McKesson Medical-Surgical

Proper selection of Disease Specific Formulas from a Clinical and Cost-Saving Perspective

September 2017

Lisa Logan, R.D.,CNSC
Clinical Support Manager

Learning Objectives

Criteria used to determine and design an enteral formulary.
Review various categories and constituents of enteral formulas.
Summarize evidence based guidelines for selecting an enteral product.
Medical justification required to support specialty formula usage.
Disclosures

Some of the information contained in this presentation obtained from the ASPEN Clinical Webinar Series on July 9, 2014.

Benefits of an Enteral Formulary

Reduces product redundancy
Controls inventory cost and space
Helps maintain consistent supply of standard products
Reinforces an opportunity for staff education
Designing a Formulary

Assess your patient population and facility needs
Common nutritional requirements related to calorie and protein needs
Determine which products support the majority of your patient in your care setting

Formula Selection Criteria

- Functional status of GI tract
- Digestion and absorption capacity of resident
- Macro/micronutrient content
- Fiber content
- Cost (packaging)
- Fluid/electrolyte needs
Macro/Micronutrient Content

Carbohydrates

- Primary energy source in most enteral formulas. (Corn Syrup Solids, Hydrolyzed Corn Starch, Maltodextrin, Sucrose and Fructose)

Protein

- Polymeric intact protein: Whole protein or protein isolates (casein, soy), lactalbumin, egg albumin and whey
- Elemental / Semi-Elemental: Hydrolyzed protein, di- and tri- peptides, amino acids

Fat

- Concentrated source of energy
- Source of essential fatty acids (linoleic and linolenic acid)
- MCT: Structured Lipids or Omega 3 fatty acids
Fiber Content

Soluble Fiber – fermented to SCFA in colon by bacteria. This promotes sodium and water absorption.
Insoluble Fiber – increases fecal weight/bulk

Purpose -
  • Maintain bowel regularity
  • Prevent constipation
  • Helps decrease incidence of diarrhea

Prebiotic Fibers – “non-digestible food ingredients that stimulate growth of bacteria and SCFA” – FOS and Inulin

Prebiotics vs. Probiotics

• Prebiotic fibers increase the number of beneficial anaerobic bacteria and decrease the population of potential pathogenic microorganisms
• Probiotics stimulate mucosal immune mechanisms by stimulating non-immune mechanisms through antagonism and competition with potential pathogens

Ciorba, Clin Gastroenterol Hepatol, 2012
Water/Electrolyte requirements

**Water**
Standard: ~ 1 cal/ml - 82-85% per liter
High calorie: 1.5 cal/ml - 76-78%
High Calorie: 2 cal/ml - 70%
Disease-specific: varies

**ELECTROLYTES**
- Most formulas contain adequate amounts
- Hepatic/renal/cardiac formulas have modified amounts of electrolytes

---

Categories of Enteral Nutrition Formulas

<table>
<thead>
<tr>
<th>Less Ill</th>
<th>Nutrient Dense</th>
<th>Elemental</th>
<th>Very Ill</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard formula</td>
<td>Nutrient Dense</td>
<td>Elemental</td>
<td>Condition specific</td>
</tr>
<tr>
<td>Stroke</td>
<td>Cancer</td>
<td>Malabsorption/ Malnutrition</td>
<td>Liver, kidney, or respiratory disease</td>
</tr>
<tr>
<td>Fluid restriction</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Conditions Requiring Specialized Formulas

- Pediatric
- Diabetic
- Pulmonary
- Renal
- Immune Enhancing

Modular/Formula Additives

Carbohydrate powders
Protein – Glutamine/Arginine
Fat additives – Medium Chain Triglycerides
Fiber (Soluble/Insoluble)– Prebiotics
Vitamins/Minerals – Antioxidants
Diabetic Formulas

Intended for individuals with glucose intolerance to reduce incidence of hyperglycemia

Nutrient composition typically (40% CHO, 40% Fat and 20% Protein)

Fiber and fat content may slow gastric emptying and prevent elevated BS levels

Pulmonary Formulas

To reduce carbon dioxide production - these formulas contain >50% total cals from fat

May contain omega 3 fatty acids due to anti-inflammatory properties

Calorically dense
Renal Formulas

Contain lower amounts of electrolytes (primarily potassium, sodium and phosphate)
Protein content varies with regard to amount of essential or non-essential amino acids
Calorically dense – fluid restricted

Hepatic Formulas

Contains lower protein content
Higher % of BCAA and lower AAA to help prevent hepatic encephalopathy
Reduced water and sodium content
Immune enhancing

Constituents
• Arginine
• Glutamine
• Fish oil
• Nucleotides

There is believed to be a synergistic effect between arginine and fish oils; use in combination

Pierre et al., 2013

---

Arginine

Conditionally essential amino acid
Supplemental arginine can theoretically induce increased nitric oxide production
• May need to be withheld in septic patients
• May also need to be withheld in hemodynamic instability
Glutamine

The most abundant free amino acid in circulation (normal); levels are usually inadequate during critical illness or with GI disorders
It is the preferred fuel source for enterocytes and the immune cells of GALT
Most available research shows decreased rate of infection and improved gut function when used in burn and trauma patients

Omega 3 Fatty acids

Isolated from cold water fish species, flaxseeds, and canola oil sources
PUFAs with carbon-carbon double bond at the 3rd carbon
Essential fatty acid
3 main types
• Alpha-linolenic acid (ALA)
• Eicosapentaenoic acid (EPA)
• Docosahexaenoic acid (DHA)
Nucleotides

Small compounds found in all cells that are used to synthesize RNA and DNA

When there are low levels of nucleotides, there is reduced adaptive mediated immune response

Used in combination with glutamine, arginine, and omega 3 fatty acids
Product Selection
What's the Evidence?

- ASPEN/SCCM Critical Care Guidelines 2009
- AND Evidence Analysis Library (EAL)
- Canadian Critical Care Nutrition Guidelines 2013 (CCPG)
- ESPEN Enteral Feeding Guidelines
- UK guidelines
- ASPEN Core Curriculum (ASPEN CC)

Product Selection

- Standard 1 kcal/mL product – workhorse

- Concentrated formula (1.5-2 kcal/mL)
  - Respiratory distress requiring volume restriction (ASPEN/SCCM)
  - Cirrhosis with ascites (ESPEN)

- Modulars (protein, carbohydrate and fat)
Product Selection: High Protein

- To meet estimated needs for trauma, sepsis, burn, surgery, medical ICU patients not meeting criteria for immune enhancing formulas
- No evidence for head injury or critical illness (CCPG)
- Recommended for pancreatitis (ESPEN)
- Wound healing (ASCPN CC)

Product Selection: High Fiber

- Soluble fiber may benefit hemodynamically stable patients with diarrhea. Avoid insoluble fiber. Avoid any fiber if high risk of bowel ischemia or severe dysmotility. (ASCPN/SCCM, Grade C)
- Insufficient evidence for critical illness (CCPG)
- Not contraindicated in critical illness, but consider soluble fiber (guar gum) (EAL, Fair evidence)
Product Selection: Diabetes Specific

- Insufficient evidence regarding cost of medical care, mortality, LOS, infectious complications or days of mechanical ventilation in critically ill patients with diabetes (EAL, Grade V)
- More important to avoid overfeeding in diabetes. Consider diabetes-specific product only if problematic glycemic control, despite insulin. (ASPEN CC)

Product selection: Low CHO, High Fat

- Not recommended in ICU with acute respiratory failure (ASPEN/SCCM, Grade E)
- Insufficient evidence to recommend for critically ill patients (CCPG)
- More important to avoid calorie overfeeding (UK)
Product Selection: Renal Specific

- For AKI with significant electrolyte abnormalities (ASPEN/SCCM)
- Fluid and electrolyte management (UK)
- Otherwise use standard or standard concentrated product. Use high protein for CRRT.

Product Selection: Branched Chain Amino Acids

- Insufficient evidence for IV supplementation of BCAAs + EN in critical illness (CCPG)
- Rare cases of hepatic encephalopathy refractory to lactulose and antibiotics. (ASPEN/SCCM, Grade C). Otherwise, use standard formula, do not restrict protein.
- Recommended if encephalopathy arises while on EN (ESPEN)
Product Selection: Intact Protein vs. Peptides

- Whole protein should be considered when initiating feeding (CCPG, downgraded)
- Whole protein recommended for Crohn’s, cirrhosis, acute pancreatitis (if tolerated) (ESPEN)
- Use peptide product if all other causes of diarrhea ruled out. Use for pancreatitis if polymeric not tolerated. (ASPEN/SCCM)
- Consider peptide-based medium chain triglyceride products for pancreatitis (ASPen/International Guidelines, Grade B: Gold)

Product Selection: Immune Enhancing

- Recommendations for arginine, glutamine, nucleic acid, omega-3- FA and antioxidants
  - Surgical ICU, trauma, burns, head/neck cancer, mechanical ventilation (ASPen/SCCM, Grade A)
  - Non-severely septic medical ICU patients. (ASPen/SCCM, Grade B)
  - Reduces infectious complications in some critically ill patients (EAL, Grade III, Limited)
Product Selection: Immune Enhancing

• Arginine supplemented formulas
  – Not recommended in severe sepsis, "safe enough" in mild-moderate sepsis (ASPEN/SCCM)
  – Arginine and other select nutrients not recommended (CCPG)
  – Increased mortality in subgroup of higher quality studies of severe critically ill (EAL)

Product Selection: Immune Enhancing

• Fish oils, borage oils, antioxidants
  – Recommended for ARDS/ALI (ASPEN/SCCM, Grade A)
  – Should be considered for ARDS/ALI (CCPG, downgraded)
Product Selection: Glutamine Enhanced

- Should be considered in burn and trauma patients. Insufficient evidence for critical illness. (CCPG)
- Supplemental glutamine should be considered in burn, trauma, and mixed ICU patients (ASPEN/SCCM, Grade B)
- Routine supplementation not recommended, except for burn patients (EAL, Fair)

Additives: Probiotics

- Decreased infection in transplant, major abdominal surgery and severe trauma. No recommendation in other populations. No recommendation in severe pancreatitis. (ASPEN/SCCM)
- Should be considered in critical illness (CCPG, upgraded)
Categorization of Enteral Formulas

B4150 – nutritionally complete with intact nutrients

B4149 – blenderized natural foods with intact nutrients

B4152 – nutritionally complete, calorically dense (equal to or greater than 1.5 Kcal.ml) with intact nutrients

B4153 – nutritionally complete, hydrolyzed protein/amino acids

B4154 – nutritionally complete for special metabolic needs (excludes inherited disease of metabolism)

B4155 – nutritionally incomplete/modular nutrients
Additional Medical Necessity

B4149

• Documented allergy or intolerance to a standard, semi-synthetic nutrient (formula)

B4153, B4154 and B4155

• Must document reason(s) why a standard B4150 or B4152 formula is not being used

• Specific information must be provided to support reason(s) for use – needs to be documented in resident’s medical record

Summary

• Enteral formulas should be selected according to a patient’s nutritional requirements.

• Standard polymeric formulas are indicated for most patients.

• Evaluate medical necessity prior to the selection of specialized and more costly formulas

• Utilize guidelines provided by national and internationally professional societies when selecting enteral formulas.
References


Brown, Britta, Roehl, K, Betz, M. Enteral Nutrition Formula Selection: Current Evidence and Implications for Practice, 2015: 72-85


Questions?
Thank You!

Lisa Logan R.D.,CNSC
Lisa.Logan@mckesson.com

To reach any member of our Clinical Resource Team, call us at 1-877-611-0081

McKesson makes no representations or warranties about, and disclaims all responsibility for, the accuracy or suitability of any information in the webinar and related materials; all such content is provided on an “as is” basis. MCKESSON FURTHER DISCLAIMS ALL WARRANTIES REGARDING THE CONTENTS OF THESE MATERIALS AND ANY PRODUCTS OR SERVICES DISCUSSED THEREIN, INCLUDING WITHOUT LIMITATION ALL WARRANTIES OF TITLE, NON-INFRINGEMENT, MERCHANTABILITY, AND FITNESS FOR A PARTICULAR PURPOSE. The content of webinar and related materials should not be construed as legal advice and is intended solely for the use of a competent healthcare professional.

© 2017 McKesson Medical-Surgical, Inc. All trademarks and registered trademarks are the property of their respective owners.