

Assessment Tools and Guidelines: Parenteral Nutrition Therapy

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Malnutrition is associated with an increased frequency of treatment complications and length of stay in the intensive care unit (ICU) and hospital, as well as increased costs of medical care. Patients at high risk for malnutrition should be identified and evaluated for specialized nutrition support (SNS).¹

It is important to choose the appropriate route of nutrition support for patients at risk for malnutrition to positively influence patient outcomes.¹ In patients with a functioning gastrointestinal (GI) tract, enteral nutrition (EN) can improve outcomes. EN has been shown to improve nutritional status and reduce length of stay in the ICU, and it is associated with fewer infectious complications than parenteral nutrition (PN).² The major limitation of EN is the need to gain enteral (post-pyloric) access so that the nutrient infusion is tolerated and serious complications, such as aspiration pneumonia, are avoided.¹ Techniques are available to facilitate access to the GI tract so that enteral tube feedings may be administered safely. For patients who have nonfunctioning GI tracts, PN is the available method



of nutritional support.³ PN is essential for patients who are severely malnourished and have GI tract problems that are not expected to resolve within 7 days.^{1,4} PN is complex and has been associated with a unique set of complications, some of which can be serious or even life-threatening.³ In addition, few published reports can be found that demonstrate a consistently favorable effect of PN on patient outcomes.⁴

This educational review discusses nutritional assessment, nutritional requirements, PN formulation design, medication compatibility with PN, and guidelines for special diseases, as well as an overview of evidence-based guidelines published by the American Society for Parenteral and Enteral Nutrition (ASPEN).^{1,5} Also included in the review is a discussion of FDA regulations

Table 1. Classification of Malnutrition

	Mild	Moderate	Severe
Weight			
% of ideal body weight	80-90	70-79	<70
% of usual body weight	85-95	75-84	<74
Recent Weight Loss			
% weight loss in 1 wk	—	1-2	>2-5
% weight loss in 1 mo	—	5	>5-7.5
% weight loss in 3 mo	—	7.5	>7.5-10
% weight loss in 6 mo	—	10	>10
Visceral Protein Values			
Prealbumin, mg/dL normal = 17-42	—	11-17	<10
Serum albumin, g/dL normal = 3.5-5.5	2.8-3.5	2.1-2.7	<2.1
Transferrin, mg/dL normal = 200-400	150-200	100-150	<100

Based on references 1, 4, and 8.

concerning aluminum-contamination of PN,⁵ United States Pharmacopeia (USP) standards for sterile compounding,⁶ and recommendations on the use of insulin in PN.⁷

Nutrition Assessment

The purpose of nutrition assessment is to identify the degree to which a patient’s current or future nutritional status will influence his or her outcome. The current nutritional status is determined by several factors, including the patient’s weight and how it compares with ideal and usual weights (Table 1)^{1,4,8}; the duration of any weight loss; visceral protein status; laboratory values indicative of fluid, electrolyte, and potential nutritional deficits; clinical condition; and whether the patient may be nourished by oral, enteral, or parenteral means.^{1,8} Inflammation due to underlying disease has evolved as a potentially important factor in the development of and recovery from malnutrition. Malnutrition may occur as the result of decreased nutrient intake or as a response to inflammatory mediators that decrease appetite, increase nutrient requirements, or interfere with incorporation of nutrients into lean body mass.⁸ During PN, both pharmaceutical and metabolic calculations are used to assess nutritional support.

Figure 1 is a useful algorithm for determining the appropriate indications for PN. Clinicians should

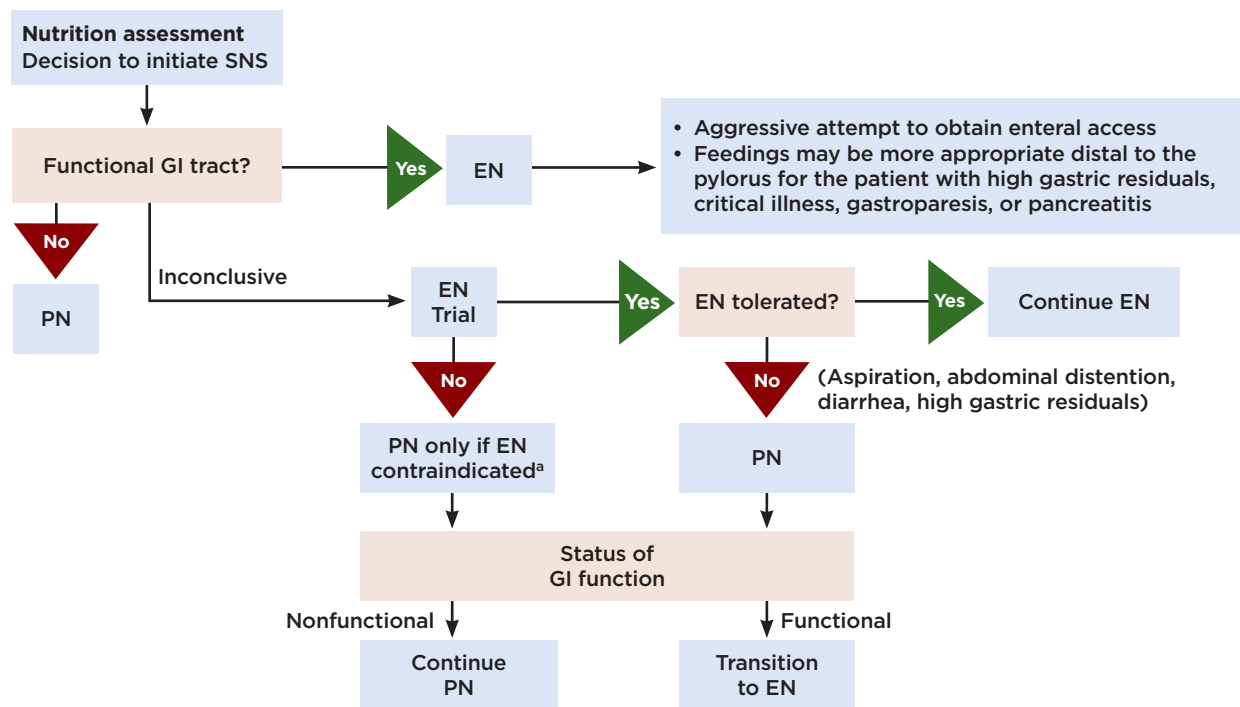


Figure 1. Algorithm for the administration of nutrition support.

EN, enteral nutrition; SNS, specialized nutrition support

^a Obstruction, peritonitis, paralytic ileus, mesenteric ischemia, short bowel syndrome, enterocutaneous fistula, malabsorption

consider PN if a trial of enteral feedings has failed, if the enteral route is contraindicated, or if the GI tract has severely diminished function because of underlying disease or treatment and GI function is not expected to return within 7 days.^{1,4} Contraindications to PN include a functional GI tract; an inability to achieve appropriate venous access; an unstable clinical condition; and terminal disease, critical illness, or metabolic derangement for which a favorable response to therapy is not feasible or the risk for complications is too high.⁴ In these conditions, the metabolic profile is such that exogenous nutrients are poorly used and frequently cause complications that require prolonged mechanical ventilation, intensive care, or hospitalization.⁴ Table 2 lists some metabolic derangements that necessitate cautious use of PN until the patient's condition improves.⁴

Using the aforementioned concepts in a nutrition consultation form can help improve use of PN. Such a form also documents the need for SNS, and, with the nutritional assessment, can include a recommendation for route and dose of nutrients to be provided.

Nutritional Requirements

Over the past several years, there has been continual refinement of PN, focusing on the delivery of the safest, most effective doses. Guidelines provide a framework for nutrient doses in a variety of disease states.^{1,3} In general, there has been a decline in recommended caloric doses, a liberalization of protein doses, especially for renal and liver failure, and more specific recommendations for fat doses (Table 3).^{1,3,4,9} The guidelines list 2 specific purposes for fat—nonprotein calories and prevention of essential fatty acid deficiency. Obesity (body mass index [BMI] >30 kg/m²)¹ is becoming more prevalent and needs to be considered in dosing of PN. Hypocaloric PN has been reported to be beneficial in obese patients, resulting in the achievement of positive nitrogen balance and weight loss. However, using newer classifications of obesity, class I patients (BMI 30-35 kg/m²) may be required to maintain their weight during PN; if so, they should receive a more normal dose of calories.¹⁰

Overfeeding of calories and protein can have serious consequences in patients receiving PN and has led to the specific recommendations provided in Table 3.^{1,3,4} When maximum doses of macronutrients are exceeded, the consequences outlined in Figure 2 are frequently reported.^{1,4,11,12}

Micronutrients—electrolytes, trace elements, and vitamins—are essential to the incorporation of macronutrients into the body cell mass. The content of micronutrients in the body tends to fluctuate on the basis of cellular needs and deficits created by periods of low or no intake or losses, and often occurs in patients with nonfunctional GI tracts. Daily monitoring of serum electrolytes and periodic (initial and every 2-3 weeks) assessment of vitamin and trace element status is essential for a patient requiring PN. Bariatric

Table 2. Metabolic Derangements Requiring Caution in Use of PN

Metabolic Derangement	Abnormality To Be Corrected
Azotemia	Blood urea nitrogen >100 mg/dL
Hemodynamic instability	Fluid deficits, perfusion pressures
Hyperchloremic metabolic acidosis	Serum Cl >115 mEq/L
Hyperglycemia	Serum glucose >300 mg/dL
Hypernatremia	Serum sodium >150 mEq/L
Hyperosmolality	Serum osmolality >350 mOsm/kg
Hypochloremic metabolic alkalosis	Serum Cl <85 mEq/L
Hypokalemia	Serum potassium <3 mEq/L
Hypophosphatemia	Serum phosphorus <2 mg/dL

Based on reference 4.

(gastric bypass) surgery for morbid obesity may result in protein calorie malnutrition as well as deficiencies of thiamine, vitamin B₁₂, folic acid, vitamin E, and calcium due to malabsorption and/or inadequate intake caused by complications of the surgery.¹³ In these patients, assessment for vitamin deficiencies should be more frequent. Guidelines for dosing of micronutrients in PN are outlined in Table 4.^{3,4,14}

PN Formulation Design

Formulations of PN are extremely complex products intended for IV use. Careful consideration of nutrient dose and avoidance of unstable or incompatible ingredients are necessary. Inconsistent compounding practices have led to serious harm in patients receiving PN.³ In an effort to provide consistent, specific guidelines for PN, the National Advisory Group on Standards and Practice Guidelines for Parenteral Nutrition published "Safe Practices for Parenteral Nutrition." These guidelines provide recommendations for the PN label and order, as well as for PN compounding, compatibility, stability, and administration.³ They call for a standardized PN label format to promote correct interpretation of PN contents across all health care environments; describe the pharmacist's duty to review the PN formula to ensure it is complete and balanced and will be stable and compatible upon admixture; and include admixture processes and quality control requirements

Table 3. Macronutrients: PN Dosing Guidelines

	Normal Range	Usual Doses	Maximum	Special Considerations
Calories	20-35 kcal/kg per day	20-30 kcal/kg per day		<i>Obesity:</i> Hypocaloric doses have been used. Measurement of energy expenditure is advised. <i>Critically ill:</i> <25 kcal/kg per day.
Glucose	70%-85% of nonprotein calories		7 g/kg per day; 4-5 mg/kg per minute	Improved outcomes have been observed when blood glucose has been maintained at <110 mg/dL in critically ill patients and <150 mg/dL in the general patient population.
Fat	15%-30% of nonprotein calories	<30% of nonprotein calories	2.5 g/kg per day	Limited benefit to fat dose >30% nonprotein calories. When administered separately from PN, infusion should be completed within 12 hours. Safest when administered continuously over a 24-h period.
Protein	0.8-2 g/kg per day	1.1-1.5 g/kg per day	2 g/kg per day	Provided as high biologic value (ie, content high in essential AAs). Dose should be modified in conditions of renal and hepatic disease to the lowest dose needed to achieve positive nitrogen balance. Renal failure <i>Chronic RF, no dialysis:</i> 0.6-0.8 g/kg per day. <i>Chronic RF, hemodialysis, or peritoneal dialysis:</i> 1.2-1.3 g/kg per day. <i>RF, continuous hemofiltration:</i> 1 g/kg per day. <i>Acute RF:</i> Balanced mixture of essential/nonessential AAs. <i>Acute RF with severe MN or hypercatabolic state:</i> 1.5-1.8 g/kg per day. Liver failure Protein restriction should be used for acute management of hepatic encephalopathy but not for chronic use. Specialized AA formulations only indicated in chronic encephalopathy unresponsive to pharmacotherapy.
Fat (lipids)	Prevention of essential fatty acid deficiency	1%-2% of caloric dose as linoleic acid and 0.5% of caloric dose as α -linolenic acid.		Contraindicated in patients with pancreatitis induced by hyperlipidemia. Withhold doses for triglyceride level >400 mg/dL.

AA, amino acid; MN, malnutrition; RF, renal failure
Based on references 1, 3, 4, and 9.

that foster safe and accurate compounding of PN formulas (Table 5).^{3,15}

The United States Pharmacopeial Convention, Pharmacopeial Forum, includes a chapter on compounding sterile products.⁶ The USP distinguishes 3 levels of risk based on the probability of exposing multiple patients to microbial or physical contaminants.^{6,15} PN compounding, which involves drawing a sterile product into a syringe or transferring a sterile product from a vial into a plastic bag, is classified as a USP low-risk process; automated compounding is classified as a USP medium-risk process.⁶ The addition of nonsterile ingredients, such as glutamine, is classified as a USP high-risk process. USP standards specify requirements for the compounding environ-

ment and garb used by compounding personnel at each level of risk.⁶ USP standards also provide criteria for beyond-use dating (designated as “do not use after” dating) for formulations, based on sterility and stability concerns. Beyond-use dating is dependent on USP risk level (low, medium, or high) and temperature (room, refrigerated, or frozen) for sterile products.⁶

The presence of aluminum as a contaminant in PN has caused complications in patients at risk.¹⁶ Patients at risk are neonates and adults with renal compromise on long-term PN.¹⁷ Toxicity primarily affects the bone and central nervous system (CNS).¹⁸ Aluminum interference with bone formation and mineralization results in bone pain or fractures. The CNS effect

is a dementia similar to the dialysis dementia that occurred in dialysis patients who received dialysate contaminated with aluminum.¹⁸ Because aluminum is ubiquitous, it is very difficult, if not impossible to remove it from products that are used in PN preparation. As a result, the FDA proposed a set of regulations, which went into effect on July 26, 2004, requiring manufacturers to cite aluminum content on the labels of products used in preparing PN (Table 6).⁵ The maximum safe limit of aluminum loads established by the FDA is 5 mcg/kg body weight per day. For PN, salts of calcium and phosphorus have the highest aluminum content.¹⁸ In response to these regulations, ASPEN released a statement advising clinicians to identify “at-risk” patients, such as neonates and long-term PN patients with renal compromise, and attempt to minimize aluminum intake in these patients.¹⁷

Recently, there has been a renewed interest in standard PN formulations, which prompted ASPEN to create a Statement on Parenteral Nutrition Standardization.¹⁹ This evidence-based analysis of the literature resulted in the recommendations provided in Table 7.¹⁹ This statement recommends a standardized PN process, recognizes the need for clinicians with PN expertise to be involved with the process, and addresses the patient with complex needs for whom a customized PN formulation may be necessary.

Medication Compatibility With PN

Patients receiving PN usually need medications to be administered intravenously. Multiple-lumen central venous catheters have alleviated some problems associated with coadministration of medications with PN.¹ Although it is recommended that the catheter or port for PN administration be used solely for PN, this is not always possible in patients with limited venous access. Medication administration with PN may be unavoidable. In these situations, compatibility concerns are relevant.

The pharmacist’s objective is to ensure the safe, compatible, and efficacious provision of both pharmacologic therapy and nutrition support. In reviewing a patient’s regimen for compatibility, it is important to consider whether the PN contains fat emulsion. Studies have shown differences in compatibility based on the PN formulation used. Table 8 was developed to provide consistent, reliable, and up-to-date information on the compatibility of drugs administered via Y-site injection with PN.²⁰⁻⁵⁵ If no compatibility data exist, the medication should not be administered with PN.

There is a distinction between Y-site administration and direct admixture of the drug with PN. Adequate assessment of specific pharmacotherapeutic criteria for direct admixture of drugs (eg, ranitidine or famotidine) in PN is required.⁵⁶ These criteria may be summarized as follows:

- Stability and compatibility of the drug with the specific PN admixture over a 24-hour period must be determined before the medication is added.

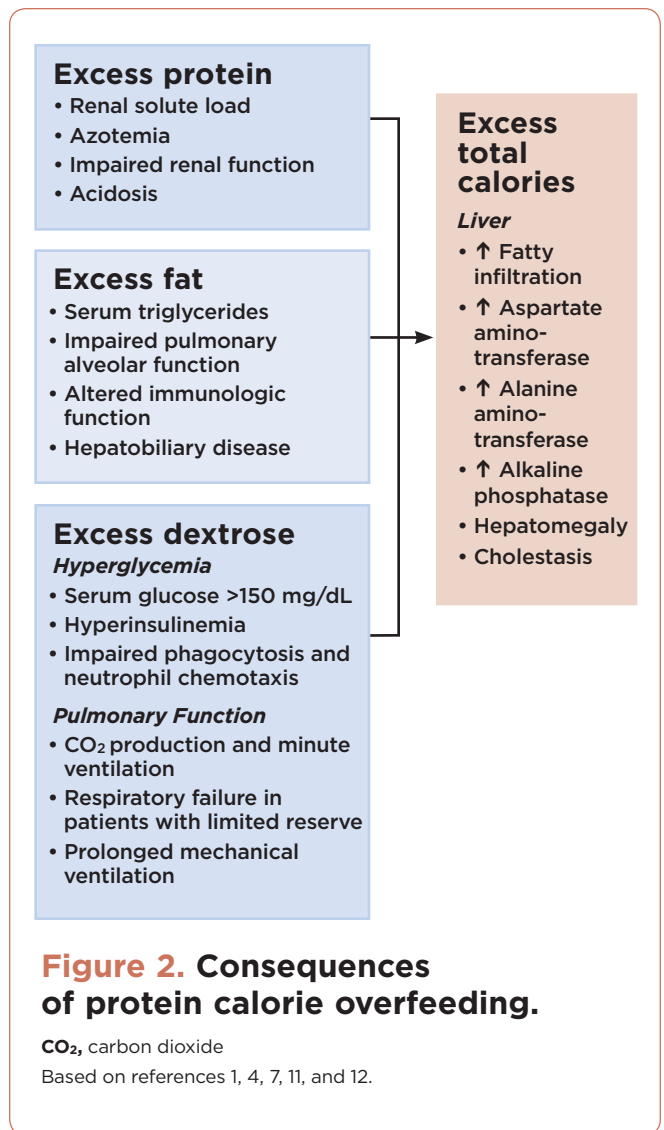


Figure 2. Consequences of protein calorie overfeeding.

CO₂, carbon dioxide

Based on references 1, 4, 7, 11, and 12.

- The medication must have appropriate pharmacokinetics and proven efficacy for continuous infusion.
- The medication dose must have remained constant throughout the previous 24-hour period before admixture in PN.
- There must be a stable PN infusion rate for at least 24 hours before the medication is added.
- PN must include appropriate labeling to avoid pharmacotherapeutic problems associated with abrupt discontinuation.⁵⁶

In general, only H₂ antagonists and insulin have been admixed in 3-in-1 admixtures. These drugs also may be admixed with 2-in-1 solutions. Other drugs that have been shown to be stable and efficacious in 2-in-1 solutions are heparin, aminophylline, hydromorphone, hydrochloric acid (maximum concentration, 100 mEq/L), and iron dextran.^{22,57}

Not all issues with medications and PN are due to incompatibility during admixture or administration. An FDA Safety Alert issued for ceftriaxone (Rocephin, Roche Laboratories) alerts clinicians to

Table 4. Micronutrients: PN Dosing Guidelines

		Normal Daily Requirements	Usual Daily Doses
Electrolytes	Na, K	1-2 mEq/kg	Individualize, variable
	Cl, acetate	As needed for acid-base balance	Equal amounts as sodium or potassium salt.
	Phosphorus	20-40 mmol	
	Calcium	10-15 mEq	Gluconate salt preferred for PN. Stability limited by concentration of calcium and phosphorus.
	Magnesium	8-20 mEq	
Vitamins	Thiamine (B ₁)	6 mg	Provided by addition of multiple vitamin injection product.
	Riboflavin (B ₂)	3.6 mg	
	Niacin (B ₃)	40 mg	
	Folic acid	600 mcg	FDA mandated reformulation of vitamin products to increase thiamine, folic acid, pyridoxine, and ascorbic acid.
	Pantothenic acid	15 mg	
	Pyridoxine (B ₆)	6 mg	Monitor warfarin carefully during transition to products with vitamin K.
	Cyanocobalamin (B ₁₂)	5 mcg	
	Biotin	60 mcg	
	Ascorbic acid	200 mg	
	Vitamin A	3,300 IU	
	Vitamin D	200 IU	
	Vitamin E	10 IU	
	Vitamin K	150 mcg	
Trace Elements	Chromium	10-15 mcg	Use manganese with caution in patients with elevated bilirubin. Accumulation may result in neurologic toxicity.
	Copper	0.3-0.5 mg	
	Manganese	60-100 mcg	Zinc requirements increase with high GI output.
	Zinc	2.5-5.0 mg	Selenium is indicated for long-term care and critically ill patients.
	Selenium	20-60 mcg	Patients on long-term PN are prone to iron deficiency. Iron status should be assessed initially and every 3 months in these patients.
	Iron	Not routinely added	

Based on references 3, 4, and 14.

the potential precipitation of calcium and ceftriaxone in vital organs leading to complications and death when these agents are administered within 48 hours of each other.⁵⁸ This reaction is possible even when the PN and ceftriaxone are administered via separate infusion catheters. Thus, use of calcium in PN concurrently with ceftriaxone should be avoided; calcium administration can be resumed 48 hours after ceftriaxone therapy is completed.

Glucose Control

Maintaining serum glucose levels below 110 mg/dL has been shown to improve clinical outcome (ie, shorter ICU stay, less ventilator use, and lower mortality) in some critically ill surgical patients.⁹ This has led to a keen interest in tight glucose control during PN.⁷ A reasonable target level for blood glucose is between 100 and 150 mg/dL.⁷ Glucose should be monitored

every 4 to 6 hours when insulin is added to PN. If the patient's glucose level exceeds this goal, supplemental insulin should be administered every 4 to 6 hours based on the previous day's sliding-scale insulin use. The frequency of glucose monitoring only can decrease once glycemic control has been achieved. If glucose values consistently exceed 150 mg/dL over 24 hours, regular insulin should be increased by 0.05 units per gram of dextrose each day in the PN formulation. It is recommended not to exceed approximately 0.2 units of insulin per gram of dextrose.⁴

Recent PN Guidelines

Guidelines for PN in cancer and critically ill patients were published in 2009.^{59,60} In cancer patients, nutrition should not be used routinely. However, when nutrition is indicated, EN is preferred over PN.⁵⁹ In most instances, a standard diet is preferred over PN,

Table 5. ASPEN Safe Practice Guidelines

Section	Practice Guidelines
Ordering PN	<ol style="list-style-type: none"> Standardized order forms should be used. PN formula is assessed to determine that the contents are appropriate for patient condition (adult or pediatric), or if the patient’s disease state warrants a dose outside the standard range. Nutrients are indicated as total daily dose. Percent concentration should not be used on the order form. Avoid potentially dangerous abbreviations. All components of the PN order are rewritten when PN is reordered.
Labeling PN formulations	<ol style="list-style-type: none"> Labels for PN admixtures should be standardized: <ul style="list-style-type: none"> The amount per day is required; Quantity per liter also may be used; Dosing weight is required on the label. Auxiliary labels may be used, especially when orders are written in a different format from the label. Patient transfer between health care environments such as hospital to home requires pharmacist-to-pharmacist communication of the PN prescription. The PN label should be compared with the order, and the beyond-use date should be checked before administration.
Standard nutrient requirements	<ol style="list-style-type: none"> The pharmacist should assess the PN contents to ensure that the dose of all nutrients is appropriate to the patient’s needs. IVFE should be provided to adult and pediatric patients to avoid essential fatty acid deficiency when fat is not included in the base formula. All PN patients should receive a parenteral vitamin preparation daily. PN products should be chosen with the lowest aluminum content when possible. Parenteral iron should not be used routinely in PN therapy.
Compounding of PN formulations	<p>Screening</p> <ol style="list-style-type: none"> Review of PN contents is required to ensure that a balanced and complete formulation is provided. Each PN component is assessed for adequacy of dose and potential for a compatibility or stability problem. Any dose outside the accepted range and not explained by a specific patient condition should be clarified prior to compounding PN. <p>PN Compounding</p> <ol style="list-style-type: none"> The additive sequence is optimized and validated as a safe, efficacious method. A review of the compounding method is recommended if PN is compounded manually or if there has been a change in commercial source of PN products. Manufacturers of automated methods of PN compounding should provide the additive sequence that ensures the safety of the compounding device based on the nutrient products used at the institution. Each PN formulation compounded must be inspected for signs of particulate contamination and/or phase separation of TNA. <p>Quality Assurance</p> <ol style="list-style-type: none"> Gravimetric analysis of PN formulations can be applied, focusing on the most dangerous additives tolerating the least margin of error (eg, potassium salts). Chemical analysis can be incorporated into the PN compounding operations of the pharmacy. Refractometric analysis is an alternative, but is limited to formulations that do not contain fat. Daily in-process or end-product testing of PN formulations is recommended. Compounding accuracy of PN prepared by automated compounding devices should be verified by end-product testing. Aseptic extemporaneous preparation of PN formulations should adhere to the <i>USP <797> Guidebook to Pharmaceutical Compounding—Sterile Preparations</i>.

(continued)

Table 5. ASPEN Safe Practice Guidelines (continued)

Section	Practice Guidelines
PN administration	<p>Venous catheters</p> <ol style="list-style-type: none"> 1. Central PN should be administered via CVC with distal tip in SVC adjacent to right atrium. 2. Avoid use of femoral catheters for PN administration. 3. Proper CVC placement should be confirmed prior to initiating PN and any time signs/symptoms of malposition are present. 4. Care for CVC according to published standards. <p>Equipment</p> <ol style="list-style-type: none"> 1. A 0.2-micron filter should be used for 2-in-1 formulations and a 1.2- to 5-micron filter should be used for TNAs. 2. Alternatively, a 1.2-micron filter may be used for all PN formulations to remove larger particles. The FDA requires a 1.2-micron filter for TNA and a 0.2-micron filter for 2-in-1 formulations. 3. A filter that clogs during administration may be replaced but never removed entirely. 4. Use containers and sets free of DEHP if IVFE is used. 5. Change administration sets for IVFE given separately from PN after use, or at least every 24 hours if administered as a continuous infusion. 6. Change TNA administration sets every 24 hours. 7. Change 2-in-1 administration sets every 72 hours. 8. PN infusion pumps should have adequate “free-flow” protection. 9. Medical devices should be selected that protect the user from needlesticks and exposure to bloodborne pathogens. <p>Administration</p> <ol style="list-style-type: none"> 1. The label should be used to verify the patient identity prior to administration. 2. The PN should be inspected prior to set-up and not used if its integrity appears to be compromised (precipitate, color change, or cracked emulsion). 3. The PN infusion should be completed within 24 hours of its initiation. 4. The PN patient should be monitored for PN efficacy, complications, change in clinical condition, and to document clinical outcomes. 5. Policies and procedures should be in place to deal with PN compounded by an outside facility.
Stability and compatibility of PN formulations	<ol style="list-style-type: none"> 1. All PN processes are confirmed to ensure that all components are stable and compatible. 2. The pharmacist ensures that the co-infusion of medications with PN admixtures is safe, stable, and compatible. 3. If no information exists about a medication’s compatibility with PN, it should be administered separate from PN. 4. Compatibility information should be evaluated according to the concentration of medication and whether the PN formulation is a 2-in-1 or TNA. 5. Insulin use in PN should be consistent throughout the health system. 6. Decisions are made based on the most recent evidence from the literature or from the manufacturer. 7. Use of 2-in-1 formulas with separate administration of IVFE is recommended for neonatal/infant patients.

CVC, central venous catheter; **DEHP**, diethylhexyl phthalate; **IVFE**, intravenous fat emulsion; **SVC**, superior vena cava; **TNA**, total nutrient admixture

Adapted from references 3 and 6. American Society for Parenteral and Enteral Nutrition (ASPEN) does not endorse this material in any form other than in its entirety.

except in the severely malnourished patient having surgery. These patients may benefit from PN therapy if it is administered 7 to 14 days prior to surgery, as long as the potential medical risks associated with delaying surgery are acceptable.⁵⁹ In critically ill patients, EN is superior to PN.⁶⁰ If EN is not feasible and the patient is well nourished prior to the critical illness, it is prudent to withhold PN for up to 7 days. PN should be used if EN is contraindicated and the patient is malnourished

(recent weight loss >10% to 15% or weight <90% of ideal) prior to critical illness. To improve outcomes, glucose should be controlled in critically ill patients receiving PN at a level of 110 to 150 mg/dL.⁶⁰

Withholding and Withdrawing PN

The decision to use PN can be difficult when a patient is unresponsive to therapy or in the terminal stages of disease. The decision to withhold or with-

Table 6. FDA Requirements For Labeling Aluminum Content Of PN Products

<p>Large-volume parenterals</p> <ul style="list-style-type: none"> • Concentrated dextrose, amino acids, parenteral lipids, sterile water for injection, saline, and electrolyte solutions 	<p>Must contain ≤ 25 mcg/L of aluminum.</p>
<p>Small-volume parenterals and pharmacy bulk packages</p> <ul style="list-style-type: none"> • Electrolyte salts of calcium, phosphorus, potassium, magnesium, and sodium • Multivitamins • Trace elements 	<ol style="list-style-type: none"> 1. Must be labeled with the maximum level of aluminum in the product at expiration. 2. If reconstituted, must be labeled with the maximum level of aluminum at expiration in the reconstituted form. 3. Maximum amount of aluminum may be determined by any of the following methods: <ul style="list-style-type: none"> • Highest level measured in batches over the last 3 years. • Highest level for the last 5 batches. • Maximum historical level.

Based on reference 5.

draw PN should be discussed with the medical staff and the patient or a designee. The discussion should include the elucidation of the patient's preferences, goals, and values (including religious beliefs), as well as a detailed list of the possible benefits and burdens of therapy. If the benefit versus risk is not easy to predict, a time-related trial period to evaluate effectiveness, benefits, and burdens should be considered. This process requires an understanding of ethical issues concerning nutrition support.⁶¹ When necessary, a bioethics committee should be consulted.

Conclusion

PN can be effective in treating malnutrition. Its properties, however, confer a unique set of complications that may adversely affect patient outcome. Optimal use of PN requires careful consideration of the patient's clinical condition and nutritional state, and the physical and chemical characteristics of the admixture. Additionally, use of guidelines for determining the proper indication, mode of delivery, and mode of administration of PN facilitates the provision of the most appropriate nutritional therapy.

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Table 7. ASPEN Recommendations For PN Standardization

1. A standardized process for PN management is advocated. This may include use of standardized PN formulations (including standardized, commercial PN products), but it also includes aspects of ordering, labeling, screening, and administration of PN.

2. The evidence on patient safety does not support the general use of standardized PN formulations across health care organizations.

3. The evidence suggests advantages in efficiency, economy, and clinical appropriateness with the use of standardized PN formulations compared to individualized PN formulations in select patient populations.

4. When an organization implements standardized PN formulations (including standardized, commercial PN products), a mechanism should be established to provide, compound, or make available, customized PN formulations for individuals who have complex requirements secondary to disease or underlying illness, or when otherwise warranted by routine monitoring of electrolytes, organ function, growth, and development.

5. A standardized process must include clinicians with expertise in the area of nutrition support.

6. PN compounding practices should adhere to recommendations promulgated by national professional organizations.

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Table 8. Y-Site Injection Compatibility of IV Medications With PN^a

Medication	Admixture Type		
	2-in-1	3-in-1	IVFE
Acetazolamide	I	—	—
Acyclovir	I	I	I
Amikacin sulfate	C	C/I	C/I
Aminophylline	C/I	C	C
Amphotericin B	I	I	I
Ampicillin sodium	C/I	C	C
Ampicillin sodium-sulbactam sodium	C	C	C
Atracurium besylate	C	—	—
Aztreonam	C	C	C
Bumetanide	C	C	C
Buprenorphine HCl	C	C	C
Butorphanol tartrate	C	C	C
Caffeine	C	—	—
Calcium gluconate	C	C	C
Carboplatin	C	C	C
Cefazolin sodium	C/I	C	C
Cefepime	C	—	—
Cefoperazone sodium	C	C	C
Cefotaxime sodium	C	C	C
Cefotetan disodium	C	C	C
Cefoxitin sodium	C	C	C
Ceftazidime sodium	C	C	C
Ceftizoxime sodium	C	C	C
Ceftriaxone sodium	I	I	I
Cefuroxime sodium	C	C	C
Chloramphenicol sodium succinate	C	—	C
Chlorpromazine HCl	C	C	C
Cimetidine	C	C	C
Ciprofloxacin lactate	I	C	C
Cisplatin	I	C	C
Clindamycin phosphate	C	C	C
Cyclophosphamide	C	C	C
Cyclosporine	C/I	C/I	C/I
Cytarabine	I	C	C
Dexamethasone sodium phosphate	C	C	C
Digoxin	C	C	C
Diphenhydramine HCl	C	C	C
Dobutamine HCl	C	C	C
Dopamine HCl	C	C/I	C/I
Doxorubicin HCl	I	I	—
Doxycycline hyclate	C	I	I
Droperidol	C	I	I
Enalaprilat	C	C	C
Epinephrine HCl	C	—	—
Epoetin alfa	C	—	—
Erythromycin lactobionate	C	C	C
Famotidine	C	C	C
Fentanyl citrate	C	C	C
Fluconazole	C	C	C
5-Fluorouracil	C/I	C/I	—
Foscarnet	C	—	—
Furosemide	C/I	C	C
Gallium nitrate	C	C	C
Ganciclovir sodium	I/C	I	I
Gentamicin sulfate	C	C	C
Granisetron HCl	C	C	C
Heparin sodium	C	I	I
Hydrochloric acid	C ^b	—	—
Hydrocortisone sodium phosphate ^c	C	C	C
Hydromorphone HCl	C	I/C	—
Ifosfamide	C	C	C

Medication	Admixture Type		
	2-in-1	3-in-1	IVFE
Imipenem-cilastatin sodium	C	C	C
Immune globulin	—/C	—	—
Indomethacin sodium trihydrate	I	—	—
Insulin, regular	C	C	C
Iron dextran	C/I	I/C	—
Isoproterenol HCl	C	C	C
Kanamycin sulfate	C	C	C
Leucovorin calcium	C	C	C
Levorphanol tartrate	C	I	—
Lidocaine HCl	C	C	C
Linezolid	C	—	—
Lorazepam	C	I	I
Magnesium sulfate	C	C	C
Mannitol	C	C	C
Meperidine HCl	C	C	C
Meropenem	—	C	C
Mesna	C	C	C
Methotrexate	I	C	C
Methyldopate HCl	C	C/I	C/I
Methylprednisolone sodium succinate	C	C	C
Metoclopramide HCl	I/C	C	C
Metronidazole	C	C	C
Miconazole	C	C	C
Midazolam HCl	I/C	I	I
Milrinone lactate	C	—	—
Mitoxantrone HCl	I	C	C
Morphine sulfate	C	C/I ^d	C/I
Nafcillin sodium	C	C	C
Nalbuphine HCl	C	I	—
Nitroglycerin	C	C	C
Norepinephrine bitartrate	C	C	C
Octreotide acetate	C	C	C
Ondansetron HCl	C	I	I
Oxacillin sodium	C	C	C
Paclitaxel	C	C	C
Penicillin G potassium	C	C	C
Penicillin G sodium	C	—	—
Pentobarbital sodium	C	I	I
Phenobarbital sodium	C	I	I
Phenytoin sodium	I	—	—
Piperacillin sodium-tazobactam sodium	C	C	C
Potassium chloride	C	C	C
Potassium phosphate	I	I	I
Prochlorperazine edisylate	C	C	C
Promethazine HCl	C/I	C	C
Propofol	C	—	—
Ranitidine HCl	C	C	C
Sargramostim	C	—	—
Sodium bicarbonate	I/C	C	C
Sodium nitroprusside	C	C	C
Sodium phosphate	I	I	—
Tacrolimus	C	C	C
Ticarcillin disodium	C	C	C
Ticarcillin disodium-clavulanate potassium	C	C	C
Tobramycin sulfate	C	C	C
Trimethoprim-sulfamethoxazole	C	C	C
Urokinase	C	—	—
Vancomycin HCl	C	C	C
Vecuronium bromide	C	—	—
Vitamin K ₁ phytonadione	C	C	—
Zidovudine	C	C	C

^a During simulated studies of compatibility, a 1:1 volume ratio of drug mixture with PN is used. For example, 1 mL of drug solution is combined with 1 mL of test PN admixture for a period consistent with that usually observed in practice during Y-site administration of the drug with PN.

^b Hydrochloric acid: Not to exceed a concentration of 100 mEq/L. Maintain pH of final solution >3.0.

^c Available only as part of Hydrocortone, Merck.

^d Morphine sulfate incompatible at concentration of 15 mg/mL, compatible at concentration of 1 mg/mL.

—, compatibility data not available; **C**, compatibility has been demonstrated. When Y-site compatibility was not available, medications compatible in-solution for 24 hours were assumed to be Y-site compatible; **C/I**, conflicting compatibility has been demonstrated and strength of the evidence supports compatible;

I, Incompatibility has been demonstrated; **I/C**, conflicting compatibility has been demonstrated and strength of evidence supports incompatible; **HCl**, hydrochloride; **IVFE**, intravenous fat emulsion; **PN**, parenteral nutrition; all forms of IV nutrition including 3-in-1 and 2-in-1 admixtures or IV fat emulsions. Also known as parenteral nutrient solution; **Y-site injection**, drug administration via piggyback, IV push, or other IV methods at the Y-site injection port or other access port (ie, stopcock), between the PN solution and the central venous catheter; **2-in-1**, traditional parenteral nutrient admixtures containing dextrose and amino acids and having a yellow appearance similar to that of IV solutions containing multivitamins. Also known as dextrose-amino acid solution; **3-in-1**, combination of dextrose, amino acids, and fat in 1 final container, resulting in an IV fluid having a milky white appearance. Also referred to as a total nutrient admixture.

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Suggested Readings

American Society for Parenteral and Enteral Nutrition, 8630 Fenton St., Suite 412, Silver Spring, MD 20910-3805. (301) 587-6315. E-mail: aspennutrition.org, Web access: www.nutritioncare.org. ASPEN guidelines are available at no charge.

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