

Small-Volume Parenteral Solutions Shortages Suggestions for Management and Conservation

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Introduction

This fact sheet summarizes the status of the current acute shortage of small-volume parenteral solutions and provides an outline of potential actions for organizations to consider in managing the shortage. Healthcare professionals should use their professional judgment in deciding how to use the information in this document, taking into account the needs and resources of their individual organizations.

Why is conservation necessary?

Intermittent shortages of small-volume parenteral solutions (SVPs) continue to plague hospitals, health-care systems, and ambulatory care infusion centers. At times the supply of these products is so heavily impacted that alternative strategies are needed. SVPs are the foundation of basic IV compounding for hundreds of drugs that need further dilution. Hospitals that do not serve a large population of pediatric patients often don't routinely utilize syringe pump infusion technology, instead using large volume infusion pumps that require the final compounded solution to be in bags or bottles. Glass bottles are not only cumbersome, they are hazardous to staff and patients if they break, and their use is only recommended if the drug requires a glass container based upon stability needs.

Definitions:

Small-volume parenteral solutions (SVPs) – a solution volume of 100 mL (as defined by USP) or less that is intended for intermittent intravenous administration (usually defined as an infusion time not lasting longer than 6-8 hours).

IV Push – Despite the often ambiguous nature of this term, it generally is considered administration of a final IV product that can be injected over 5 minutes or less. Best practice recommends that whenever possible the actual rate of IV push administration specific to a given drug be noted and that terms such as IV push (unspecified), IV bolus (unspecified), slow or fast/rapid IV push should be avoided.

Ready-to-administer: A dosage form/concentration that can be administered to the patient without further manipulation.

What can clinicians do to conserve?

- Review the use of SVPs as supplies. Many areas use SVPs to start intravenous lines, administer blood, or flush lines. During this shortage, consider changing to the use of 500 mL or 1 L bags to start intravenous lines or flush with single-use flush syringes.
- Switch administration of products to IV push whenever possible. Adhere to the [CDC use guidelines for vials](#).¹
 - System-wide communication will be needed to alert all clinicians who administer medications.
- Switch therapy to a clinically appropriate oral product whenever possible.
 - Work with P&T committee to review current IV to oral (PO) policies. There may be a need to expand policy language to include additional drug categories.
 - Anti-infectives
 - ✓ Switch to oral when clinically appropriate, especially for anti-infectives that have good bioavailability properties.
 - Consider changing IV electrolyte supplements to oral when clinically appropriate (many electrolytes are also available via liquid formulations if solid-dosage forms are not suitable to patient needs).
- If oral route is not feasible or indicated, some medications may be administered via intramuscular and/or subcutaneous injection (being cautious of maximum volume for a single injection; doses may need to be divided into more than one syringe).
- Review drug formulations and available products that may allow changes to an alternative route of administration.
- Explore opportunities to use large-volume parenterals for continuous infusions (e.g., piperacillin/tazobactam, cefepime, oxacillin, magnesium).
- Consider changes in the EHR to allow flexibility to use either dextrose or saline for drugs compatible with both solutions. This will help create better flexibility based upon which products are available at the time.
 - Use alerts or forced functions when a drug is compatible in only one diluent.
- Review the stock of SVPs and vials to determine stock on hand that is compatible with mix-on-demand supplies such as Vial2Bag®, Add-Vantage®, or Mini-Bag™ Plus.

Inventory control strategies

- Evaluate supplies on a health-system-wide basis and redeploy SVPs to areas of greatest need.
- Realign stock so the pharmacy has control over all SVPs. (Remember procedural areas, ORs, etc.)
- Stock SVPs only in areas where final medication solutions for administration must be prepared.
- Ensure that purchasing agents have active backorders in place, and are obtaining allocations as available. Ensure that additional accounts are set up for direct purchases.

Pharmacy operational strategies

- Purchase imported product. FDA has [allowed Baxter to import SVPs](#).²
- Take the opportunity to review institutional and departmental procedures to ensure that they are pertinent and up-to-date. All hospitals and health-systems should have existing policies and procedures related to drug shortages.
- Transition to premixed solutions where possible
 - Adhere to beyond use dating (BUD) as outlined in USP Chapter <797> for appropriate dating given the temperature environment.
 - Consider either purchasing frozen products or storing compounded products in the freezer to maximize BUD in order to reduce waste.
- Consider conversion for a limited list of products to alternative point-of-care activated systems (Vial2Bag®, Add-Vantage®, or Mini-Bag™ Plus).
- Consider compounding and dispensing medications that may be administered via **IV push in ready-to-administer concentrations packaged in syringes**.
 - Home infusion references can provide information on maximum concentrations to minimize volumes to be administered.
- If your institution can utilize syringe infusion pumps, consider compounding and dispensing non-IV push medications in ready-to-administer syringes to be infused via syringe pump.
- If empty bags are available, and **all other options have been exhausted**, consider compounding SVPs of 5% Dextrose in water or 0.9% Sodium Chloride. There are two options for this: 1) Use 1 L bags of commercially available 5% Dextrose in water or 0.9% Sodium Chloride and **repackage** into small bag sizes (50 or 100 mL), OR 2) compound Dextrose 5% in water or Sodium Chloride 0.9% using concentrated dextrose or sodium chloride, respectively (considered medium-risk) and further diluting with sterile water.
 - **Option 1 is considered to be a safer practice than option 2. Consider option 2 only if the 1 L commercial bags are also in short supply and on conservation/allocation.**
 - ✓ Repeater pumps can be used for compounding and will help minimize employee fatigue and over-use injuries.
 - ✓ If compounded or repackaged bags have been frozen to extend dating, thoroughly inspect the bag before dispensing to ensure the bag did not crack or split during frozen storage.
 - If repackaging, follow [Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities](#), authored January 2017 by the FDA.
 - Follow all guidance for BUD as dictated by USP Chapter <797> and state rules and regulations.
 - Only compound in a container that adequately reflects the volume on the label. If necessary to compound in a bag whose capacity is larger than the volume of compounded contents, the label should be affixed so that it covers the total capacity printed on the bag (i.e. if compounding 50 mL total volume in a 150 mL container the pharmacy label should cover the 150 mL print on the bag).
- Ensure that refrigerators and freezers are continuously monitored
 - Double check that they are plugged into emergency power outlets.

- Do not overfill the refrigerator or freezer; that would be detrimental to maintaining optimal temperatures.

Infusion pumps / Informatics strategies

- Do not underestimate the informatics resources that will be needed during the time of this shortage.
- Drug records, order-sets, and treatment protocols will need to be reviewed for route changes of some IV medications.
 - Examples are anti-emetics within oncology protocols.
- Take the opportunity to review, revise, and/or develop good infusion pump practices and protocols.
 - These are needed to ensure that the institution knows how many pumps are available at all times and where they need to be allocated.
- Some infusion pumps have syringe adapter sets that allow a syringe to be given using the large volume parenteral (LVP) module.
- Consider where and when other types of pumps can be used such as PCA, CADD, or elastomeric pumps.
- Try to maintain standardization whenever possible, especially if the same pumps are used for both adult and pediatric patients.
- When building drug records use alerts or forced functions when a drug is compatible in only one diluent to prevent the ordering individual from choosing an incompatible solution.

Caveats / Safety information

- Adequately communicate any changes to current practice using established communication channels within your hospital or health system, such as daily huddles, flyers, labeling, etc.
 - Be sure that Information Technology is aware of the need to make priority changes in drug files, charge description masters, and infusion pump libraries and recognize that they will not have the normal lead time that this process generally requires.
 - Consider having a physician and nursing champion in addition to the pharmacy lead who can assist with routine communication, practice changes and stock updates.
- Compounding sodium chloride solutions from sterile water for injection and concentrated sodium chloride injection is error-prone and labor-intensive, and may worsen the existing shortage of concentrated sodium chloride injection. In addition, the large amount of product necessary to meet patient needs makes compounding impractical. Limit compounding to urgent short-term needs when commercial products are unavailable.
- Reflect changes in product (e.g. use of regular 100 mL bags of saline vs. Mini-Bag Plus) in all pharmacy automation.
- Make sure all health care professionals administering medications have access to IV push policies and guidelines and have been trained and assessed for competency in administering medications via the IV push route. Use [available best practices](#) and concepts for IV push.³
 - Consider an IV push administration competency assessment tool if one is not already in place.

- If transitioning medications to syringes for syringe infusion pump administration, make sure staff are adequately trained to use the technology.
 - It may be necessary to change or add to drug libraries. If so, use clinical, safety/quality, and informatics teams to ensure that any additions or changes have been vetted through appropriate channels.
- Specialized references (e.g., Handbook on Injectable Drugs, AHFS Drug Information) and/or the manufacturer's labeling should be consulted for details about whether and how specific drugs may be administered by IV push.

Please contact ASHP's Center for Medication Safety and Quality at quality@ashp.org with questions.

References

1. Centers for Disease Control and Prevention. One & Only Campaign. US Department of Health and Human Services. Accessed 2017 Oct 18 at <http://www.oneandonlycampaign.org/>
2. Baxter. Dear Healthcare Professional Letter. Temporary importation of intravenous drug products to address drug shortages. 2017 Oct 9. Accessed 2017 Oct 17 at <https://www.fda.gov/downloads/drugs/drugsafety/drugshortages/ucm579560.pdf>
3. Institute for Safe Medication Practices. ISMP safe practice guidelines for adult IV push medications: a compilation of safe practices from the ISMP Adult IV Push Safety Summit. 2015. Accessed 2017 Oct 18 at <https://www.ismp.org/Tools/guidelines/IVSummitPush/IVPushMedGuidelines.pdf>