INS GUIDANCE TO ADDRESS IV SOLUTION SHORTAGES AS A RESULT OF HURRICANE HELENE

Due to extensive damage sustained by Baxter's North Cove, NC, facility from Hurricane Helene, the Infusion Nurses Society (INS) has issued the following guidance, based on the 2024 *Infusion Therapy Standards of Practice*. INS is dedicated to assisting health care providers in managing product shortages while maintaining high standards of care. Below, you'll find recommendations for optimizing resource use during this challenging period. INS continues to monitor the situation closely and is collaborating with Baxter and other health care organizations to provide timely updates.

Important Note: Every health care professional should rely on their professional judgment to guide clinical practice. While guidelines can address the broader issues, the specific needs of each patient population should be defined by experts within their organization. For further information, we recommend consulting the INS *Infusion Therapy Standards of Practice*.

INS RESOURCES BASED ON THE 2024 *INFUSION THERAPY STANDARDS OF PRACTICE:*

40. ADMINISTRATION SET MANAGEMENT

Parenteral Nutrition (PN) (refer also to Standard 61, Parenteral Nutrition)

40.1 Administration set use and replacement is performed with adherence to Aseptic Non Touch Technique (ANTT®) at a frequency based upon factors such as patient condition, solution administered (type, rate, and frequency), immediately upon suspected contamination, and when the integrity of the product or system has been compromised.

II. Primary and Secondary Continuous Infusions

A. Replace primary and secondary continuous administration sets used to administer solutions other than lipid, parenteral nutrition, blood, or blood products at least every 7 days (unless otherwise stated in manufacturers' directions for use) or when clinically indicated (eg, any loss of product integrity such as contamination or dysfunction), whichever occurs sooner.

III. Primary Intermittent Infusions

A. Change intermittent primary and secondary administration sets every 24 hours.

V. Propofol Infusions

A. Replace administration sets (and any add-on devices such as stopcocks) used to administer propofol infusions at least every 6 to 12 hours, per the manufacturers' directions for use.

61. PARENTERAL NUTRITION

B 4. Replace solution containers and administration sets used for PN (total nutrient mixture [TNA] and amino acid/dextrose formulations) and lipids every 24 hours; replace administration sets used for lipid injectable emulsion (ILE) with each new infusion. Hang time for PN should not exceed 24 hours.

a. In a laboratory study, TNA and ILE support Candida albicans growth after minimal initial contamination with microorganisms migrating from the fluid bag to the central vascular access device (CVAD). Attention to ANTT® during management of the administration set is imperative, and administration sets should be replaced daily (see Standard 40, Administration Set Management).

b. Limit separate ILE infusion to a 12-hour maximum time; if volume limitations require separate ILE administration for a period longer than 12 hours, ASPEN recommends strong consideration for a new ILE container and administration set for the second 12-hour portion. The hang time of a TNA can be extended to 24 hours because bacterial growth in these solutions is inhibited due to reduced pH and to increased total osmolarity compared to infusing ILE separately.

57. INFUSION MEDICATION AND SOLUTION ADMINISTRATION

K. Administer solutions and medications prepared and dispensed from the pharmacy or as commercially prepared solutions and medications whenever possible; do not add medications to infusing solution containers (refer to Standard 56, Compounding and Preparation of Parenteral Solutions and Medications).

M. Replace IV solution containers in accordance with organizational policy, procedures, and/or practice guidelines.

1. There is insufficient evidence to recommend the frequency of routine replacement of IV solution containers, with the exceptions of parenteral nutrition (PN) solutions, which are replaced every 24 hours. One study found no relationship between length of time used and likelihood of colonization and suggests that routine replacement at regular time intervals may not be necessary. Further research is needed (see Standard 61, Parenteral Nutrition).

38. FLUSHING AND LOCKING

A. Use single-dose systems (eg, single-dose vials and syringes or prefilled labeled syringes) for all vascular access device (VAD) flushing and locking.

1. A syringe or needle should be considered contaminated once it has been used to enter or connect to a patient's intravenous (IV) solution container or administration set.

2. Use commercially manufactured prefilled flush syringes (when available) to reduce the risk of catheter-associated bloodstream infection (CABSI) and device failure, save time for syringe preparation, and aid optimal flushing technique and objectives.

3. Do not use IV solution containers (eg, bags or bottles) as a source for obtaining flush solutions (see Standard 56, Compounding and Preparation of Parenteral Solutions and Medications).

4. Use new, unopened, single-use, commercially available prefilled syringes for flushing before and after medications. Using the same prefilled syringe to flush a VAD before and after the medications can potentially contaminate the prefilled syringe tip and thereby transfer the contamination to the VAD.

Do not use prefilled flush syringes for dilution of medications. Differences in gradation markings, an unchangeable label on prefilled syringes, partial loss of the drug dose, and possible contamination increase the risk of serious medication errors with syringe-to-syringe drug transfer

56. COMPOUNDING AND PREPARATION OF PARENTERAL SOLUTIONS AND MEDICATIONS

A. Administer, whenever possible, medications that have been compounded (prepared, mixed, packaged, and labeled) in a pharmacy that complies with compounding standards and regulations.

Use infusions supplied by the manufacturer or pharmacy in a ready-to-administer form to minimize the need for manipulation outside the pharmacy sterile compounding area. Infusions prepared or manipulated outside the pharmacy are more likely to contain microbial contamination.

B. Avoid unnecessary manipulation to decrease the risk of dosing errors and contamination.

1. Do not withdraw IV push medications from commercially available, cartridge-type syringes into another syringe for administration.

2. After measuring the dose in an appropriately sized syringe, do not transfer the medication to another (eg, larger) syringe prior to administration.

3. Avoid unnecessary dilution. Only dilute IV push medications when recommended by the manufacturer or in accordance with organizational policies, procedures, or practice guidelines.

4. Use single-use, commercially prepared, prefilled syringes of appropriate solution to flush and lock VADs.

5. Dedicate multidose vials (eg, multidose vial if used for IV flush) to a single patient.

REFERENCE: Nickel B, Gorski LA, Kleidon TM, et al. *Infusion Therapy Standards of Practice*. J Infus Nurs. 2024;47(suppl1):S1-S285. doi:10.1097/NAN.0000000000000532

OTHER RESOURCES WITH COLLABORATING ORGANIZATIONS:
Baxter website Hurricane Helene Clinical Resources (baxter.com)

The American Society for Parenteral and Enteral Nutrition (ASPEN)
ASPEN Response to FDA Temporary Guidance October 2024.pdf (nutritioncare.org)

American Society of Health-System Pharmacists (ASHP)
https://www.ashp.org/drug-shortages/shortage-resources/publications/fluid-shortages-suggestions-for-management-and-conservation?loginreturnUrl=SSOCheckOnly

The Society of Critical Care Medicine (SSCCM)
Crisis Response | SCCM

National Home Infusion Association (NHIA)
IV Fluid Shortage Resource Center - National Home Infusion Association (nhia.org)
Microsoft Word - NHIA letter to HHS CMS Baxter NC_100824_final2
Guidance-Document-Disruptions-in-Manufacturing.pdf