

**MEDICAL NUTRITION TERMINOLOGY AND REGULATIONS IN THE UNITED STATES AND EUROPE: A SCOPING REVIEW**

**APPENDICES**

**Appendix 1. Inclusion and exclusion criteria for selection of studies and records**

Inclusion criteria	Exclusion criteria
<p>1. <b>Disease Related Malnutrition</b> resulting from:</p> <p>a. <b>Medical Conditions*</b> such as: liver failure from viral hepatitis, hemochromatosis, Wilson’s disease; respiratory failure from e.g. cystic fibrosis, Duchenne myopathy, <math>\alpha</math> 1-antitrypsin deficiency; short bowel syndrome; inflammatory bowel disease; necrotizing enterocolitis; chronic metabolic acidosis from inherited renal tubular acidosis</p> <p>b. <b>Patients with other conditions:</b> dysphagia resulting from cancer of the upper gastrointestinal tract; neurological disorders including multiple sclerosis, muscular dystrophy, Parkinson's disease.</p> <p>c. <b>Patients with inherited biochemical disorders and organic academia’s</b> such as Phenylketonuria (PKU); maple syrup urine disease (MSUD); diagnosed lactase deficiency in infancy resulting in galactosemia without dietary management; propionic academia</p> <p>2. <b>Infants diagnosed food allergy</b> (cow’s milk allergy)</p> <p>3. <b>Patients with the inability (or reduced ability) to chew and</b></p>	<p>1. “Life stages” such as pregnancy</p> <p>2. Classical nutrient deficiency disease such as scurvy or pellagra</p> <p>3. Weight loss or Diabetes persons suffering from carbohydrate metabolism disorders (diabetes)</p> <p>4. Full term infant formula and follow-on formula</p> <p>5. Processed cereal-based food and baby food</p> <p>6. Total diet replacement for weight control</p> <p>7. Meal replacement for weight control</p> <p>8. Lactose-free or lactose</p>

<p>swallow (and regurgitation in infants)</p> <p><b>4. Infants born prematurely</b></p> <p><b>5. Surgical patients and trauma patients</b></p> <p><b>6. Medical Nutrition:</b></p> <p><b>Enteral nutrition (EN; Food for Special Medical Purposes (FSMP))</b></p> <p>a. (Enteral) Tube feeds</p> <p>b. Oral nutrition supplements (ONS)</p> <p>c. Special formulas (incl. special infant formulas e.g. extensively hydrolyzed, free amino acids formulas, preterm formulas, special formulas for Gastro esophageal Reflux Disease etc.)</p> <p><b>Parenteral nutrition (PN)</b></p> <p><b>7. All health care settings including hospitals, outpatient, and community</b></p> <p><b>8. European and US regulation</b></p> <p><b>9. Publication year 1/2000 to 8/2015</b> (update search: 9/2015 to 4/2017)</p>	<p>intolerance in adults</p> <p>9. Gluten-free or very low gluten supplements</p> <p>10. Food supplement</p> <p>11. Fortified food</p> <p>12. Ordinary foodstuff</p> <p>13. Non-European and US regulation</p> <p>14. Letters, commentaries, posters, conference preceding and records without available full text articles.</p> <p>15. Other language than English</p>
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\* This is a non-exhaustive list

## Appendix 2. Search Strategy

(oral nutritional supplement\* OR ONS OR nutritional support OR nutritional intervention OR nutritional therap\* OR oral nutrition OR oral feed\* OR oral supplement\* OR enteral nutrition OR enteral feed\* OR enteral supplement\* OR parenteral nutrition OR parenteral feed\* OR sip feed\* OR sip nutrition OR food for special medical purposes OR FSMP OR medical nutrition OR medical food OR tube nutrition OR tube feed\* OR clinical nutrition) **AND** (nutritional status OR nutritional risk OR malnutrition OR undernutrition OR under nutrition OR malnourished OR undernourished OR underweight OR frail OR frailty OR sarcopenia OR sarcopenic OR cachexia OR cachectic OR nutritional deprivative OR nutrition depleted\* OR trauma OR surgery OR metabolic stress OR fasting OR critical illness OR critically ill) **NOT** (animal\* OR rat\* OR mice OR mouse OR rodent\* OR dog OR vitamin supplement\* OR mineral supplement\* OR fortified food OR pregnant OR pregnancy)

### Additional restrictions:

- Language: English
- Document types excluded: Conference Abstract, Letter, Comment, Editorial, Case Reports, Erratum, Book, Practice Guideline, Validation Studies
- Publication years: Jan 2000 – August 2015 (initial search) and from Sept 2015 – April 2017 (update search)

### **Appendix 3. Predefined MN terms**

1. Food for special medical purposes (FSMP)
2. Foods for special dietary use
3. Parenteral nutrition
4. Total parenteral nutrition (TPN)
5. Intradialytic parenteral nutrition
6. Enteral nutrition
7. Home enteral nutrition (HEN)
8. Tube feeding
9. Enteral tube feeding (ETF)
10. Gastric tube feeding
11. Duodenal tube feeding
12. Oral nutrition
13. Oral nutritional supplements (ONS)
14. Nutrition supplement
15. Medical nutrition
16. Malnutrition
17. Disease related malnutrition (DRM)
18. Disease associated malnutrition
19. Undernutrition
20. Other

#### Appendix 4. Records Including Full or Partial Health Economic Analysis\*

Types of Health Economic Evaluations		Initial analysis (n=19/459)	Update search (n=10/110)	
Full Economic Analysis	Cost-minimization analysis	1 (0.2%)	0	
	Cost-effectiveness analysis	6 (1.1%)	5 (4.5%)	
Partial Economic Analysis	Cost analysis	8 (1.5%)	5 (4.5%)	
	Cost of illness analysis	4 (0.7%)	0	
<i>Trends according to year of publication</i>				
Search period	Original search			Update search
Timespan	2000-2004	2005-2009	2010-2015 Aug	2015 Sept – 2017 April
No. of HE analyses / total no. of records	1/96 (1.0%)	3/113 (2.7%)	15/250 (6.0%)	10/110 (9.1%)

\* Data shown as n (%)

**Appendix 5. List of Records Including Full or Partial Health Economic Analysis\* (n=29)**

<b>29 records including full or partial health economic analysis</b>
<b>Arnaud-Battandier F, Malvy D, Jeandel C, et al. Use of oral supplements in malnourished elderly patients living in the community: a pharmaco-economic study. Clin Nutr 2004; 23: 1096-103.</b>
<b>Beck AM, Gogsig Christensen A, Stenbaek Hansen B, et al. Study protocol: cost-effectiveness of multidisciplinary nutritional support for undernutrition in older adults in nursing home and home-care: cluster randomized controlled trial. Nutr J 2014; 13: 86.</b>
<b>Cereda E, Klersy C, Andreola M, et al. SUN-PP252: Cost-Effectiveness of a Disease-Specific Oral Nutritional Support for Pressure Ulcer Healing. Clin Nutr 2015; 34: S117.</b>
<b>Corkins MR, Guenter P, DiMaria-Ghalili RA, et al. A.S.P.E.N. data brief 2014: use of enteral and parenteral nutrition in hospitalized patients with a diagnosis of malnutrition: United States, 2010. Nutr Clin Pract 2014; 29: 698-700.</b>
<b>Curtis CS, Busch RA, Crass RL, et al. Use of Premixed Parenteral Nutrition During a Phosphate Shortage in a Non-Critically Ill Population. Nutr Clin Pract 2016; 31: 218-22.</b>
<b>Doig GS, Chevrou-Severac H, Simpson F. Early enteral nutrition in critical illness: a full economic analysis using US costs. Clinicoecon Outcomes Res 2013; 5: 429-36.</b>
<b>Doig GS, Simpson F. Early parenteral nutrition in critically ill patients with short-term relative contraindications to early enteral nutrition: a full economic</b>

**analysis of a multicenter randomized controlled trial based on US costs.**

**Clinicoecon Outcomes Res 2013; 5: 369-79.**

**Elia M, Parsons EL, Cawood AL, et al. Cost-effectiveness of oral nutritional supplements in older malnourished care home residents. Clin Nutr 2017, doi:**

**10.1016/j.clnu.2017.02.008**

**Ferrie S, Allman-Farinelli M, Daley M, et al. Protein Requirements in the Critically Ill: A Randomized Controlled Trial Using Parenteral Nutrition. JPEN 2016; 40: 795-805.**

**Freijer K, Nuijten MJ, Schols JM. The budget impact of oral nutritional supplements for disease related malnutrition in elderly in the community setting. Front Pharmacol 2012; 3: 78.**

**Freijer K, Tan SS, Koopmanschap MA, et al. The economic costs of disease related malnutrition. Clin Nutr 2013; 32: 136-41.**

**Gamsjager T, Brenner L, Schaden E, et al. Cost analysis of two approaches to parenteral nutrition in critically ill children. Pediatr Crit Care Med 2009; 10: 163-5.**

**Harvey SE, Parrott F, Harrison DA, et al. 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). Health Technol Assess 2016; 20: 1-144.**

**Joffe A, Anton N, Lequier L, et al. Nutritional support for critically ill children. Cochrane Database Syst Rev 2016: CD005144.**

**Lucha PA, Jr., Butler R, Plichta J, et al. The economic impact of early enteral**

**feeding in gastrointestinal surgery: a prospective survey of 51 consecutive patients. Am Surg 2005; 71: 187-90.**

**Magee G, Zaloga GP, Turpin RS, et al. A retrospective, observational study of patient outcomes for critically ill patients receiving parenteral nutrition. Value Health 2014; 17: 328-33.**

**Meijers JM, Halfens RJ, Wilson L, et al. Estimating the costs associated with malnutrition in Dutch nursing homes. Clin Nutr 2012; 31: 65-8.**

**Moran Lopez JM, Piedra Leon M, Beneitez Moralejo B, et al. Efficiency, cost-effectiveness and need of inversion in nutritional therapy. Importance of detecting and documenting undernutrition. Clin Nutr 2016; 13: e28-e32.**

**Neelemaat F, Thijs A, Seidell JC, et al. Study protocol: cost-effectiveness of transmural nutritional support in malnourished elderly patients in comparison with usual care. Nutr J 2010; 9: 6.**

**Nuijten M, Mittendorf T. The health economic impact of oral nutritional supplements (ONS) in Germany. Aktuelle Ernährungsmedizin 2012; 1: 126-33.**

**Palm NM, McKinzie B, Ferguson PL, et al. Pharmacologic Stress Gastropathy Prophylaxis May Not Be Necessary in At-Risk Surgical Trauma ICU Patients Tolerating Enteral Nutrition. J Intensive Care Med 2016; doi 10.1177/0885066616678385**

**Philipson TJ, Snider JT, Lakdawalla DN, et al. Impact of oral nutritional supplementation on hospital outcomes. The American journal of managed care 2013; 19: 121-28.**

**Pradelli L, Iannazzo S, Zaniolo O, et al. Effectiveness and cost-effectiveness of**



**supplemental glutamine dipeptide in total parenteral nutrition therapy for critically ill patients: a discrete event simulation model based on Italian data.**

**Int J Technol Assess Health Care. 2012; 28: 22-8.**

**Rice N, Nugent A, Byrne D, et al. Potential of Earlier Detection and Treatment of Disease-Related Malnutrition with Oral Nutrition Supplements to Release Acute Care Bed Capacity. Ir Med J 2016; 109: 422.**

**Russell CA. The impact of malnutrition on healthcare costs and economic considerations for the use of oral nutritional supplements. Clin Nutr Supplements 2007; 2: 25-32.**

**Stehle P, Ellger B, Kojic D, et al. Glutamine dipeptide-supplemented parenteral nutrition improves the clinical outcomes of critically ill patients: A systematic evaluation of randomised controlled trials. Clin Nutr ESPEN. 2017; 17: 75-85.**

**Sun DL, Li WM, Li SM, et al. Comparison of multi-modal early oral nutrition for the tolerance of oral nutrition with conventional care after major abdominal surgery: a prospective, randomized, single-blind trial. Nutr J 2017; 16: 11.**

**Troyer JL, McAuley WJ, McCutcheon ME. Cost-effectiveness of medical nutrition therapy and therapeutically designed meals for older adults with cardiovascular disease. J Am Diet Assoc 2010; 110: 1840-51.**

**Zhong Y, Cohen JT, Goates S, et al. The Cost-Effectiveness of Oral Nutrition Supplementation for Malnourished Older Hospital Patients. Appl Health Econ Health Policy 2017; 15: 75-83.**