

## A.S.P.E.N. Parenteral Nutrition Safety Consensus Recommendations: Translation Into Practice

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**Phil Ayers, PharmD, BCNSP, FASHP-Chairperson<sup>1</sup>; Stephen Adams, MS, RPh, BCNSP<sup>2</sup>; Joseph Boullata, PharmD, RPh, BCNSP, FASPEN<sup>3</sup>; Jane Gervasio, PharmD, BCNSP, FCCP<sup>4</sup>; Beverly Holcombe, PharmD, BCNSP, FASHP<sup>5</sup>; Michael D. Kraft, PharmD, BCNSP<sup>6</sup>; Neil Marshall, RN, BSN, CRNI, CNSC<sup>7</sup>; Antoinette Neal, RN, CRNI, CNSC, VA-BC<sup>8</sup>; Gordon Sacks, PharmD, BCNSP, FCCP<sup>9</sup>; David S. Seres, MD, ScM, PNS<sup>10</sup>; Patricia Worthington, MSN, RN, CNSC<sup>11</sup>; and Peggi Guenter, PhD, RN<sup>5</sup>**

### Keywords

parenteral nutrition; safety; patient safety; evidence-based practice; consensus

Parenteral nutrition (PN) serves as an important therapeutic modality that is used in adults, children, and infants for a variety of indications. The appropriate use of this complex therapy aims to maximize clinical benefit while minimizing the potential risk for adverse events. Despite being classified and acknowledged as a high-alert medication,<sup>1</sup> only 58% of organizations have precautions in place to prevent errors and patient harm associated with PN.<sup>2</sup> Complications can occur as a result of the therapy and as the result of the PN process. The American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) Parenteral Nutrition Safety Consensus Recommendations are based on practices that are generally accepted to minimize errors with PN therapy. However, the broad range of healthcare settings in which PN administration occurs—from critical care to home care—raises the potential for disparities to exist in the knowledge and skills of the healthcare professionals responsible for PN prescribing, review, preparation (including compounding, labeling, and dispensing), and administration. Regardless of the setting or the number of patients treated in a given facility, the classification of PN as a high-alert medication requires all healthcare organizations to develop evidence-based policies and procedures related to PN. With these concepts in mind, the A.S.P.E.N. Parenteral Nutrition Safety Task Force developed the A.S.P.E.N. Parenteral Nutrition Safety Consensus Recommendations, available online in the *Journal of Parenteral and Enteral Nutrition (JPEN)* in late 2013 and published in March 2014.<sup>3</sup>

The last version of the A.S.P.E.N. Safe Practices for Parenteral Nutrition document was published in 2004.<sup>4</sup> At that time, a survey was conducted on current practices for PN and published in 2005.<sup>5</sup> This survey of current practice was repeated in 2011, and despite what the authors of the Safe Practices document thought was wide dissemination of their recommendations, not much had actually improved in practice over those 8 years.<sup>6</sup> With this in mind, the Consensus Recommendations task force put into place a wider dissemination protocol using a

variety of promotional techniques and tool development that will be described in this article.

### Dissemination of the Article

The A.S.P.E.N. Parenteral Nutrition Safety Consensus Recommendations were published in *JPEN* online using an open-access option such that the paper did not require a subscription or A.S.P.E.N. membership for readers to access it. This allowed the A.S.P.E.N. staff to send the link to the article to over 30 clinical, safety, regulatory, and accrediting organizations representing many disciplines and clinicians in a variety of healthcare settings. Since the online release of the article, over 10,340 full-text downloads of the paper have occurred. The task force also strategized on ways the paper could be

From <sup>1</sup>Baptist Health Systems, Department of Pharmacy, Jackson, Mississippi; <sup>2</sup>Vitaline Infusion Pharmacy Services, Geisinger Medical Center, Danville, Pennsylvania; <sup>3</sup>University of Pennsylvania, School of Nursing, Philadelphia; <sup>4</sup>Butler University College of Pharmacy and Health Science, Indianapolis, Indiana; <sup>5</sup>American Society for Parenteral and Enteral Nutrition, Silver Spring, Maryland; <sup>6</sup>University of Michigan Health System, Department of Pharmacy Services, Ann Arbor; <sup>7</sup>Walgreens Infusion Services, Sun Valley, California; <sup>8</sup>Infusion Pharmacy, Cleveland Clinic at Home, Independence, Ohio; <sup>9</sup>Department of Pharmacy Practice, Harrison School of Pharmacy, Auburn University, Auburn, Alabama; <sup>10</sup>Division of Preventive Medicine and Nutrition, New York Presbyterian Hospital–Columbia University Medical Center, New York; and <sup>11</sup>Thomas Jefferson University Hospital, Philadelphia, Pennsylvania.

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### Corresponding Author:

Peggi Guenter, PhD, RN, American Society for Parenteral and Enteral Nutrition, 8630 Fenton Street, Suite 412 Silver Spring MD 20910, USA. Email: [peggig@nutritioncare.org](mailto:peggig@nutritioncare.org)

## Parenteral Nutrition (PN) Safety: Minimize the Risk for your Patients

- Access the parenteral nutrition tools and resources you need to deliver PN
- Incorporate these best practice recommendations to optimize safe and effective PN

**Overview:** The American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) champions the best evidence-based practices that support parenteral nutrition therapy in varying age populations and disease states. Approximately 350,000 patients in the U.S. receive parenteral nutrition (PN) during hospital stays and many more receive PN at home and in alternative care settings ([www.hcupnet.ahrq.gov](http://www.hcupnet.ahrq.gov)). The appropriate use of this complex therapy aims to maximize clinical benefit while minimizing the potential risks for adverse events.

**Clinical Evidence:** Complications can occur as a result of the therapy and as the result of the PN process. These consensus recommendations are based on best practices that are generally accepted to minimize errors with PN therapy. These recommendations are categorized in the areas of PN prescribing, order review and verification, compounding, and administration.

Recommendations:



**PRESCRIBING**

1. Prescribe PN using a standardized PN order format and review process applicable to patients of every age and disease state within a healthcare organization
2. Reorder PN in its entirety, including full generic names and doses.
3. Educate all prescribers, including physicians, pharmacists, nurse practitioners, physician assistants, and dietitians, on basic PN prescribing and monitoring.



**ORDER REVIEW**

1. Avoid verbal and telephone orders for PN, except for pharmacist to prescriber communication to modify or clarify the order.
2. Require transcription of PN order data to undergo an independent double-check process prior to compounding.
3. Develop criteria to evaluate and identify pharmacists who are competent to review and verify PN orders.
4. Develop a policy and procedure/protocol for standardized labeling of PN formulations.
5. Develop, communicate, and implement protocols for PN component substitution and/or conservation strategies to be used in the event of a PN component shortage or outage.



**COMPOUNDING**

1. Provide an in-depth training program focusing on CSPs for all staff members participating in the preparation process with an ongoing competency assessment program.
2. Implement specific computerized soft limits and hard (catastrophic) limits for PN ingredients based upon pharmacists' reviews that are consistent with the needs of their patient population.
3. Comply with USP Chapter <797> standards.
4. Consider outsourcing as an alternative to in-house compounding or standardized, commercially available PN products when the healthcare organization does not possess the technological resources or staffing to prepare PN admixtures according to USP Chapter <797>.



**ADMINISTRATION**

1. Conduct ongoing validation of competency in PN administration.
2. Visually inspect the integrity of the PN container and formulation before spiking the container.
3. Verify the PN label against the original prescriber order and avoid verbal orders.
4. Trace administration tubing to the point of origin in the body at the initiation of the infusion and at all handoffs.
5. Infuse PN infusions through a filter appropriate for the type of formulation. Never remove an occluded filter in response to occlusion alarms, thus allowing the unfiltered formulation to continue to infuse.
6. Maintain PN infusion at the prescribed rate using verified correct pump settings via an independent double check.

For full recommendations, rationale, and references, go to Ayers P, Adams S, Boullata J, Gervasio J, Holcombe B, Kraft M, et al. A.S.P.E.N. Parenteral Nutrition Safety Consensus Recommendations. *JPEN J Parenter Enteral Nutr.* 2013. [www.nutritioncare.org/pnsafety](http://www.nutritioncare.org/pnsafety)



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**Figure 1.** Parenteral Nutrition (PN) Safety: Minimize the Risk for Your Patients.

translated into educational offerings for members and nonmembers of A.S.P.E.N. This has resulted in actual or planned presentations at the American Society of Health-System Pharmacists (ASHP) meetings, CNW13 and 14, Infusion Nurses Society, and multiple chapter and section meetings. A.S.P.E.N. held a 4-part series of training webinars on the topic in March 2014 to educate all members of the healthcare team who work with PN in order to optimize their knowledge base of safe PN practices. Attendees received a Certificate of Training in Parenteral Nutrition Safety if they participated in all 4 parts and claimed continuing education credit.


### Development of a Toolkit and Customizable Tools

Another effort to help translate the PN safety recommendations was the development of a PN safety toolkit ([www.nutritioncare.org/pnsafety](http://www.nutritioncare.org/pnsafety)).

The purpose of this toolkit was to bring together helpful tools and resources clinicians need to bring optimal PN therapy to patients. This toolkit offers the Consensus Recommendations and a series of tools and checklists that will be described below. It also includes related publications, educational offerings, drug shortages information, and connections to the Parenteral Nutrition Adverse Event/Error Reporting Program developed in conjunction with the Institute of Safe Medication Practices (ISMP). A short overview of the Consensus recommendations was provided to attendees at the 2013 ASHP Midyear meeting in order to communicate the essential points of the document (see Figure 1).

### Safety Checklists

In 2009, surgeon and journalist Dr Atul Gawande published the simple idea of the checklist as a tool to help deal with the



## PN Order Review and Verification CHECKLIST

The **American Society for Parenteral and Enteral Nutrition** (A.S.P.E.N.) champions the best evidence-based practices that support parenteral nutrition therapy in varying age populations and disease states. The appropriate use of this complex therapy aims to maximize clinical benefit while minimizing the potential risks for adverse events.

The **purpose of this checklist** is to promote safe practices by pharmacists and other clinicians in the PN order review and verification process.

**Verify PN order elements for:**

- Patient name- or other identifier
- Birth date and/or age
- Allergies and associated reactions
- Height and dosing weight (metric units)
- Diagnosis/diagnoses
- Indication(s) for PN
- Administration route/vascular access device (peripheral vs central)
- Prescriber contact information
- Date and time order submitted
- Administration date and time
- Volume and infusion rate
- Infusion schedule (continuous or cyclic)
- Type of formulation (dextrose/amino acids with separate infusion of IVFE or total nutrient admixture)

**Verify PN ingredients for:**

- Adults - amounts/day
- Pediatrics - amounts/kg/day
- Neonates - amounts/kg/day
- Electrolytes as complete salt form
- A dose for each macronutrient
- A dose for each electrolyte
- A dose for multivitamins
- A dose for individual vitamins, if ordered
- A dose for multi-trace elements
- A dose for individual trace elements, if ordered
- A dose for insulin, if ordered
- A dose for non-nutrient medications, if ordered

**Perform clinical review of PN order for:**

- Indication consistent with published guidelines
- Appropriate dose of each additive
- Appropriate osmolarity for route of administration (peripheral vs. central)


**Compare order to previous day's order to assess component doses for substantial changes**

**Perform PN order safety review for:**

- Compatibility of ingredients
- Stability of formulation

**Perform independent double-check for:**

- Transcribed order data prior to compounding
- Calculations or conversion of units of measure



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For full recommendations, rationale, and references, go to Ayers P, Adams S, Boullata J, Gervasio J, Holcombe B, Kraft M, et al. A.S.P.E.N. Parenteral Nutrition Safety Consensus Recommendations. *JPEN J Parenter Enteral Nutr.* 2013.  
[www.nutritioncare.org/pnsafety](http://www.nutritioncare.org/pnsafety)  
[www.nutritioncare.org](http://www.nutritioncare.org)

**Figure 2.** PN Order Review and Verification Checklist.

complexities of healthcare.<sup>7</sup> He felt that errors occur due to the volume and complexity of knowledge and how it has exceeded the ability of clinicians to properly deliver consistent and safe care to patients. He makes a compelling argument that we can do better by using the simplest of methods: the checklist. He revealed what checklists can do, what they can't, and how they could bring about striking improvements in a variety of fields, from medicine and disaster recovery to professions and businesses of all kinds. A simple surgical checklist from the World Health Organization has been adopted in more than 20 countries as a standard for care. With this in mind, the task force created a series of checklists to assist in communication, protocol development, and delivery of safe care around PN prescribing, order review, compounding, and administration. These 4 checklists

are available at [www.nutritioncare.org/pnsafety](http://www.nutritioncare.org/pnsafety). An example of the order review and verification and administration checklists can be found in Figures 2 and 3. Documentation at each step of the PN process may include checking each box and signing off on the checklist, which can then be maintained as part of the permanent record.


### *Convincing Your Organization to Make Changes*

Another step in translating recommendations to practice includes convincing your institution to make improvements to policies, protocols, and practices. Another set of tools to help with this process can be found at [www.nutritioncare.org/](http://www.nutritioncare.org/)

## PN Administration Checklist

**PURPOSE OF THIS CHECKLIST:** The American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) champions the best evidence-based practices that support parenteral nutrition therapy in varying age populations and disease states. Approximately 350,000 patients in the U.S. receive parenteral nutrition (PN) during hospital stays and many more receive PN at home and in alternative care settings ([www.hcupnet.ahrq.gov](http://www.hcupnet.ahrq.gov)). The appropriate use of this complex therapy aims to maximize clinical benefit while minimizing the potential risks for adverse events.

<ul style="list-style-type: none"> <li><input type="checkbox"/> <b>Perform hand hygiene</b></li> <li><input type="checkbox"/> <b>Use sterile technique when manipulating vascular access device</b></li> <li><input type="checkbox"/> <b>Inspect PN container, check for:</b> <ul style="list-style-type: none"> <li><input type="checkbox"/> Integrity of container: no defects or leaks present</li> <li><input type="checkbox"/> No visible particles or precipitates</li> <li><input type="checkbox"/> No oiling, streaking, clumping, or separation</li> </ul> </li> <li><input type="checkbox"/> <b>Confirm correct formulation, check for:</b> <ul style="list-style-type: none"> <li><input type="checkbox"/> Patient's name on label</li> <li><input type="checkbox"/> Match all components listed on the label against the PN order</li> <li><input type="checkbox"/> Route of administration (central vs peripheral)</li> <li><input type="checkbox"/> Documentation of proper VAD tip placement</li> <li><input type="checkbox"/> Start time</li> <li><input type="checkbox"/> Infusion rate with taper if appropriate</li> <li><input type="checkbox"/> Beyond use date and time</li> </ul> </li> <li><input type="checkbox"/> <b>Verify patient identification</b> <ul style="list-style-type: none"> <li><input type="checkbox"/> Confirm patient identity using two identifiers</li> <li><input type="checkbox"/> Inspect armband (not applicable in home care)</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li><input type="checkbox"/> <b>Initiate PN infusion</b> <ul style="list-style-type: none"> <li><input type="checkbox"/> Use appropriate size filter on distal end of tubing</li> <li><input type="checkbox"/> Spike container</li> <li><input type="checkbox"/> Prime tubing</li> <li><input type="checkbox"/> Set infusion pump settings using double check</li> <li><input type="checkbox"/> Trace catheter system to point of origin</li> <li><input type="checkbox"/> Disinfect needleless adapter on VAD hub</li> <li><input type="checkbox"/> Connect PN to patient</li> <li><input type="checkbox"/> Initiate PN infusion at prescribed rate</li> </ul> </li> <li><input type="checkbox"/> <b>Initiate monitoring protocol which includes:</b> <ul style="list-style-type: none"> <li><input type="checkbox"/> Patient response</li> <li><input type="checkbox"/> Glucose monitoring</li> <li><input type="checkbox"/> Serial weights</li> <li><input type="checkbox"/> Intake and Output</li> <li><input type="checkbox"/> Bloodwork</li> <li><input type="checkbox"/> Vital signs</li> </ul> </li> </ul>
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For full recommendations, rationale, and references, go to Ayers P, Adams S, Boullata J, Gervasio J, Holcombe B, Kraft M, et al. A.S.P.E.N. Parenteral Nutrition Safety Consensus Recommendations. *JPEN J Parenter Enteral Nutr.* 2013.

[www.nutritioncare.org/pnsafety](http://www.nutritioncare.org/pnsafety)

[www.nutritioncare.org](http://www.nutritioncare.org)

**Figure 3.** PN Administration Checklist.

pnsafety and are called *How to Make Changes in Your Institution*. These tools will help to prepare a presentation to your institution's Pharmacy and Therapeutics and/or Nutrition Committees. It starts off with a checklist of questions you should answer prior to the presentation, as seen in Figure 4.

Once these data are gathered through the checklist, you are ready to prepare a presentation. Another helpful tool here is a customizable PowerPoint program entitled "Improving Parenteral Nutrition (PN) Safety: Prescribing and Labeling in

Our Facility." You can insert your data, the name of your institution, and the gaps you have identified as compared with best practices, and then present this program to your administrators, encouraging your care teams to make changes. Finally in this toolkit are the order and labeling templates in Word that will again allow you to customize your order and labeling system to be in compliance with the A.S.P.E.N. recommended methods. A description of another institution's quality improvement initiatives around the PN process can also be instructive.<sup>8,9</sup>

**PN Safety Preparation Checklist**

Learn how many PN admixtures are used by your institution daily

Patient Group	In-house Compounded		Outsource Compounded	Commercially Premade
	Customized	Standardized		
Adult				
Pediatric				
Neonate				

▪ If outsourcing is utilized, have compounding pharmacies been visited and inspected?

List the members of the Pharmacy and Therapeutics (P & T) Committee or Nutrition Committee if appropriate. Consider introducing yourself to them ahead of time.

Identify key individuals from medicine, pharmacy, nutrition, nursing and information technology with an interest in PN and/or medication safety. Get to know them and advocate for their support.

List the members of the formal or informal nutrition support team (adults and pediatrics)

List the clinicians with nutrition support certification (CNSC, BCNSP) in your institution

Trace the flow map that best represents the PN-use process at your institution

- Compare with best practices described in A.S.P.E.N. documents
- Select one node of the process as a focus of safety (e.g., prescribing, order review, compounding, labeling & dispensing, storage & administration, or documentation)

Prescribing

Evaluate your electronic and/or paper PN order forms and compare with A.S.P.E.N. templates and recommendations.

Electronic Order Entry: CPOE

- Is the entry process standardized as per A.S.P.E.N. templates?
- Are dosing guidelines and decision support tools built into the system?
- Can the order be submitted before all required fields are complete?
- Are check boxes used instead of free text?
- If free text is used, is the space limited?
- Does the program auto-populate as many fields as possible?
- Does the order interface with the automated compounding device on which PN is prepared?

Paper Order Form:

- Are the forms standardized as per A.S.P.E.N. templates?
- Are they handwritten or can they be completed using word processing?
- Do they match the order entry sequence when transcribed onto the computer?

Determine the process for revision of the PN order process or CPOE in your institution

Order Review

- Who is the pharmacist dedicated to review the daily PN orders? Are they board-certified? Do they perform both a clinical review and a pharmaceutical review of each patient's PN order?

Evaluate the PN Labels for bags compared with the A.S.P.E.N. templates

Example: is component sequence and units of measure the same between the order form and label?

Determine the process for revision of the PN labels in your institution

Documentation

Determine if your institution has a Medical Safety Officer or Equivalent

Learn if PN errors are collected, analyzed and reported in your institution

Describe your institution's procedure for coping with Drug Shortages

- How is this communicated with prescribers, nutrition support team, and the P&T Committee?
- Which of the PN component items are unavailable? For how long? Have alternate sources been evaluated?
- Have alternate suppliers of products been inspected or certified? What are the obstacles to obtaining the unavailable products?
- Do you have management protocols such as those provided by A.S.P.E.N.? ([www.nutritioncare.org/drugshortages](http://www.nutritioncare.org/drugshortages))

Identify champions for PN Safety in your institution who can assist with the process

- Making changes to the process
- Finding out how to collect data before and after changes are made to assess impact

**Figure 4.** PN Safety Preparation Checklist.

## Conclusion

The PN Safety Consensus Recommendations have set the best practices and the author group has now provided tools to make these recommendations as easy as possible to understand, communicate with others, and implement in your institutions.

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