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Compounding vs Standardized Commercial Parenteral Nutrition Product: Pros and Cons

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Abstract

Standardized commercial parenteral nutrition (PN) formulations have advantages and disadvantages as compared with PN formulations compounded using an automated compounding device. These advantages and disadvantages are discussed along with the supporting available research.

Standardized commercial parenteral nutrition (PN), known as “premixed” PN, is a manufactured compounded, sterile product available in peripheral and central line formulations. The products are available with or without electrolytes, in 1- and 2-liter volumes. In the United States, the premixed PN formulations are provided as 2-compartment premixed products, with one compartment containing dextrose and the other protein or an amino acid component. Various concentrations of these macronutrients are available, with dextrose ranging from 5%–25% and amino acids from 2.75%–5%. A seal separates these macronutrients, and a simple opening of the seal allows for mixing of the ingredients. Fat emulsions may be added to the premixed solution after the dextrose and amino acids are mixed, or the fat emulsions may be infused separately via a Y-site connection. Three-compartmental premixed PN solutions, composed of dextrose, amino acids, and fat emulsions, are available in other parts of the world.

Standardized commercial PN solutions are not a new product but have received greater attention since 2005, when The Joint Commission, formerly the Joint Commission on Accreditation of Healthcare Organizations or JCAHO, published National Patient Safety Goal 3B. The goal recommended standardizing and limiting the number of drug concentrations used by hospital or health organizations. Many institutions questioned whether PN was considered in this goal. Initially, The Joint Commission stated that PN was a drug, recognizing that standardized commercial products were available that placed PN in the goal. Concerns about using these standardized PN products without regard to appropriate patient selection were alarming, prompting the American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) to form and charge a Task Force on PN Standardization.¹ This task force worked with The Joint Commission and together helped identify a better application of the goal as it related to patient safety and PN. The Joint Commission recognized that standardization of multicomponent solutions such as PN is much more complex than single drug solutions for which the requirement was originally intended. In 2008, National Patient Safety Goal 3B was dropped from The Joint Commission goals.²

Regardless, recognition that PN as a class of medications is associated with a high potential for hospital errors is important. Errors with PN are due to the complexity of the drug.^{3,4} These errors have resulted in increases in morbidity and mortality and may be attributed to lack of practitioner education and knowledge with PN, as well as errors in prescribing, transcribing, compounding, administering, and monitoring.⁵ Standardization of PN may decrease these complications.¹ The A.S.P.E.N. Task Force on PN Standardization did state, “A standardized process for PN management is advocated in order to reduce variation and promote uniformity among clinicians and between health care facilities.”¹ However, standardization of the PN “process” may include not only use of commercially available PN products but also other aspects such as ordering, labeling, screening, and administration of PN. Institutions may elect to implement the use of specific standardized PN formulations designed to meet the nutrient requirements of the majority of their patient populations.¹

Standardization is advantageous as it provides guidance in decision making and promotes ease and convenience to prescribers, minimizes misinterpretation of orders and calculation errors, decreases compounding errors, and increases time focused on patient care.

Therefore, standardized commercial PN can offer the advantage of improved safety. The standardized commercial PN products are regulated by the U.S. Food and Drug Administration, follow good manufacturing practices, and are compliant with U.S. Pharmacopeia Chapter <797>, offering accurate and stable PN solutions. At the present time, these standardized commercial PN formulations do not contain vitamins, minerals, or trace elements, and these must be added to the PN. The fat emulsions may be infused separately or infused via a Y-site port. These additional steps may increase the risk of contamination but are still less complex than the process involved with compounding PN.

Will the reduction in preparation and compounding associated with the use of premixed PN formulations reduce solution contamination and catheter-related bloodstream infections? In a 2011 study, Turpin et al⁶ performed a review of per-patient costs associated with compounded PN vs standardized commercial PN on underlying infection risk using claims data from a nationally representative group of more than 400 U.S. hospitals. Adult patients receiving any PN formulation were included with the exception of patients admitted with infection, hepatic dysfunction, acute cholecystitis, phlebitis, thrombophlebitis, renal failure, or cirrhosis. A total of 44,358 patients were included, with 41,102 patients receiving compounded PN and 3256 patients receiving a standardized commercial PN. After adjusting the baseline variables, the probability of developing a bloodstream infection was 30% higher in patients receiving compounded PN than in those receiving a standardized commercial PN (16.1% vs 11.3%; odds ratio = 1.56; 95% confidence interval, 1.37–1.79; P < .0001). The researchers indicated that \$1545 per PN patient could have been saved if standardized commercial PN had been used.⁶ Interestingly and understandably, patients who received the compounded PN were “sicker.” A statistically significantly greater number of patients receiving compounded PN were intensive care unit patients (45% vs 34%); had greater comorbidities, including nutrition deficiencies (30.5% vs 28.6%), cancer (40.8% vs 34.8%), and Crohn’s disease (3.2% vs 1.6%); and received PN longer

(7.8 days vs 5.2 days).⁶ Whether these differences contributed to the variance in bloodstream infections was not reported in this study.

The standardized commercial PN may also offer the advantage of cost savings and convenience. The standardized commercial PN formulations do not require refrigeration, offer a 2-year shelf life and decreased preparation time, and may be provided in a more timely fashion. The cost savings incurred from a decrease in pharmacy and nursing time may be compounded by the cost savings seen with associated decreased infectious complications.

There are limitations to using standardized commercial PN. Limited products are available in the United States. Practitioners are challenged to identify standardized commercial PN formulations for use in patients with higher protein requirements and obese patients. Education is necessary if these PN formulations are to be used within institutions. Healthcare providers will need to be instructed on implementing the new technology, as well as how to break the seal, add fat emulsions, or use as a separate infusion. The standardized commercial PN formulations come in either 1- or 2-liter bags; often, 24-hour infusions are not possible. This will account for an increase in nursing time. To appropriately evaluate the patient's laboratory serum values, timing of blood draws will need to be reorganized with respect to administration of the PN infusion. These products are not "total" PN in that they still require additives such as multivitamins and trace elements and may require the addition of electrolytes and fat emulsions.

Considerations of institution size, patient population, and safety as well as cost and available resources must be considered when determining if standardized commercial PN is valuable to the institution. A review of existing PN populations and PN prescribing patterns, as well as identification of existing problem areas, must be performed before implementing standardized commercial products. This will allow the healthcare provider to identify if the standardized commercial PN will offer an advantage to the institution and help in the selection of which formulations will work optimally. With patient care and safety being the utmost concern and as further research becomes available in the area, the healthcare provider must stay abreast of this information to best serve the patient. A more in-depth review of this topic is provided in "Commercial Premixed Parenteral Nutrition: Is It Right for Your Institution?"⁷

Conclusion

Standardized commercial PN products have advantages and limitations. Clinicians must be aware of both and consider their patient populations when making decisions about using this form of PN therapy. Further research must be done to study the cost-effectiveness of these products.

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