



DATE:	10/16/2017
TO:	Health Alert Network
FROM:	Dr. Rachel Levine, Acting Secretary of Health and Physician General
SUBJECT:	Saline Product Availability
DISTRIBUTION:	Statewide
LOCATION:	Statewide
STREET ADDRESS:	Statewide
COUNTY:	Statewide
MUNICIPALITY:	Statewide
ZIP CODE:	Statewide

This transmission is a “Health Advisory”: provides important information for a specific incident or situation; may not require immediate action.

HOSPITALS: PLEASE SHARE WITH ALL MEDICAL, PEDIATRIC, INFECTION CONTROL, NURSING, AND LABORATORY STAFF IN YOUR HOSPITAL

EMS COUNCILS: PLEASE DISTRIBUTE AS APPROPRIATE

FQHCs: PLEASE DISTRIBUTE AS APPROPRIATE

LOCAL HEALTH JURISDICTIONS: PLEASE DISTRIBUTE AS APPROPRIATE

PROFESSIONAL ORGANIZATIONS: PLEASE DISTRIBUTE TO YOUR MEMBERSHIP

The Pennsylvania Department of Health (PADOH) is providing the following guidance to providers after multiple facilities have experienced shortfalls resulting from disruption in the supply chain of sterile saline solution and related products.

Since 2014, there has been a national concern with supply chain availability of sterile saline solution and related products. These concerns have been exacerbated over the past few weeks by the recent FDA action taken against a B. Braun manufacturing plant and with the impacts of recent hurricanes on a Baxter manufacturing facility in Puerto Rico. These issues have resulted in some products being placed on allocation limitation from manufacturers with some facilities receiving less than 50% of normal baseline orders. Data collected by PADOH indicates that primarily small volume preparations of these products (≤ 250 mL) are most affected.

The Federal Food and Drug Administration (FDA) is working to support these supply chain issues, including temporarily licensing products currently being manufactured in Europe, and by working to enhance production and distribution from the Puerto Rico facility.

Additionally, the FDA has announced that “Baxter Healthcare Corporation in conjunction with FDA has initiated temporary importation of Sodium Chloride 0.9% w/v Intravenous Infusion BP in MINI-BAG Plus container in VIAFLEX (PVC) plastic container into the U.S. market to address the drug shortage.”

Information on ordering these products to help alleviate facility shortfalls can be found online here: <https://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM579560.pdf>

In the meantime, however, clinicians and facilities should consider using common sense approaches to addressing supply chain issues that may be impacting your operations. The American Society of Health-System Pharmacists (ASHP) has developed a guidance document for strategies in conserving limited IV solution supplies (attached). Key points include:

- Use oral hydration whenever possible.
- Implement an organization-specific action plan to conserve IV fluids where possible. Allow flexibility as the shortage status of specific products may change frequently.
- Develop medical staff-approved policies for substitution of IV solutions based on product availability within the organization.
- Frequently evaluate the clinical need to continue intravenous fluid.

The guidance from ASHP was originally created for shortages of large-volume presentations of IV fluids, so not all recommendations may be applicable in the current shortage situation; however, many recommendations are equally pertinent. ASHP is also scheduled to release additional updated guidance; providers are encouraged to regularly check the ASHP drug shortage page at <https://www.ashp.org/Drug-Shortages> for updated guidance and information.

With the current shortage primarily affecting small volume products, the Department wants to expressly caution against practices that may increase the risk to patients, such as repackaging larger volume products or using a saline solution bag for multiple patients. All products that are designed for single patient use must only be used as such.

If in times of critical need, a facility chooses to repackage aliquots from a larger volume intravenous preparation, the facility must not violate manufacturer's instructions for use and must prepare, store and use the intravenous product in the same way it would prepare a compounded medication strictly following all USP General Chapter 797 best practices. As an alternative to repackaging in-house, facilities could consider contracting with a FDA-registered outsourcing facility. (<https://www.cdc.gov/injectionsafety/cdcposition-singleusevial.html>)

The PADOH Bureau of Public Health Preparedness (BPHP) will be continuing to monitor and collect information on supply chain levels across the commonwealth utilizing the KC-HIMS platform. BPHP is continuing to monitor and share information regarding this shortage situation. Information is currently being shared on the KC-HIMS platform and through emergency preparedness channels. Questions regarding supply chain or logistics should be directed to your Hospital & Healthsystem Association of Pennsylvania (HAP) Regional Preparedness Manager; contact information can be found online here: <http://www.health.pa.gov/My%20Health/Emergency%20Preparedness/Pages/Health-Care-Coalition-HCC-Preparedness.aspx>

Facilities are also encouraged to inform our federal partners of the shortages and impacts that are being felt in your facility. Guidance on how to report specific shortages you are experiencing can be found here: <https://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm142398.htm>

Categories of Health Alert messages:

Health Alert: conveys the highest level of importance; warrants immediate action or attention.

Health Advisory: provides important information for a specific incident or situation; may not require immediate action.

Health Update: provides updated information regarding an incident or situation; unlikely to require immediate action.

This information is current as of October 16, 2017, but may be modified in the future.

Intravenous Solution Conservation Strategies

(Compiled by the American Society of Health-System Pharmacists and the University of Utah Drug Information Service, March 20, 2014)

Introduction

This fact sheet summarizes the status of the current acute shortage of certain large-volume intravenous solutions and provides a list of potential actions to conserve them that organizations might consider to manage 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?

There is a national shortage of 0.9% Sodium Chloride Injection, 0.45% Sodium Chloride Injection, Lactated Ringer's Injection, and 5% Dextrose Injection that is not expected to resolve until May or June, 2014. Products most affected by this shortage are large-volume (i.e., 1000 mL) bags.

What can clinicians do to conserve?

- Use oral hydration whenever possible.
- Review the suggested clinical approaches and product conservation strategies in collaboration with the organization's stakeholders and the Pharmacy and Therapeutics (P&T) Committee or other organization-wide medication policy group for applicability to the organization.
- Implement an organization-specific action plan to conserve IV fluids where possible. Allow flexibility as the shortage status of specific products may change frequently. For example, Lactated Ringer's Injection may be more available than 0.9% Sodium Chloride Injection and vice-versa depending product availability and allocation schedules.
- Develop medical staff-approved policies for substitution of IV solutions based on product availability within the organization. Example: an organization might allow substitution of Lactated Ringer's Injection for 0.9% Sodium Chloride Injection or vice-versa depending on what is in stock. [Table 1](#) provides a comparison of common intravenous fluid components.

Patient Clinical Evaluation

- Frequently, or at minimum once each shift, evaluate the clinical need to continue intravenous fluid therapy. Consider identifying specific clinical personnel to actively monitor usage for each patient.
- Discontinue infusions as soon as appropriate. Consider stop orders for infusions, for example 24–48 hour automatic stops, if not reordered.
- Frequently, or at minimum once each shift, assess need to continue “keep vein open” (KVO) orders.
- Consider locking catheters rather than infusing 0.9% sodium chloride injection at a KVO rate when possible.

- Consider flushing central venous access devices (CVADs) 1–3 times per week rather than daily.
- Evaluate total fluid requirements for surgeries. The *American College of Surgeons: Principles and Practice 2014* notes that total volume replacement needs for elective surgeries are much less (500 mL to 3000 mL total) than previously thought (4500 mL to 6000 mL total).¹

Product Conservation

- Use small-volume bags for low infusion rates (see [Table 2](#)).
- Consider reserving some products for specific clinical situations. [Table 3](#) outlines potential suggestions, but is not inclusive of all possible actions.
- Consider deferring elective procedures and surgeries requiring 0.9% Sodium Chloride Injection or other solutions in short supply.
- Consider hang times longer than 24 hours for solutions (if infusion is spiked immediately prior to administration). There is no nationally published guideline recommending a maximum hang time for an infusion. If longer hang times are used, hospital leadership; medical, nursing and pharmacy staff; infection control; risk management; and other stakeholders should weigh the risk of infection against the need to conserve intravenous solutions. Note: hang times should not exceed manufacturers' instructions, if available, or beyond-use dating assigned according to *USP-NF Chapter <797>, Compounding Sterile Preparations* for compounded solutions.
- Evaluate the clinical practice of using flush bags for intermittent medications when no primary solution is being administered. 0.9% Sodium Chloride flush syringes are an alternative.
- Use commercially available dialysis solutions whenever possible, instead of compounding with 0.9% sodium chloride.

Inventory Control Strategies

- Evaluate IV fluid supplies on a health system-wide basis in order to redeploy solutions to areas of greatest need.
- Minimize unit stock of large-volume bags to the extent possible or stock product only in critical care areas where fluids are an essential component of emergency supplies.
- Ensure smaller volume bags are stocked in other supply areas, especially pediatric areas.
- Limit quantities of bags placed in warmers.
- Ensure purchasing agents have active backorders in place and are obtaining allocations as available.
- Frequently communicate with distributor as allocations and shipment dates may be unpredictable.
- Establish routine conference calls or meetings among stakeholders to discuss supply status before supplies become critically low.
- Avoid buying products from sources outside the traditional supply chain. Report suspected illegal activity by nontraditional distributors to the state board of pharmacy, state attorney general, or [FDA's Office of Criminal Investigation](#).
- Provide regular or as needed updates on shortage status and action plan adjustments to clinicians and other organizational stakeholders (e.g., risk management/patient safety, leadership, etc.)
- The use of multiple communication methods is highly recommended.

Caveats / Safety information

- Compounding sodium chloride solutions from sterile water for injection and concentrated sodium chloride injection is error-prone, labor-intensive, and may worsen the existing shortage of concentrated sodium chloride injection. In addition, the high-volume of product needed to meet patient needs makes compounding impractical. Compounding should be limited to solutions needed to meet urgent short-term needs for sodium and fluid replacement therapy, when commercial products are unavailable.
- Reflect use of smaller volumes in infusion pump libraries, pre-printed or electronic order sets, and standard IV fluid labels as needed.
- Avoid intravenous use of sodium chloride irrigation solution. Sterility requirements and limits on particulate matter differ between these two products.

Table 1. Comparison of Selected Intravenous Fluids²⁻⁷

Product	mOsm /L	Na (mEq/L)	Cl (mEq/L)	Dextrose (g/L)	K (mEq/L)	Ca (mEq/L)	Lactate (mEq/L)	Mg (mEq/L)	Acetate (mEq/L)	Gluconate (mEq/L)
0.9% Sodium Chloride Injection	308	154	154	---	---	---	---	---	---	---
0.45% Sodium Chloride Injection	154	77	77	---	---	---	---	---	---	---
5% Dextrose and 0.225% Sodium Chloride Injection	329	38.5	38.5	50	---	---	---	---	---	---
5% Dextrose and 0.45% Sodium Chloride Injection	406	77	77	50	---	---	---	---	---	---
5% Dextrose and 0.9% Sodium Chloride Injection	560	154	154	50	---	---	---	---	---	---
5% Dextrose Injection	252	---	---	50	---	---	---	---	---	---
Lactated Ringer's Injection	273	130	109		4	2.7	28	---	---	---
Lactated Ringer's and 5% Dextrose Injection	525	130	109	50	4	2.7	28	---	---	---
Normosol-R	294	140	98	---	5	---	---	3	27	23
Plasma-lyte A	294	140	98	---	5	---	---	3	27	23

Table 2. Recommended Container Volumes Based on Infusion Rates

Infusion Rate	Bag Size
20 mL/hour or less	250 mL
21 mL/hour to 40 mL/hour	500 mL
41 mL/hour or greater	1000 mL

Table 3. Considerations for Reserving Products for Selected Clinical Situations⁸⁻¹¹

Clinical Situation	Product	Comments
Large volume replacement (surgery)	Lactated Ringer's Injection	Large volumes of 0.9% sodium chloride may contribute to hyperchloremic acidosis.
Patients requiring sodium restriction	Products containing Dextrose 5% Injection	Consider reserving a supply of fluids with lower sodium content for these patients.
Patients susceptible to hypoglycemia	Products containing Dextrose 5% Injection	Women and children may be more susceptible to hypoglycemia following fasts > 24 hours.
Pediatric patients requiring volume replacement	0.9% Sodium chloride Injection	Pediatric patients are susceptible to water intoxication and hyponatremia if sodium chloride replacement is inadequate.

References

1. Evolution of Intraoperative Fluid Therapy for Elective Surgeries: Historical and Current Fluid Requirements. In: Souba WW, Fink MP, Jurkovich GJ, Kaiser LR, Pearce WH, Pemberton JH, Soper NJ. *ACS Surgery: Principles and Practice 2014*. Accessed March 1, 2014 via STAT!Ref Online Electronic Medical Library. <http://online.statref.com/Document.aspx?fxId=61&docId=158>.
2. Hospira. Lactated Ringer's Injection USP, Lactated Ringer's and 5% Dextrose Injection, USP [product information]. Lake Forest, IL: Hospira; 2009.
3. Hospira. Dextrose and Sodium Chloride Injection, USP [product information]. Lake Forest, IL: Hospira; 2009.
4. Hospira. Sodium Chloride Injection, USP [product information]. Lake Forest, IL: Hospira; 2010.
5. Hospira. Dextrose Injection, USP [product information]. Lake Forest, IL: Hospira; 2010.
6. Hospira. Normosol-R [product information]. Lake Forest, IL: Hospira; 2009.
7. Baxter. Plasma-Lyte A [product information]. Deerfield, IL: Baxter; 2013.
8. Intravenous Fluids. In: Morgan GE, Michail MS, Jurray MJ, eds. *Clinical Anesthesiology*. 4th ed. New York, NY: Lange Medical Books / McGraw-Hill Medical; 2005: 692-6.
9. Peng ZY, Kellum JA. Perioperative fluids: a clear road ahead? *Curr Opin Crit Care*. 2013 Aug;19(4):353-8.
10. Raghunathan K, Shaw AD, Bagshaw SM. Fluids are drugs: type, dose and toxicity. *Curr Opin Crit Care*. 2013 Aug;19(4):290-8.
11. Institution for Safe Medication Practices Medication Safety Alert: Regarding the Current IV Solution Shortage Affecting U.S. Hospitals. 2014 Jan 30. <http://www.ismp.org/newsletters/acutecare/showarticle.aspx?id=69> Accessed March 9, 2014.

This information was developed by the Drug Information Center of University of Utah in collaboration with the American Society of Health-System Pharmacists. ASHP and the University of Utah neither endorse nor recommend the strategies for the use of any drug or product, nor assume any liability for persons providing medications or other medical care in reliance upon this information. Users of this information must exercise their independent professional judgment when using this information to make decisions regarding the use of drugs and drug therapies.