PRACTICE TOOL

# Safety in Parenteral Nutrition Compounding

Parenteral nutrition (PN) compounding is a complex process that requires knowledge and training to optimize the safety and efficacy of this form of nutrition support. Unfortunately, errors and lack of adherence to safe PN compounding recommendations and sterile compounding requirements have resulted in patient injury and death. These lapses in the safe provision of PN have been the result of a lack of understanding of PN compatibility, stability, and sterility requirements, as well as drug product shortages and order entry errors.[1]

This practice tool is designed to help with the education and training related to PN compounding, compatibility, and stability of PN admixtures, as well as the simultaneous administration of nonnutrient medications with PN admixtures. It also addresses the challenges faced while dealing with special populations such as neonates, pediatrics, and those on home PN. Based on the article 'Safety in Parenteral Nutrition Compounding' in *Nutr Clin Pract*, December 2023.

## Education and Training for PN Compounding

Many pharmacy students do not receive adequate education and training in nutrition, while institutions often struggle to provide comprehensive compounding training. Below are some solutions to these challenges:

- Michigan Medicine developed a compounding compliance team that oversaw pharmacy staff training, documentation, and auditing of staff performance.[2]
- ASPEN standards of practice for nutrition support pharmacists provide standards that nutrition support pharmacists should follow to provide competent care.[3]

## Regulations Involving Compounding

USP <797>, which provides guidance for compounding, has just been updated.[4] Concerns about PN and this updated guidance include:

- Risk levels are Categories 1, 2, and 3.
- PN falls into Category 2 since it is traditionally prepared from only sterile-starting components and would align with beyond-use dates (BUDs) for Category 2 compounded sterile preparations (CSPs).
- The instability of a PN admixture can take away from activity of a component or generate risk from toxic byproducts or particulate matter.[5]

## PN Admixture Requirements

- The nutrition support clinician needs to design and prepare PN that considers sterility, compatibility, and stability.[1]
- Incompatibility can limit the therapeutic effect of PN or increase the risk of adverse events from precipitate infusion. Ex: calcium-phosphate precipitation.
- Instability is the irreversible decomposition and/or degradation of active ingredients or dosage form due to pH, temperature, light, oxygen, solvents, and/or reactants. Lipid Injectable Emulsions (ILEs) are unstable systems that are stabilized by an emulsifying agent such as egg lecithin phospholipid.[5]
- ASPEN recommends 1.2-micron filters for all PN administration. This is for both total nutrient admixtures (formerly 3-in-1 PN) and dextrose-amino acid admixture with co-infused ILEs (formerly 2-in-1 PN).[6]
- Compatibility and stability data are specific to the products used in testing and should not be extrapolated across different products.



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## Challenges of PN Compounding for Pediatric and NICU Populations

- Accurate measurement of small doses of PN products is challenging. Use the nearest size IV syringe for necessary volume or dilution of the commercially available product. Use of robotic technology may be warranted.[1]
- Increased need for calcium and phosphorus for healthy bone development. Solubility of calcium and phosphate within the PN admixture is dependent on many factors.[1] Calcium:phosphate solubility curves are available but the curves must be specific to a given PN admixture and the ingredients used to compound it.[1]

## PN Compounding and Medication Compatibility

- ASPEN recommends the addition of nonnutrient medications within a PN admixture only when evidence supports the physico-chemical compatibility and stability of the medication and PN admixture, as well as confirmation of the therapeutic actions of the medication when included in a PN admixture.[7]
- Because the PN admixture will be administered either over a period during the day (eg, cyclic) or as a continuous infusion, the nonnutrient medication should be therapeutically active throughout the administration period.[5]
- Additionally, for the appropriate amount of the nonnutrient medication to be added to the PN admixture, the nonnutrient medication must already have an established, stable dose for the given patient.[5]

## Transition of Care

- Transitioning a patient receiving a high-alert medication such as PN from one care setting to another presents an increased opportunity for medical errors and adverse events.[8]
- Discharge checklists have been suggested as a best-practice method to ensure patients are ready for discharge and PN therapy will continue as prescribed at home without interruption.[9]
- A standardized list of items to be completed before discharge home can ensure that patients have adequate understanding of their home PN and how it will differ from the hospital PN, including weekly supplies and additives, and that orders have been reviewed with the home infusion provider to verify product availability and dispensing format the patient will receive at home.[9]

## Compounding for Home PN

- In the outpatient setting, pharmacies compound 7 days' worth of PN, and components without extended stability are dispensed separately for patients and caregivers to add daily themselves such as individual and multivitamin products, or cysteine in pediatric patients.[1]
- With some of these products, patients/caregivers may receive prefilled syringes, or that individual may need to measure the dose and inject into the PN bag.[1]

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