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2024 Parenteral Nutrition Product Shortage Recommendations: Sterile Water for Injection

ASPEN has developed shortage recommendations to assist members and other clinicians in coping with parenteral nutrition (PN) shortages for their patients. These sterile water for injection product shortage recommendations were developed by the ASPEN Parenteral Nutrition Committee and approved by the ASPEN Board of Directors.

Document Contents:

Important Notes:

- These recommendations do not constitute medical or professional advice and should not be taken as such. To the extent the information published herein may be used to assist in the care of patients, this is the result of the sole professional judgment of the attending health professional whose judgment is the primary component of quality medical care. The information presented herein is not a substitute for the exercise of such judgment by the health professional.
- No single strategy will work for all organizations, and all are less than ideal for providing safe and optimal patient care. Institutions must carefully consider options and weigh the risks and benefits prior to implementation.

Questions regarding these recommendations should be directed to clinicalpractice@nutritioncare.org.

General Recommendations for Sterile Water for Injection Shortage Management

During a sterile water for injection shortage, ASPEN recommends consideration of the following general measures:

1. **For all patients,** routinely assess and reassess patient-specific indication(s) for nutrition support and requirement for PN; provide nutrition via the oral or enteral route when possible and clinically **appropriate.**[1,2]
2. **Communicate with all key stakeholders** (e.g., pharmacy department, nursing department, central supply). Communication is essential to understanding the current stock, procurement issues, and bedside practice. Establish a process to maintain clear communication across departments.
3. **Do not stockpile.** Purchase only as much supply as needed in the interest of fair allocation to all patients.

4. **Maintain or incorporate the following sterile compounding practices:**
    - Compound PN in a single, central location (either in a centralized pharmacy or as outsourced preparation) to decrease inventory waste. Consider a supply outreach to other facilities in your geographic location.
    - Facilities must continue to observe and comply with the product labeling (e.g., package insert), USP General Chapter <797> Pharmaceutical Compounding-Sterile Preparations and associated USP chapters, and state Boards of Pharmacy and federal rules and regulations.[3]
5. **Ensure PN compatibility and stability with all changes during times of PN component shortages.**
6. **Develop an organizational strategy.** Include PN component and product shortages in the healthcare organization's strategies and procedures for managing medication shortages. These procedures should include processes to:
    - identify and monitor patients who are receiving a PN regimen that has been modified due to a product shortage,
    - notify clinicians when a shortage of a PN component or product occurs,
    - notify clinicians when PN formulations are adjusted due to shortages of PN components and products,
    - notify patients receiving long-term (e.g., more than 1 month) PN therapy and their caregivers when their PN formulation has been adjusted for shortages of PN components and products,
    - notify clinicians when a PN component shortage has resolved, and
    - **resume normal dosing practices when a PN component shortage has resolved**.
7. **Report shortages and errors.**
    - Report severe drug product shortage information to the FDA Center for Drug Evaluation and Research (CDER) Drug Shortage Program.
    - Report any patient adverse events or medication hazards related to shortages to the ISMP Medication Errors Reporting Program (MERP).

Specific Considerations for Sterile Water for Injection Shortage Management

1. Assess all patients for appropriate indications for PN prior to initiation; frequently reassess patients for ongoing appropriate indications for continuation of PN.[1]
2. Conserve supply for the following populations:
    - Neonatal and pediatric patients
    - Patients with disorders of malabsorption or fluid balance who are unable to tolerate enteral or oral intake
    - Patients who cannot receive secondary intravenous fluids
3. Ensure PN compatibility and stability with all changes to the admixture during times of PN component shortages.
4. Consider using an oral rehydration solution to support hydration in those who can tolerate oral or enteral nutrition.[4]

5. Minimize the use of sterile water in PN to meet fluid needs. Consider secondary intravenous fluids to meet patients' volume requirements.
6. Refer to ASPEN's Recommendations for Appropriate Dosing for Parenteral Nutrition and other guidance when determining fluid requirements.[5,6]
7. Consider all sources of fluid intake (oral or enteral intake, medication, flushes, blood products, intravenous fluids) and output (urine, stool/ostomy/fistula, wound/drain) when determining fluid needs.[7] Evaluate the use of medications that may impact fluid balance (e.g., diuretics or medications known to affect stool/output consistency and/or frequency).
8. Consider using lower concentrations of amino acid and dextrose products to increase PN volume when needed. For example, if available, utilize a 10% amino acid product instead of a 15% product to provide additional volume. Prior to any amino acid product modification, the amino acid profile must be evaluated for clinical appropriateness. Amino acid products may have different pHs, calcium-phosphorus solubilities, amounts of inherent electrolytes, as well as other characteristics that should be considered prior to substitution. ONLY use neonatal/pediatric-specific amino acids for the indicated patient populations.
9. Strongly consider the use of multi-chamber bag PN products, if clinically feasible.[8]
10. Collaborate with the multidisciplinary care team on the appropriate frequency of laboratory monitoring with changes in the PN admixture composition to ensure patient safety.
11. Consider the universal ingredient on the ACD; if it is sterile water for injection, consider changing to dextrose or other appropriate intravenous solutions, if available.
12. When evaluating alternatives to sterile water for injection in PN, consider the composition of all PN additives (IVF, electrolytes, etc.) when determining daily patient needs.[5]
    - Bicarbonate-containing and balanced crystalloid intravenous fluids (Lactated Ringers, Plasma-Lyte, Normosol) will cause stability and compatibility issues and should not be added to the PN admixture.
13. Do not use Sterile Water for Irrigation, USP as a substitute for Sterile Water for Injection. Sterile Water for Injection must meet USP <788> Particulate Matter for Injections. There is no corresponding requirement for the irrigation product.[9]
14. Please note the use of any alternative products will require modification to electronic health record systems, automated compounding devices (ACDs), and ACD-supporting applications to reflect current product availability and to prevent the inclusion of incorrect or unavailable ingredients in PN orders.[10]

ASPEN Resources

PN/EN Indications:

- When Is Parenteral Nutrition Appropriate?
- When Is Enteral Nutrition Indicated?

PN Dosing and Safe Practices:

- Appropriate Dosing for Parenteral Nutrition: ASPEN Recommendations
- ASPEN Clinical Guidelines: Parenteral Nutrition Ordering, Order Review, Compounding, Labeling, and Dispensing
- ASPEN Parenteral Nutrition Safety Consensus Recommendations

PN Compatibility and Stability:

- Parenteral Nutrition Compatibility and Stability: A Comprehensive Review
- Parenteral Nutrition Compatibility and Stability: Practical Considerations

Multi-Chamber Bag Parenteral Nutrition (MCB-PN):

- Multi-Chamber Bag Parenteral Nutrition: Indications, Product Availability, and Patient Safety

References

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2. Bechtold ML, Brown PM, Escuro A, et al. When is enteral nutrition indicated? *JPEN J Parenter Enteral Nutr.* 2022;46(7):147-1496.
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4. Wall B. ORS: The Solutions to Optimize Hydration in Short Bowel Syndrome. *Pract Gastroenterol.*2020:196:24-31.
5. Appropriate Dosing for Parenteral Nutrition: ASPEN Recommendations. 2020. American Society for Parenteral and Enteral Nutrition. Available at https://www.nutritioncare.org/uploadedFiles/Documents/Guidelines_and_Clinical_Resources/PN%20Dosing%201-Sheet-Nov%202020-FINAL.pdf. Accessed October 9, 2024.
6. Meyers RS. Pediatric Fluid and Electrolyte Therapy. *J Pediatr Pharmacol Ther*. 2009;14(4):204-211.
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8. Multi-Chamber Bag Parenteral Nutrition: Indications, Product Availability, and Patient Safety Practice Tool. 2024. American Society for Parenteral and Enteral Nutrition. Available at: https://www.nutritioncare.org/uploadedFiles/Documents/Guidelines_and_Clinical_Resources/PN_Resources/MCB-PN-Practice-Tool.pdf. Accessed October 8, 2024.
9. USP General Chapter <788> Particulate Matter in Injections. United States Pharmacopeial Convention. 2012. Accessed October 16, 2024.
10. Ayers P, Foster J, Kanorwala A, et al. Electronic Health Record and Parenteral Functionality: A Gap Analysis. *Nutr Clin Pract*. 2021;36(2):433-439.

About ASPEN

The American Society for Parenteral and Enteral Nutrition (ASPEN) is dedicated to improving patient care by advancing the science and practice of nutrition support therapy and metabolism. Founded in 1976, ASPEN is an interdisciplinary organization whose members are involved in the provision of clinical nutrition therapies, including parenteral and enteral nutrition. With members from around the world, ASPEN is a community of dietitians, nurses, nurse practitioners, pharmacists, physicians, PAs, researchers, scientists, and students from every facet of nutrition support clinical practice, research, and education. For more information about ASPEN, please visit www.nutritioncare.org.