013	1					
751310	01 mei 2013	31		01 jun 2013	else if End$_k$ > Last episode$_{k-1}$ then	01 jan 2013	01 jun 2013	1					
751251	01 mei 2013	31		01 jun 2013	episode$_k$ = episode$_{k-1}$	01 jan 2013	01 jun 2013	1					
751310	01 jun 2013	30		01 jul 2013	First episode$_k$ = First episode$_{k-1}$	01 jan 2013	01 jul 2013	1					
751251	01 jun 2013	30		01 jul 2013	Last episode$_k$ = End$_k$	01 jan 2013	01 jul 2013	1					
751310	01 apr 2014	30		01 mei 2014		01 apr 2014	01 mei 2014	2	01 apr 2014		2	01 apr 2014	14 jul 2014
751251	01 apr 2014	30		01 mei 2014		01 apr 2014	01 mei 2014	2		14 jul 2014			
751251	01 mei 2014	31		01 jun 2014		01 apr 2014	01 jun 2014	2					
751310	01 mei 2014	31		01 jun 2014		01 apr 2014	01 jun 2014	2					
751310	01 jun 2014	30		01 jul 2014	1. Start an episode.	01 apr 2014	01 jul 2014	2					
751251	01 jun 2014	30		01 jul 2014	2. Keep using the first date as long as the current date isn't past the current end date. The episode also remains the same.	01 apr 2014	01 jul 2014	2					
751310	01 jul 2014	13		14 jul 2014		01 apr 2014	14 jul 2014	2					
751251	01 jul 2014	13		14 jul 2014		01 apr 2014	14 jul 2014	2					
751310	25 jul 2014	7		01 aug 2014	3. If the current date is past the current end date, start a new episode.	25 jul 2014	01 aug 2014	3	25 jul 2014		3	25 jul 2014	01 sep 2014
751251	25 jul 2014	7		01 aug 2014		25 jul 2014	01 aug 2014	3		01 sep 2014			
751310	01 aug 2014	31		01 sep 2014		25 jul 2014	01 sep 2014	3					
751251	01 aug 2014	31		01 sep 2014		25 jul 2014	01 sep 2014	3					

Use the first and last date per episode as start and end

We noticed several gaps in reimbursement periods that suggest invoicing practice rather than separate clinical episodes. We therefore decided to merge episodes of enteral nutrition if the gap was less than 31 days; and episodes of parenteral nutrition if the gap was less than five days. We based this decision on the distribution of the gaps (see Figure 31 and Figure 32).

Figure 31 – Distribution of gaps between enteral episodes in days between 2008 and 2016.

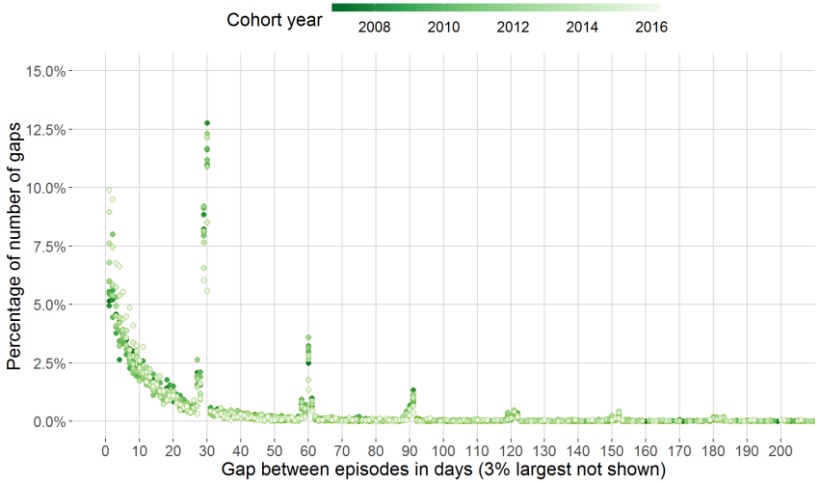
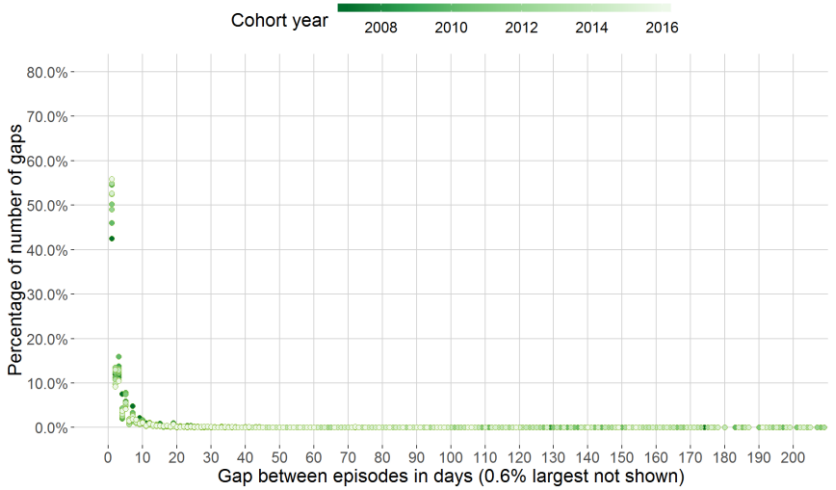


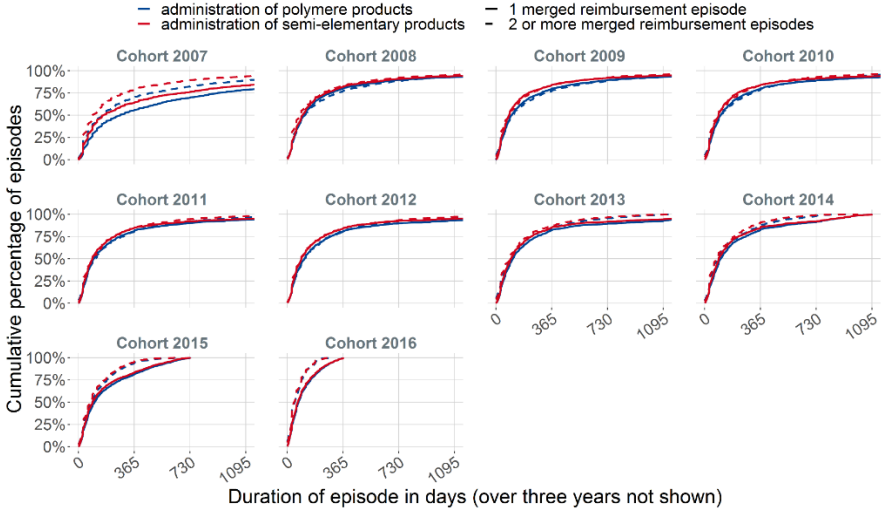
Figure 32 – Distribution of gaps between parenteral episodes in days between 2008 and 2016.



Appendix 2.5. Subgroup analysis duration at home

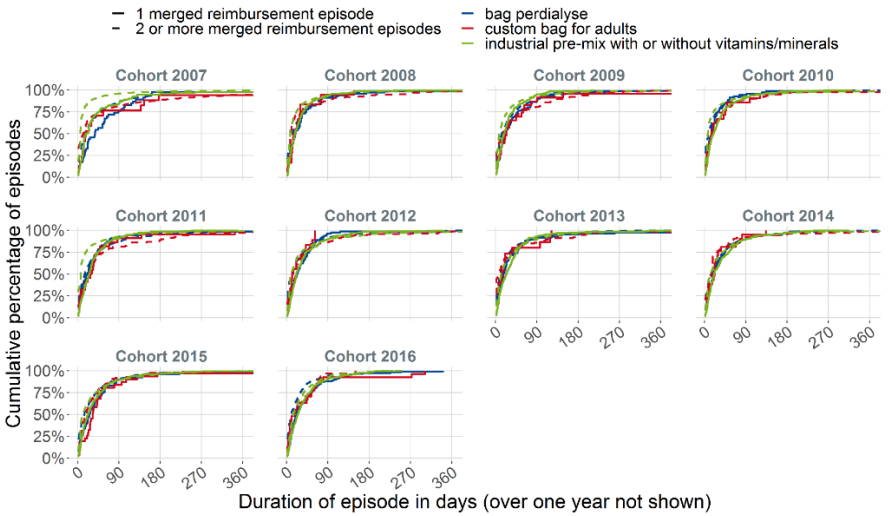
The duration of episodes for enteral semi-elementary solutions tends to be slighter shorter than for polymeric solutions (see Figure 33; in 2016 semi-elementary median = 65, IQR = 105; polymeric median = 71.5, IQR = 115).

Figure 33 – Cumulative percent of enteral merged reimbursement episodes at home by duration, product type and cohort year



There is little difference in duration between perdialyse bags and industrial pre-mixture solutions for parenteral nutrition (see Figure 34). The duration of episodes of patients using custom bags for adults tends to differ from the other solutions, but this is in part because very few patients are on these custom bags, compared to the other solutions.

Figure 34 – Cumulative percent of parenteral merged reimbursement episodes at home by duration, product type and cohort year



APPENDIX 3. LITERATURE REVIEW OF ECONOMIC STUDIES PN EN VS TPN

Appendix 3.1. Search strategies of reviews of economic evaluations

In February 2018, the websites of HTA institutes (http://www.inahta.org/members/) were searched using free text such as parenteral nutrition and enteral nutrition. The aim was to find both reviews and primary studies.

Table 31 – List of INAHTA member websites

Abbreviation	Institute	Country
AHTA	Adelaide Health Technology Assessment	Australia
ASERNIP-S	Australian Safety and Efficacy Register of New Interventional Procedures -Surgical	Australia
CADTH	Canadian Agency for Drugs and Technologies in Health	Canada
HealthPACT	Health Policy Advisory Committee on Technology	Australia
IECS	Institute for Clinical Effectiveness and Health Policy	Argentina
IHE	Institute of Health Economics	Canada
INESSS	Institut national d'excellence en santé et en services sociaux	Canada

Table 32 – Selection of non-member websites

Abbreviation	Institute	Country
EUnetHTA	European Network for HealthTechnology Assessment	Europe
HTAi	Health Technology Assessment International	International
iHEA	International Health Economics Association	International
INAHTA	International Network of Agencies for Health Technology Assessment	International
NICE	National Institute for Health and Care Excellence	United Kingdom

The following databases were searched between February and March 2018 for reviews of economic evaluations: Centre for Reviews and Dissemination Health Technology Assessment databases (CRD-HTA, NHS Health Technology Assessments), CRD EED (Economic Evaluation Database) and Medline(OVID). Table 33 up to Table 37 provide an overview of the applied search strategies.

Table 33 – Search strategy and results for CRD HTA (2018-02-16)

Database	CRD HTA		
Date			16 February 2018
Date covered			No restriction
Search Strategy	**#**	**Searches**	**Results**
	1	MeSH DESCRIPTOR Nutritional Support EXPLODE ALL TREES IN HTA	35
	2	MeSH DESCRIPTOR Enteral Nutrition EXPLODE ALL TREES IN HTA	20
	3	MeSH DESCRIPTOR Parenteral Nutrition EXPLODE ALL TREES IN HTA	14
	4	MeSH DESCRIPTOR Parenteral Nutrition, Home EXPLODE ALL TREES IN HTA	1
Note	According to the number of hits we choose to export line 1 (35 articles).		

Table 34 – Search strategy and results for CRD NHS EED (2018-03-16)

Database	CRD EED		
Date			16 March 2018
Date covered			No restriction
Search Strategy	#	**Searches**	**Results**
	1	MeSH DESCRIPTOR Nutritional Support EXPLODE ALL TREES IN NHSEED	98
Note			

Table 35 – Search strategy and results of economic systematic reviews for Medline @ OVID (2018-02-16)

Database	Ovid MEDLINE(R) <1946 to February Week 2 2018>		
Date			16 February 2018
Date covered			1946 to February Week 2 2018
92Search Strategy	#	**Searches**	**Results**
	1	economics/	26860
	2	exp "Costs and Cost Analysis"/	211895
	3	"Value of Life"/ec [Economics]	240
	4	Economics, Dental/	1890
	5	exp Economics, Hospital/	22638
	6	Economics, Medical/	8934
	7	Economics, Nursing/	3978
	8	Economics, Pharmaceutical/	2730
	9	(econom$ or cost or costs or costly or costing or price or prices or pricing or pharmacoeconomic$).tw.	552888
	10	(expenditure$ not energy).tw.	21512
	11	(value adj1 money).tw.	5
	12	budget$.tw.	20733
	13	or/1-12	687358
	14	(metabolic adj cost).ab,hw,ti.	1012
	15	((energy or oxygen) adj cost).ab,hw,ti.	3083
	16	14 or 15	3977
	17	13 not 16	683381
	18	letter.pt.	924910
	19	editorial.pt.	404184
	20	historical article.pt.	343214
	21	18 or 19 or 20	1654944
	22	17 not 21	650771
	23	Animals/	6146499
	24	human/	16868467
	25	23 not (23 and 24)	4391837
	26	22 not 25	603325
	27	exp Nutritional Support/	41779
	28	26 and 27	1802
	29	limit 28 to systematic reviews	140
	30	remove duplicates from 29	137
Note			

Table 36 – Search strategy and results of primary economic evaluations for Medline @ OVID (2018-03-16)

Database	**Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily, Ovid MEDLINE and Versions(R) <1946 to March 14 2018>**		
Date			16 March 2018
Date covered			1946 to March 14 2018
92Search Strategy	**#**	**Searches**	**Results**
	1	economics/	26971
	2	exp "Costs and Cost Analysis"/	212891
	3	"Value of Life"/ec [Economics]	241
	4	Economics, Dental/	1891
	5	exp Economics, Hospital/	22690
	6	Economics, Medical/	8938
	7	Economics, Nursing/	3978
	8	Economics, Pharmaceutical/	2742
	9	(econom$ or cost or costs or costly or costing or price or prices or pricing or pharmacoeconomic$).tw.	669946
	10	(expenditure$ not energy).tw.	25061
	11	(value adj1 money).tw.	5
	12	budget$.tw.	25221
	13	or/1-12	809222
	14	(metabolic adj cost).ab,hw,ti.	1194
	15	((energy or oxygen) adj cost).ab,hw,ti.	3626
	16	14 or 15	4698
	17	13 not 16	804524
	18	letter.pt.	979746
	19	editorial.pt.	452710
	20	historical article.pt.	343720
	21	18 or 19 or 20	1758729
	22	17 not 21	770792
	23	Animals/	6167453
	24	human/	16936769
	25	23 not (23 and 24)	4400883
	26	22 not 25	723060
	27	exp *Nutritional Support/	28612
	28	nutritional support.ti,kw.	2030
	29	enteral nutrition.ti,kw.	3221
	30	parenteral nutrition.ti,kw.	8333
	31	total parenteral nutrition.kw.	113
	32	28 or 29 or 30 or 31	13119
	33	27 or 32	30901
	34	26 and 33	1458
	35	limit 34 to yr="2008 - Current"	520
	36	remove duplicates from 35	518
Note	51 duplicates between the specific search on economic reviews and primary studies.		

Table 37 – Results of search strategy

Database	
CRD HTA	34
CRD EED	98
Medline@OVID (economic reviews)	137
Medline@OVID (primary studies)	518
Total (incl. duplicates)	**787**
Duplicates	51
Total (excl. duplicates)	**736**

Appendix 3.2. Selection process of reviews of economic evaluations

Figure 35 – Study flow of selection