Ensuring Safe and Appropriate Use of Parenteral Nutrition Therapy

A Midday Symposium and Live Webinar conducted at the 52nd ASHP Midyear Clinical Meeting and Exhibition
Tuesday, December 5, 2017 | 11:30 a.m. – 1:00 p.m. | Orlando, Florida

Agenda

11:30 a.m. – 11:35 a.m.
Welcome and Introduction
Joseph I. Boullata, Pharm.D., BCNSP, FACN, FASPEN

11:35 a.m. – 11:50 a.m.
Assessing the Nutrition Status of Patients in the Hospital Setting
Phil Ayers, Pharm.D., BCNSP, FASHP

11:50 a.m. – 12:20 p.m.
Applying Best Practices to Ensure Safe and Appropriate Use of Parenteral Nutrition
Joseph I. Boullata, Pharm.D., BCNSP, FACN, FASPEN

12:20 p.m. – 12:50 p.m.
Initiating and Managing Parenteral Nutrition Therapy: Clinical Case Studies
Joseph I. Boullata, Pharm.D., BCNSP, FACN, FASPEN, and Phil Ayers, Pharm.D., BCNSP, FASHP

12:50 p.m. – 1:00 p.m.
Faculty Discussion and Audience Questions

Provided by ASHP
Supported by an educational grant from Fresenius Kabi USA, LLC
Ensuring Safe and Appropriate Use of Parenteral Nutrition Therapy

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- Joseph I. Boullata, Pharm.D., BCNSP, FASPEN, FACN
  - Fresenius Kabi USA, LLC: consultant, speakers bureau

- Phil Ayers, Pharm.D., BCNSP, FASHP
  - Fresenius Kabi USA, LLC: speakers bureau

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Ensuring Safe and Appropriate Use of Parenteral Nutrition Therapy

Learning Objectives

• Examine the current state of malnutrition in hospitalized patients.
• Identify best practices for the appropriate use and safe delivery of parenteral nutrition.
• Using a clinical case study, illustrate safe and appropriate use of parenteral nutrition in an acutely ill patient.
• Using a clinical case study, illustrate considerations for the safe and appropriate use of long-term parenteral nutrition therapy.

Assessing the Nutrition Status of Patients in the Hospital Setting

Phil Ayers, Pharm.D., BCNSP, FASHP
Chief, Clinical Pharmacy Services
Baptist Health Systems
Associate Clinical Professor
University of Mississippi School of Pharmacy
Jackson, Mississippi

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Which of the following is the most accurate nutritional marker?

a. Prealbumin  
b. Albumin  
c. Transferrin  
d. None of the above

HCUP Malnutrition Facts

- In 2013, the all-cause 30-day readmission rate for patients with malnutrition was 23/100, compared with 14.9/100 for patients without malnutrition.
- For all types of malnutrition combined, the rate of readmission was highest among:
  - Ages 18-64 years
  - Medicaid patients
  - Patients in metropolitan areas


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HCUP Malnutrition Facts, 2013

- Average cost/readmission was $16,900 for patients with protein-calorie malnutrition and $17,900 for patients with post-surgical non-absorption versus $13,400 readmission cost for patients without malnutrition


HCUP Malnutrition Facts, 2013

- Septicemia was the leading diagnosis at readmission involving all types of malnutrition, except post-surgical non-absorption for which complication of device (implant or graft) was the leading reason for readmission


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Types of Malnutrition among Hospital Stays with Malnutrition, 2013


In-hospital Death by Malnutrition Type, 2013


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Nutrition Disorders and Nutrition-Related Conditions

- Malnutrition/undernutrition
- Sarcopenia and frailty
- Overweight and obesity
- Micronutrient abnormalities
- Re-feeding syndrome


Etiology-based Malnutrition Definitions


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**AND/ASPEN Clinical Characteristics to Support Diagnosis of Malnutrition**

- Energy intake
- Interpretation of weight loss
- Body fat
- Muscle mass
- Fluid accumulation
- Reduced grip strength

AND = Academy of Nutrition and Dietetics


**Body Composition and Lab Studies**

- Anthropometrics
- Bioelectrical impedance (BIA)
- Dual energy X-ray absorptiometry (DEXA)
- Imaging with CT or MRI
- Ultrasound
- Laboratory studies
  - Visceral proteins: albumin, prealbumin, transferrin, retinol binding protein, C-reactive protein
  - Nitrogen balance
  - Urine 3-methylhistidine


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Obesity Classification and Risk

<table>
<thead>
<tr>
<th>Obesity Class</th>
<th>BMI, kg/m²</th>
</tr>
</thead>
<tbody>
<tr>
<td>Underweight</td>
<td>&lt; 18.5</td>
</tr>
<tr>
<td>Normal</td>
<td>18.5-24.9</td>
</tr>
<tr>
<td>Overweight</td>
<td>25-29.9</td>
</tr>
<tr>
<td>Obesity class I</td>
<td>30-34.9</td>
</tr>
<tr>
<td>Obesity class II</td>
<td>35-39.9</td>
</tr>
<tr>
<td>Obesity class III</td>
<td>&gt; 40</td>
</tr>
</tbody>
</table>

High risk: Waist circumference, cm
Men > 102, Women > 88

BMI = body mass index

NIH publication no. 98-4083, September 1998.

Visceral Protein Compartment

- RBP
- Prealbumin
- Transferrin
- Albumin

Half life (days)

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Nutritionally-at-Risk Adults

• Involuntary loss of 10% or more of usual body weight within 6 months or involuntary loss of ≥ 5% or more of usual body weight in 1 month
• Involuntary loss or gain of 10 lb within 6 months

ASPEN. Definitions of terms – 2015.

Nutritionally-at-Risk Adults

• BMI < 18.5 kg/m² or > 25 kg/m²
• Chronic disease
• Increased metabolic requirements
• Altered diets or diet schedules
• Inadequate nutrition intake, including not receiving food or nutrition products for greater than 7 days

ASPEN. Definitions of terms – 2015.
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**Nutritionally-at-Risk Children**

- A weight for length or weight for height < 10th percentile or > 95th percentile
- BMI for age or sex < 5th percentile or > 85th percentile
- Increased metabolic requirements

ASPEN. Definitions of terms – 2015.  

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**Nutritionally-at-Risk Children**

- Impaired ability to ingest or tolerate oral feedings
- Documented inadequate provision or tolerance of nutrients
- Inadequate weight gain or a significant decrease in usual growth percentile

ASPEN. Definitions of terms – 2015.  
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**Nutritionally-at-Risk Neonates**

- Low birth weight (<2500 g) even in the absence of gastrointestinal, pulmonary, or cardiac disorders
- Birth weight > 2 standard deviations below the mean for gestational age on fetal weight curves
- Acute weight loss of 10% or more


---

**Nutrition Assessment Tools**

<table>
<thead>
<tr>
<th>Assessment Tool</th>
<th>Parameters</th>
<th>Illness Severity</th>
<th>Other Variables</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mini nutritional</td>
<td>Weight, height, mid-arm and calf circumferences,</td>
<td>Albumin, prealbumin, cholesterol, lymphocyte</td>
<td>Self-perception of nutrition and health status</td>
</tr>
<tr>
<td>assessment</td>
<td>diet history, appetite, feeding mode</td>
<td>count</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Subjective global</td>
<td>Weight history, diet history</td>
<td>Primary diagnosis, stress level</td>
<td>Physical symptoms (SC fat, muscle wasting, ankle and</td>
</tr>
<tr>
<td>assessment</td>
<td></td>
<td></td>
<td>sacral edema, functional capacity, GI symptoms)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NRS 2002</td>
<td>Weight loss, BMI, food intake</td>
<td>Stress level</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NUTRIC Score</td>
<td>Age, days in hospital to ICU admission</td>
<td>APACHE II, SOFA score, number of comorbidities, IL-6</td>
<td></td>
</tr>
</tbody>
</table>


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<table>
<thead>
<tr>
<th>Impaired Nutritional Status</th>
<th>Severity of Disease</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Absent</strong> Score 0</td>
<td>Normal nutritional status</td>
</tr>
<tr>
<td><strong>Mild</strong> Score 1</td>
<td>Wt loss &gt; 5% in 3 mos Or Food intake below 50-75% of normal requirement in preceding week</td>
</tr>
<tr>
<td><strong>Moderate</strong> Score 2</td>
<td>Wt loss &gt; 5% in 2 mos Or BMI 18.5-20.5 + impaired general condition Or Food intake 25-50% of normal requirement in preceding week</td>
</tr>
<tr>
<td><strong>Severe</strong> Score 3</td>
<td>Wt loss &gt; 5% in 1 month (15% in 3 mos) Or BMI &lt;18.5 + impaired general condition Or Food intake &lt; 25% of normal requirement in preceding week</td>
</tr>
</tbody>
</table>

| Note: If age ≥ 70 years, add 1 point | Disease states in italics are based on clinical judgement. |
| Total score = (Points for nutritional status) + (Points for disease severity) + (Points for age) |

### NUTRIC Score

- **Score ≥ 6:** High nutritional risk

### NRS 2002 and NUTRIC Score

**NRS 2002 Score**
- Score ≥ 3: enteral or parenteral nutrition should be considered
- Score ≥ 5: High nutritional risk

<table>
<thead>
<tr>
<th>Factors</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yrs)</td>
<td>&lt;50</td>
<td>50-74</td>
<td>≥ 75</td>
<td>-</td>
</tr>
<tr>
<td>APACHE II Score</td>
<td>&lt;15</td>
<td>15-19</td>
<td>20-27</td>
<td>≥ 28</td>
</tr>
<tr>
<td>Baseline SOFA Score</td>
<td>&lt;6</td>
<td>6-9</td>
<td>≥ 10</td>
<td>-</td>
</tr>
<tr>
<td># Comorbidities</td>
<td>0-1</td>
<td>≥ 2</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Days in hospital to ICU admit</td>
<td>0</td>
<td>≥ 1</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Interleukin-6 (μ/ml)</td>
<td>&lt;399</td>
<td>≥ 400</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

**Total Score** = (Total from six separate factors)

### Applying Best Practices to Ensure Safe and Appropriate Use of Parenteral Nutrition

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Ensuring Safe and Appropriate Use of Parenteral Nutrition Therapy

Outline

- Introduction
- Indication
- Route and Timing
- Dosing and Formulation
- Preparation
- Barriers to Successful PN Therapy

Introduction
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Parenteral Nutrition (PN)

- Valuable therapeutic intervention
  - Variety of practice settings and patient populations
- Most complex prescription drug
  - High-alert medication
  - Medication safety officer awareness
- PN-use process
  - Involves several departments and clinicians

PN-Use Process

- PN Prescribed
- PN Administered
- Patient Assessed, Monitored, & Re-Assessed
- PN Order Verified/Reviewed
- PN Order Compounded, Labelled, & Dispensed
- DOCUMENTATION
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Pharmacist Needs Assessment

- Malnutrition is prevalent
- Inadequate education and training
- Awareness of the wide array of PN products
- Applying pharmaceutics to clinical practice
- Management varies considerably from best practices

Guidance Documents

- Sterile products
  - American Society of Health-System Pharmacists
    - Technical assistance bulletins
    - Guidelines (compounding; use of automated compounding device; outsourcing)
  - United States Pharmacopeia (USP)
    - National Coordinating Committee for Large Volume Parenterals
    - USP Chapter <797>
  - Institute for Safe Medication Practices
    - Guidelines for safe preparation of sterile compounds

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Guidance Documents

- PN-Specific
  - American Society for Parenteral & Enteral Nutrition (ASPEN)
    - Consensus recommendations
    - Clinical practice guidelines
    - Appropriateness of use recommendations
    - Standardized competencies
  - United States Pharmacopeia
    - USP Chapter <799>

## Ensuring Safe and Appropriate Use of Parenteral Nutrition Therapy


### How many PN prescriptions do you review in your typical shift?

- a. None
- b. 1 – 5
- c. 6 – 12
- d. > 12
Indications

PN Order Verification

- Patient name and other identifiers
- Birth date and/or age
- Allergies and associated manifestations
- Height and dosing weight (metric units)
- Diagnoses
- Indication(s)
- Administration route and vascular access device
- Date/time of order submission and administration
- Volume and rate of infusion
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PN Order Form: Indications

Indications for PN
- Unable to obtain safe enteral access
- Failed trial of enteral nutrition
- Failed enteral access
- Bowel obstruction
- Paralytic ileus
- Incomplete resuscitation or hemodynamic instability
- Uncontrolled diarrhea
- High output fistula
- Intestinal failure, not otherwise specified

Consensus Recommendation

When Is Parenteral Nutrition Appropriate?

Patricia Worthington, MSN, RN, CNSC; Jane Balint, MD; Matthew Bechtold, MD, FACP, FASGE, FACG, AGAF; Angela Bingham, PharmD, BCPS, BCNSP, BCCCP; Lingtak-Neander Chan, PharmD, BCNSP, CNSC, FACN; Sharon Durfee, RPh, BCNSP; Andrea K. Jevenn, RD, LD, CNSC; Ainsley Malone, MS, RD, CNSC, FAND, FASPEN; Maria Mascarenhas, MBBS; Daniel T. Robinson, MD; and Beverly Holcombe, PharmD, BCNSP, FASHP, FASPEN


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Table 1. Elements of Appropriate PN Use.

- Identify clinical indications for PN, including manifestations of acute and chronic intestinal failure
- Recognize situations in which PN is not likely to be of benefit
- Initiate PN based on gastrointestinal function, nutrition status, and clinical status
- Select the vascular access device best suited to the therapy planned
- Implement measures to promote safety and reduce adverse outcomes
- Evaluate response to therapy
- Adjust in the therapeutic plan based on ongoing monitoring
- Assess continued need for PN
- Transition promptly to oral or enteral nutrition as feasible
- Collaborate across disciplines and departmental boundaries

PN, parenteral nutrition.

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Table 10.1. Common Indications for Home Parenteral Nutrition.25,36

- Short bowel syndrome
- Crohn’s disease
- Intestinal motility disorders
- Chronic bowel obstruction due to benign adhesions or strictures
- Radiation enteritis
- Malabsorptive disorders
- Intestinal and pancreatic fistula
- Gastrointestinal malignancy
- Malignant bowel obstruction, carcinomatosis
- Complications of bariatric surgery
- Gastrochisis
- Long-segment Hirschsprung’s disease

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Route and Timing

• Route
  – Vascular access device
    • Central vein, preferred over peripheral vein
  – Dedicated lumen
    • Distal tip in superior vena cava near right atrial junction

• Timing of initiation
  – As soon as possible if malnourished
  – Within 3-5 days if at risk for malnutrition
Table 4.1. Clinical Conditions Warranting Cautious Initiation of Parenteral Nutrition in Adults. 32,53

<table>
<thead>
<tr>
<th>Conditions</th>
<th>Suggested Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hyperglycemia</td>
<td>Glucose greater than 180 mg/dL</td>
</tr>
<tr>
<td>Azotemia</td>
<td>Blood urea nitrogen greater than 100 mg/dL</td>
</tr>
<tr>
<td>Hypertriglyceridemia</td>
<td>Serum triglycerides greater than 200 mg/dL</td>
</tr>
<tr>
<td>Hyponatremia</td>
<td>Serum sodium less than 130 mEq/L</td>
</tr>
<tr>
<td>Hypermagnesemia</td>
<td>Serum sodium greater than 150 mEq/L</td>
</tr>
<tr>
<td>Hypokalemia</td>
<td>Serum potassium less than 3 mEq/L</td>
</tr>
<tr>
<td>Hypomagnesemia</td>
<td>Serum magnesium less than 1.3 mEq/L</td>
</tr>
<tr>
<td>Hypocalcemia</td>
<td>Ionized calcium less than 4.5 mg/dL</td>
</tr>
<tr>
<td>Hypophosphatemia</td>
<td>Serum phosphorus less than 2 mg/dL</td>
</tr>
</tbody>
</table>

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Dosing and Formulation
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Which of the following represents the maximum recommended rate of IV lipid emulsion (ILE) infusion?

a. 4 mg/kg/min
b. 25 mg/kg/hr
c. 110 mg/kg/hr
d. 2 g/kg/day
e. I’m not sure

PN Dosing Review

• A dose for each nutrient “per day”
  – Macronutrient
    • Amino acids, dextrose, lipid
  – Micronutrient
    • Electrolytes, vitamins, trace elements

• Evaluate in context of clinical status
  – Indication
  – Body weight
  – Organ function
  – Concurrent medication (including previous PN order)
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Energy Requirements

• Requirements
  – Predictive equations
  – Weight-based
  – Measured

• Empiric values will vary depending on the patient
  – BMI < 30 kg/m² → 25 kcal/kg/day
  – BMI 30-39.9 kg/m² → 15 kcal/kg/day
  – BMI ≥ 40 kg/m² → 10 kcal/kg/day

Energy Requirements

• Source
  – Carbohydrate and lipid are energy substrates
  – Amino acids are primarily an anabolic substrate
  – Net physiologic effect is dependent on absolute and relative amounts of each macronutrient

<table>
<thead>
<tr>
<th>Approx IV Energy</th>
<th>Source</th>
<th>Max Dose</th>
<th>Max Infusion Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.4 kcal/g</td>
<td>Carbohydrate</td>
<td>~5 g/kg/day</td>
<td>~3-4 mg/kg/min</td>
</tr>
<tr>
<td>10 kcal/g</td>
<td>Lipid</td>
<td>~1 g/kg/day</td>
<td>~110 mg/kg/hr</td>
</tr>
</tbody>
</table>
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**Protein Requirements**

- **Requirements**
  - Weight-based
  - Measured

- **Empiric values will vary depending on the patient**
  - Maintenance ~1.0-1.5 g/kg/day
  - Repletion ~1.5-2.5 g/kg/day

---

**Daily IV Micronutrient Dosing**

<table>
<thead>
<tr>
<th>Electrolytes</th>
<th>Na 1-2 mmol/kg</th>
<th>K 1-2 mmol/kg</th>
<th>Cl and Acetate</th>
<th>Mg 4-12 mmol</th>
<th>Ca 5-7.5 mmol</th>
<th>P 20-40 mmol</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vitamins</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Retinol 1 mg</td>
<td></td>
<td>Thiamine 3-6 mg</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calciferol 5 μg</td>
<td></td>
<td>Riboflavin 3.6 mg</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tocopherol 10 mg</td>
<td></td>
<td>Niacin 40 mg</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phylloquinone 150 μg</td>
<td></td>
<td>Pyridoxine 4-6 mg</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trace Elements</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zn 3-4 mg</td>
<td>Cu 0.3-0.5 mg</td>
<td></td>
<td>Se 60-100 μg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cr &lt;12 μg</td>
<td>Mn 55 μg</td>
<td></td>
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</tbody>
</table>

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PN Formulation Review

- Osmolarity
  - Peripheral access limitation
- Compatibility
  - All ingredients (at ordered doses and PN volume)
- Stability
  - Of critical ingredients in admixture (at ordered doses and PN volume)
    - Lipid emulsion
    - Medication

Total Nutrient Admixture Formulation Limits

<table>
<thead>
<tr>
<th>Macronutrient</th>
<th>Final Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amino acids</td>
<td>4 – 8%</td>
</tr>
<tr>
<td>Dextrose</td>
<td>&gt; 10%</td>
</tr>
<tr>
<td>Lipid</td>
<td>2 – 5%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Micronutrient</th>
<th>Upper Limit Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ca (mEq/L) + PO₄ (mmol/L)</td>
<td>≤ 30</td>
</tr>
<tr>
<td>Ca (mEq/L) + Mg (mEq/L)</td>
<td>≤ 20</td>
</tr>
<tr>
<td>Na + K + Ca + Mg (mEq/L)</td>
<td>≤ 175</td>
</tr>
<tr>
<td>Zn (mg/L)</td>
<td>≤ 12</td>
</tr>
</tbody>
</table>
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• Rarely is an unstable PN admixture actually *this* obvious to the naked eye.
• Notice what appear to be free oil droplets throughout.
  • If infused, these larger particles would eventually clog or rupture the filter, but not before many smaller particles are infused through the filter and obstruct capillaries with subsequent end-organ effects.
• Thankfully not infused ... but was ordered, reviewed, verified, and made!

Documentation

• Any identified problem with dosing or formulation
• Interventions to address dosing or formulation problem
• Document all steps as required for record keeping
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Preparation
Ensuring Safe and Appropriate Use of Parenteral Nutrition Therapy

Preparing the PN

- Compounding PN
  - Automated compounding device
    - Use vendor-validated initial set-up
    - Barcode technology to verify products
    - Trace tubing from each source container
  - Activating multichambered PN product
    - Identify correct product and volume
      - Inspect for damage
      - Completely activate
      - Make necessary additions
- Manual additions
  - Independent verification

Products

- Multichambered PN product
  - Two chambers
  - Three chambers
- Macronutrients
  - Amino acids (AA) – ingredients are product-specific
  - IV lipid emulsions (ILE) – ingredients are product-specific

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Ensuring Safe and Appropriate Use of Parenteral Nutrition Therapy

### ILE Products

- **First-generation**
  - Cottonseed oil-based (e.g., Lipomul)†
- **Second-generation**
  - Soybean oil-based (e.g., Intralipid, Nutrilipid)

- **Third-generation**
  - Mixed oils
    - Medium chain-long chain triglycerides (MCT-LCT)‡
    - Soybean oil-olive oil (e.g., Clinolipid)‡
    - Soybean oil-MCTs-olive oil-fish oil (e.g., Smoflipid)
  - Modular oils
    - Fish oil (e.g., Omegaven)‡

†Removed from market.  
‡Not yet available in the U.S.

### Barriers to Successful PN Therapy
Ensuring Safe and Appropriate Use of Parenteral Nutrition Therapy

Address Barriers to Successful PN Therapy

• Administrative support
  – Integrated computerized provider order entry with clinical decision support
  – Policies, procedures, and practices based on available guidance documents
  – Training to complement or supplement knowledge and skills from pharmacy school and residencies
• Additional knowledge/skills support
  – ASHP, ASPEN, USP documents
  – ASPEN (www.nutritioncare.org)
    • Nutrition Support Fundamentals and Nutrition Support Review Course
    • Nutrition Self-Assessment program
    • PN Safety webinar series

Initiating and Managing Parenteral Nutrition Therapy: Clinical Case Studies

Joseph I. Boullata, Pharm.D., BCNSP, FASPEN, FACN, and
Phil Ayers, Pharm.D., BCNSP, FASHP
Ensuring Safe and Appropriate Use of Parenteral Nutrition Therapy

Use of Parenteral Nutrition in an Acutely Ill Patient

Joseph I. Boullata, Pharm.D., BCNSP, FASPEN, FACN

Inpatient

60-year-old man with bicuspid AV with aortic stenosis and ascending aortic dilation, admitted for elective AVR and AAA repair

PMH – GERD, dysphagia, and recurrent diverticulitis (3 episodes in 9 mo)
PSH – cholecystectomy, inguinal hernia repair with mesh placement
AEH – aspartame → headache; lobster → hives
Meds at home – famotidine, fish oil capsules, aluminum hydroxide/magnesium carbonate, and ibuprofen prn
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Inpatient: Hospital Course

Significant post-op events

- Day 1: GI bleed within hours, required resuscitation and embolization of left gastric artery
- Day 2: continued IV pantoprazole, epinephrine and phenylephrine, as well as propofol, hydromorphone, a β-blocker and antimicrobial regimen
- Day 3: NPO, extubated for 2nd time, hemodynamically stable, s/p VFSS SLP recommends standard aspiration precautions, regular diet with mechanical soft/chopped, small bites and sips
- Day 6: severe abdominal pain, fever, increased WBC, abdominal CT reveals multiple diverticular abscesses too small to drain, GI surgery recommends ‘bowel rest’ and an antimicrobial regimen
- Day 7: PN ordered for midline catheter administration

Inpatient: Nutrition Assessment on Day 7

History – poor oral intake (<75%) for several months, fatigue and weight loss with recurrent bouts of diverticulitis managed with NPO and antimicrobials

Vitals – 99°F 117/65 mmHg 78 bpm 18 bpm 75 kg and 1.75 m (BMI 24.5 kg/m²)
Is/Os 1600/1850 mL (80 kg at admission, 90 kg 6-mo ago)

Physical – no abnormal lesions, abd soft but significant bilateral tenderness, peripheral muscle wasting, grip strength not tested but BIA → FM 22 kg (29%), FFM 53 kg (70%), total body water 53%, phase angle 5.9°

Labs –

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Na</th>
<th>K</th>
<th>Cl</th>
<th>CO₂</th>
<th>Ca</th>
<th>Mg</th>
<th>P</th>
<th>BUN</th>
<th>Cr</th>
<th>AST</th>
<th>ALT</th>
<th>AP</th>
<th>TB</th>
<th>INR</th>
<th>Gluc</th>
<th>Prealb</th>
<th>CRP</th>
<th>TG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 1</td>
<td>141</td>
<td>4.2</td>
<td>117</td>
<td>21</td>
<td>8.2</td>
<td>1.8</td>
<td>2.8</td>
<td>14</td>
<td>0.8</td>
<td>19</td>
<td>20</td>
<td>89</td>
<td>0.4</td>
<td>1.2</td>
<td>138</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Day 3</td>
<td>139</td>
<td>4.0</td>
<td>110</td>
<td>20</td>
<td>--</td>
<td>--</td>
<td>--</td>
<td>18</td>
<td>1.1</td>
<td>--</td>
<td>--</td>
<td>--</td>
<td>--</td>
<td>126</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Day 7</td>
<td>143</td>
<td>3.6</td>
<td>106</td>
<td>24</td>
<td>7.9</td>
<td>1.2</td>
<td>2.1</td>
<td>22</td>
<td>0.8</td>
<td>--</td>
<td>--</td>
<td>--</td>
<td>--</td>
<td>1.1</td>
<td>102</td>
<td>15</td>
<td>22</td>
<td>142</td>
</tr>
</tbody>
</table>

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How would you describe this patient’s nutrition status?

a. Well nourished
b. At risk for malnutrition
c. Moderate malnutrition
d. Severe malnutrition
e. I’m not sure

Does this patient have an indication for PN?

a. Yes
b. No
c. I’m not sure
Ensuring Safe and Appropriate Use of Parenteral Nutrition Therapy

Inpatient: PN Order (Day 7)

Amino acids (Plenamine) 100 g
Dextrose 100 g
ILE (Nutrilipid) 50 g

NaCl  80 mmol
KCl  20 mmol
Ca gluc  5 mmol
Mg sulf  8 mmol
K phos  12 mmol

Multivitamins 10 mL
Multi-trace 3 mL
QS SWI 2000 mL

1160 kcal

Is the PN order appropriate based on clinical dosing criteria?

a. Yes
b. No
c. I’m not sure

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Is the PN order appropriate based on compatibility and stability criteria?

a. Yes  
b. No  
c. I’m not sure

Inpatient: PN Order Review (Day 7)

Clinical
- Amino acids 1.3 g/kg
- Dextrose 1.3 g/kg (~1 mg/kg/min)
- Lipid 0.7 g/kg (~30 mg/kg/hr)
- Energy 15.5 kcal/kg
- Fluid 27 mL/kg

Formulation
- Midline catheter is ‘peripheral’
  - Estimated osmolarity excessive
- Dextrose too low for TNA stability
- No micronutrient incompatibilities
Ensuring Safe and Appropriate Use of Parenteral Nutrition Therapy

Inpatient: PN Order (Day 9)

Amino acids (Plenamine) 140 g ↑
Dextrose 210 g ↑
ILE (Nutrilipid) 60 g ↑

NaCl/Na acet 80 / 30 mmol
KCl 20 mmol
Ca gluc 5 mmol
Mg sulf 8 mmol
K phos 28 mmol ↑

Multivitamins 10 mL
Multi-trace 3 mL
QS SWI 1600 mL ↓

1765 kcal

Inpatient: PN Order Review (Day 9)

Clinical
- Amino acids 1.9 g/kg
- Dextrose 2.8 g/kg (~1.9 mg/kg/min)
- Lipid 0.8 g/kg (~33 mg/kg/hr)
- Energy 23.5 kcal/kg
- Fluid 21 mL/kg

Formulation
- PICC confirmed central
- Amino acids too high
  - Increase volume to 2000 mL
- No micronutrient incompatibilities
Ensuring Safe and Appropriate Use of Parenteral Nutrition Therapy

Case Review

• Patient with severe malnutrition requiring nutrition support intervention through the central venous route

• Pharmacist, dietitian, and prescriber worked together to provide a PN order that would be a stable admixture through a central vein

• Patient received goal PN for 7 days before transitioning to a regular diet

Use of Parenteral Nutrition in Patient with Enterocutaneous Fistula (ECF)

Phil Ayers, Pharm.D., BCNSP, FASHP
Ensuring Safe and Appropriate Use of Parenteral Nutrition Therapy

Case Study

LH 37-year-old woman with ECF on home PN (HPN). Patient is currently receiving chemotherapy with plans for surgical repair of ECF January 2018.

62 inches (157.5 cm), 46 kg, BMI 18.5 k/m²

PMH: peritoneal carcinoma, multiple sclerosis

PSH: colon resection, small bowel resection, ileostomy, hysterectomy

Case Study

10/18 – PN day 161 providing 1.9 g/kg/day protein, 32 kcal/kg/day, and 52 mL/kg/day

Weekly comprehensive metabolic panel, magnesium, phosphorus, triglycerides, prealbumin, complete blood count with differential
Ensuring Safe and Appropriate Use of Parenteral Nutrition Therapy


Table 2. Medicare Criteria for HPN.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Massive small bowel resection within 3 mo of initiating HPN</td>
<td>HPN therapy needed &gt;90 d, ≤5 ft (153 cm) of small bowel distal to the ligament of Treitz</td>
</tr>
<tr>
<td>Bowel rest for at least 3 mo</td>
<td>HPN therapy needed &gt;90 d, Symptomatic pancreatitis with/without pseudocyst, Severe exacerbation of regional enteritis, or Proximal enteroenteral anastomosis where distal enteral tube feeding is not possible</td>
</tr>
<tr>
<td>Malabsorption and malnutrition</td>
<td>HPN therapy needed &gt;90 d, 10% weight loss over ≤3 mo, Severe fat malabsorption, Standard 72-h fecal fat test, Fecal fat exceeds 50% of oral/enteral intake on a diet of at least 50 g/d of fat</td>
</tr>
<tr>
<td>Short bowel syndrome</td>
<td>HPN therapy needed &gt;90 d, Enteral intake of 2.5–3 L, Enteral losses exceed 50% of enteral intake, and Urine output is &lt;1 L per 24 h</td>
</tr>
<tr>
<td>Complete mechanical small bowel obstruction</td>
<td>HPN therapy needed &gt;90 d, Inoperable</td>
</tr>
<tr>
<td>Severe mobility disorder (of small intestine and/or stomach) and malnutrition</td>
<td>HPN therapy needed &gt;90 d, 10% weight loss over ≤3 mo, Serum amylase ≤3.4 g/dL, Unresponsive to maximal doses of probiotic medication (presence of daily nausea/vomiting), Mobility disorder demonstrated via Social oral gastric emptying study or barium/iodopaque pellets that do not reach the right colon by 6 h</td>
</tr>
</tbody>
</table>

G/H: Above conditions with malnutrition and failed enteral tube feeding trial

10% weight loss in 3 mo, Serum albumin ≤3.4 g/dL, failed tube feeding trial >90 d HPN: 1 condition below:

- Moderate fat malabsorption (fecal fat >25% of enteral intake on a diet of 50 g/d of fat measured with a 72-h fecal fat test)
- Malabsorption as confirmed by Sudan stain or a-xylene stool test
- Gastroenteritis as described in scenario F where isotope or pellets fail to reach the jejunum in 3–6 h, manometric motility studies with results consistent with abnormal gastric emptying, unresponsive to probiotic mediation
- Small bowel dysmotility with gastro-intestinal transit between 3 and 6 h, unresponsive to probiotic medication
- Small bowel resection leaving ≤5 ft of small bowel beyond the ligament of Treitz
- Short bowel syndrome not as severe as scenario B
- Malnutrition moderate exacerbation of regional enteritis or enterocutaneous fistula
- Partial mechanical small bowel obstruction and surgery is not an option

HPN, home parenteral nutrition.


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Table 10.1. Common Indications for Home Parenteral Nutrition.$^{2,3,36}$

<table>
<thead>
<tr>
<th>Indications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Short bowel syndrome</td>
</tr>
<tr>
<td>Crohn’s disease</td>
</tr>
<tr>
<td>Intestinal motility disorders</td>
</tr>
<tr>
<td>Chronic bowel obstruction due to benign adhesions or strictures</td>
</tr>
<tr>
<td>Radiation enteritis</td>
</tr>
<tr>
<td>Malabsorptive disorders</td>
</tr>
<tr>
<td>Intestinal and pancreatic fistula</td>
</tr>
<tr>
<td>Gastrointestinal malignancy</td>
</tr>
<tr>
<td>Malignant bowel obstruction, carcinomatosis</td>
</tr>
<tr>
<td>Complications of bariatric surgery</td>
</tr>
<tr>
<td>Gastrochisis</td>
</tr>
<tr>
<td>Long-segment Hirschsprung’s disease</td>
</tr>
</tbody>
</table>

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Table 4.1. Clinical Conditions Warranting Cautious Initiation of Parenteral Nutrition in Adults.$^{52,53}$

<table>
<thead>
<tr>
<th>Conditions</th>
<th>Suggested Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hyperglycemia</td>
<td>Glucose greater than 180 mg/dL</td>
</tr>
<tr>
<td>Azotemia</td>
<td>Blood urea nitrogen greater than 100 mg/dL</td>
</tr>
<tr>
<td>Hypertriglyceridemia</td>
<td>Serum triglycerides greater than 200 mg/dL</td>
</tr>
<tr>
<td>Hyponatremia</td>
<td>Serum sodium less than 130 mEq/L</td>
</tr>
<tr>
<td>Hypernatremia</td>
<td>Serum sodium greater than 150 mEq/L</td>
</tr>
<tr>
<td>Hypokalemia</td>
<td>Serum potassium less than 3 mEq/L</td>
</tr>
<tr>
<td>Hypomagnesemia</td>
<td>Serum magnesium less than 1.3 mEq/L</td>
</tr>
<tr>
<td>Hypocalcemia</td>
<td>Ionized calcium less than 4.5 mg/dL</td>
</tr>
<tr>
<td>Hypophosphatemia</td>
<td>Serum phosphorus less than 2 mg/dL</td>
</tr>
</tbody>
</table>

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ASPEN-FELANPE Clinical Guidelines: Nutrition Support of Adult Patients with Enterocutaneous Fistula (ECF)

• Published in *Journal of Parenteral and Enteral Nutrition (JPEN)* in January 2017
• GRADE process
• 7 Questions addressed in the guidelines with quality of evidence


ASPEN-FELANPE Clinical Guidelines: Nutrition Support of Adult Patients with Enterocutaneous Fistula (ECF)

1. What factors best describe nutrition status?
2. What is the preferred route of nutrition support?
3. What protein and energy intake provide best clinical outcomes?
4. Is fistuloclysis associated with better outcomes than standard care?
5. Are immune-enhancing formulas associated with better outcomes than standard formulas?
6. Does the use of somatostatin or somatostatin analogue provide better outcomes?
7. When is home parenteral nutrition support indicated?


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What is the preferred route of nutrition support?

Quality of Evidence: Very low

Routes of Nutrition Therapy in ECF Patients

NPO 24-48 hours
Resuscitation
Correct fluid/electrolytes
Diagnostic workup

ECF < 500 mL/24 hours
Site:
Esophageal, Gastric or Duodenal, if feeding tube tip below ECF
Distal small intestine or colon
EN may be feasible and tolerated
PN if ECF output manageable

ECF ≥ 500 mL/24 hours
Site:
Proximal small bowel or feeding tube not possible to place below ECF
Initiate PN +/- EN


When is home parenteral nutrition support indicated?

Quality of evidence: Based on Consensus

- Patient is medically stable
- Fistula output is manageable
- High-output (>500 mL/24 hr) when surgical repair is not yet advised
- Sustain National Patient Registry for Nutrition Care: Adult HPN indication for ECF-19%

### Ensuring Safe and Appropriate Use of Parenteral Nutrition Therapy

A patient with an enteroatmospheric fistula with high output may require up to ________ protein.

- a. 0.8 g/kg/day
- b. 1 g/kg/day
- c. 1.5 g/kg/day
- d. 2.5 g/kg/day

### What protein and energy intake provide best clinical outcomes?

*Quality of Evidence: Consensus only*

- **Protein 1.5-2 g/kg/day**
  - Up to 2.5 g/kg/day in patients with enteroatmospheric fistula and high fistula output

- **Energy intake appropriate to the patient’s energy requirements based on results of nutrition assessment**
  (observational studies report 25-30 kcal/kg/day)

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**Table 13.2. Laboratory Monitoring During PN (Adult and Pediatric)**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Acute Care PN</th>
<th>Long-Term PN</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
<td>Days 1–7</td>
</tr>
<tr>
<td>Glucose, BUN, creatinine, electrolytes, calcium, magnesium, phosphorus</td>
<td>✓ Daily &gt; 3 or until stable</td>
<td>1–2×/wk or as clinically indicated</td>
</tr>
<tr>
<td>CBC with differential</td>
<td>✓ Daily &gt; 3 or until stable</td>
<td>1–2×/wk</td>
</tr>
<tr>
<td>Total bilirubin, direct bilirubin, AP, AST, ALT.</td>
<td>✓ Weekly</td>
<td>✓</td>
</tr>
<tr>
<td>PTT, PT, INR</td>
<td>✓ Weekly</td>
<td>✓</td>
</tr>
<tr>
<td>Triglyceride level</td>
<td>✓ Pediatric: daily until stable then weekly</td>
<td>✓</td>
</tr>
<tr>
<td>Serum proteins (to monitor inflammation)</td>
<td>✓ Weekly</td>
<td>✓</td>
</tr>
<tr>
<td>Iron indices</td>
<td>As clinically indicated</td>
<td>✓</td>
</tr>
<tr>
<td>Zinc, selenium, manganese, copper, chromium</td>
<td>As clinically indicated</td>
<td>✓</td>
</tr>
<tr>
<td>Vitamin A, 25-OH vitamin D, vitamin E</td>
<td>As clinically indicated</td>
<td>✓</td>
</tr>
<tr>
<td>Vitamin B&lt;sub&gt;12&lt;/sub&gt; and folate</td>
<td>As clinically indicated</td>
<td>✓</td>
</tr>
<tr>
<td>TSH</td>
<td>As indicated</td>
<td>✓</td>
</tr>
<tr>
<td>Carnitine</td>
<td>No guideline for adults</td>
<td>✓ Pediatric patients</td>
</tr>
</tbody>
</table>

ALT, alanine aminotransferase; AP, alkaline phosphatase; AST, aspartate aminotransferase; BUN, blood urea nitrogen; CBC, complete blood count; INR, international normalized ratio; PN, parenteral nutrition; PT, prothrombin time; PTT, partial thromboplastin time; TSH, thyroid-stimulating hormone.

**Home PN**

**LH PN Order (Day 161)**

<table>
<thead>
<tr>
<th>Component</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amino acids (Travasol)</td>
<td>87 g</td>
</tr>
<tr>
<td>Dextrose (70%)</td>
<td>189 g</td>
</tr>
<tr>
<td>ILE (Smoflipid)</td>
<td>50 g</td>
</tr>
<tr>
<td>NaCl</td>
<td>180 mEq</td>
</tr>
<tr>
<td>KCl</td>
<td>30 mEq</td>
</tr>
<tr>
<td>K acetate</td>
<td>30 mEq</td>
</tr>
<tr>
<td>Ca gluc</td>
<td>5 mEq</td>
</tr>
<tr>
<td>Mg sulf</td>
<td>16 mEq</td>
</tr>
<tr>
<td>K phos</td>
<td>10 mmol</td>
</tr>
<tr>
<td>Multivitamins</td>
<td>10 mL</td>
</tr>
<tr>
<td>Multi-trace (conc)</td>
<td>1 mL</td>
</tr>
<tr>
<td>Folic acid</td>
<td>1 mg</td>
</tr>
<tr>
<td>QS SWI</td>
<td>2400 mL</td>
</tr>
</tbody>
</table>

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Four-Week PN with Soybean Oil, Medium Chain Triglycerides, Olive Oil, and Fish Oil (SMOF) vs. Soybean Oil (SO) Emulsion in Patients with Intestinal Failure

- Double-blind, multicenter, randomized controlled trial
- 73 patients (n = 34 in SMOF group and n = 39 in SO group)
- PN similar: 1.3 g/kg/day IVFE, 3 g/kg/day dextrose, and 1.2 g/kg/day protein
- After 4 weeks, mean concentrations of alanine aminotransferase (ALT), aspartate aminotransferase (AST), and total bilirubin significantly lower in SMOF group vs. SO group

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LH May-November: AST/ALT/Total Bilirubin

Ceftriaxone for UTI

UTI = urinary tract infection

Which ILE has the lowest content of phytosterol?

a. Clinolipid
b. Intralipid
c. Nutrilipid
d. Smoflipid

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ILE and Phytosterol Content

![Bar chart showing phytosterol content in Intralipid, 50% MCT/50% LCT, 80% Olive/20% Soybean, and Smoflipid 20%.]


Case Review: Considerations for the Home PN Candidate

- Appropriate candidate
- Hemodynamically stable
- Competent
- Monitor for complications

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Key Takeaways

• Visceral proteins are not the gold standard for the diagnosis of malnutrition
• Competent pharmacists review every PN order
• Competent pharmacist-pharmacy technician team prepare every PN admixture
• Patient should be metabolically stable before discharging on home parenteral nutrition therapy
• P&Ps and practices reflect available best practices

What will you do as a follow-up to today’s program? (Select all that apply)

a. Interpret serum albumin and prealbumin with caution
b. Assess nutrition status before recommending PN therapy
c. Review all PN regimens against dosing & formulation guidelines
d. Revisit PN preparation steps to align with best practices
e. Revise P&P to align with current best practices

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Selected Resources

- Ensuring the Safe Use of Parenteral Nutrition → www.pnsafeuse.org

Selected Resources (cont.)

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ASHP CE Processing
✓ Deadline: January 31
✓ elearning.ashp.org
✓ Code: ___________
✓ Complete evaluation
✓ Additional instructions in handout

On-demand activity based on today’s live symposium coming March 2018

www.ashpadvantage.com/go/pntherapy

Download the handout at www.ashpadvantage.com/go/pntherapy

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About the Faculty

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Joseph I. Boullata, Pharm.D., BCNSP, FACN, FASPEN, is Pharmacy Specialist with Clinical Nutrition Support Services at the Hospital of the University of Pennsylvania in Philadelphia. In addition, he serves as Clinical Professor in the Department of Nutrition Sciences at Drexel University, also in Philadelphia.

Dr. Boullata is a recognized expert in the field of nutrition support and nutritional pharmacotherapy. He received his Doctor of Pharmacy degree from the University of Maryland after completing undergraduate degrees in both nutrition science (Penn State) and pharmacy (Philadelphia College of Pharmacy). He completed a pharmacy residency at The Johns Hopkins Hospital and a nutrition support fellowship at the University of Maryland Medical System. He has been board certified in nutrition support since 1994.

Dr. Boullata has conducted research and published in the areas of nutrition, gastroenterology, and critical care, authoring more than 75 chapters and articles in peer-reviewed journals. He is an active member of a number of professional organizations, most notably the American Society of Parenteral and Enteral Nutrition (ASPEN) through his contributions to the development of recent ASPEN recommendations on enteral and parenteral nutrition. He also has served on the editorial board of several professional journals.

Phil Ayers, Pharm.D., BCNSP, FASHP
Chief, Clinical Pharmacy Services
Baptist Medical Center
Associate Clinical Professor
University of Mississippi School of Pharmacy
Jackson, Mississippi

Phil Ayers, Pharm.D., BCNSP, FASHP, received his Bachelor of Science degree in pharmacy and Doctor of Pharmacy degree from the University of Mississippi. He is employed by Baptist Health Systems in Jackson, Mississippi. He is a clinical specialist in nutrition support and serves the Department of Pharmacy as Chief of Clinical Pharmacy Services. Dr. Ayers also is Associate Clinical Professor with the University of Mississippi School of Pharmacy.

Dr. Ayers currently serves the American Society for Parenteral and Enteral Nutrition (ASPEN) on the Board of Directors as Secretary-Treasurer and Chair of the Parenteral Nutrition Safety Committee. He is also President-Elect of the Mississippi Board of Pharmacy and the USP Healthcare Quality and Safety Expert Committee.

Dr. Ayers was awarded the Excellence in Nutrition Support Education Award by ASPEN in 2011 and the Stanley Serlick Award for parenteral nutrition safety in 2016. He is a fellow of ASHP.

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