ACMT Position Statement on Sterile Solution Shortage
January 8, 2025

Authors: Maryann Mazer-Amirshahi, PharmD, MD, MPH, PhD; Erin Fox, PharmD; Andrew I. Stolbach, MD, MPH

The position of the American College of Medical Toxicology, is as follows:

Sterile solutions are not only used for fluid resuscitation and maintenance, but also for irrigation during procedures as well as diluents for medication administration. In the wake of multiple, severe, longstanding sterile fluid shortages, ACMT calls upon stakeholders to implement measures to promote supply chain resiliency to ensure access to these basic, critical medical products.

Background

Sterile fluids are essential to the practice of medicine. Intravenous fluids are used as life-saving treatments for fluid resuscitation and for maintenance of fluid balance. Sterile fluids are also used for irrigation during procedures and for cleaning medical equipment. Smaller volumes are used for dilution and as delivery mechanisms for other medications that are administered parenterally.

Sterile fluids are an integral part of medical toxicology practice. Large volume sterile solutions, such as lactated ringers and normal saline are first line treatments for gastrointestinal losses or hypotension due to toxins. Many antidotes and general medications provided for supportive care of poisoned patients are diluted and administered via intravenous piggyback or infusions that require small volume parenteral bags. In addition, medical toxicologists often assist with the management of medication errors or adverse drug events that may occur as a result of solution shortages. For example, errors and adverse events may occur when medications that are typically given by intravenous infusions are administered via intravenous push. Substitution of products can make certain safety checks such as barcode scanning, more difficult. Increased compounding due to solution shortages can result in dilution errors that can result in toxicity. Poisoned patients may also have complications due to

alternative therapies when fluids are in short supply, such as limb ischemia when vasopressors are instituted earlier in the patient's care. Medical toxicologists are often involved in institutional or system level committees, such as pharmacy and therapeutics, that make decisions regarding shortage mitigation.

Despite their widespread use in nearly every facet of medicine, sterile fluids have been impacted by several widespread and sometimes longstanding drug shortages [1]. These shortages are often due to manufacturing problems at manufacturing facilities or increases in demand; however, in recent years, natural disasters have also precipitated critical shortages. In 2017, Hurricane Maria devastated the Baxter facility in Puerto Rico that produced nearly 50% of the small volume fluids used in the U.S. More recently, in 2024, Hurricane Helene caused damage to another Baxter facility in North Carolina that produced approximately 60% of the sterile fluid supply for the U.S [2,3]. Such shortages can have a profound impact on healthcare delivery and patient outcomes [1,4]

Sterile fluids for parenteral administration or irrigation are basic medical supplies, yet they require manufacturing and technical expertise to ensure the final products meet specifications making them safe to use. While facilities are often costly to maintain and operate, profit margins for these products are limited [5]. Because of this, manufacturers often consolidate production into a handful of facilities with limited capacity for expansion. This lack of resilience in the supply chain can lead to critical shortages when there is a problem at an individual plant or if there is a surge in demand for a product [1,5].

Given the impact sterile solution shortages can have not only on the practice of medical toxicology, but on patient care as a whole, ACMT calls upon stakeholders to implement measures to support a more resilient supply chain of these critical products.

Disclaimer

While individual practices may differ, this is the position of the American College of Medical Toxicology at the time written, after a review of the issue and pertinent literature.

Recommendations

- Develop a framework for improving the medical supply chain based on awareness, preparedness, response, and mitigation.
- FDA should collect and maintain data regarding the location of manufacturing plants and capacity of each plant to expand production or if there is flexibility in the type of fluids that can be produced there.
- Manufacturers should develop contingency plans for redirection of production when there is a shortage of a critical product(s).

· Consider addition of sterile solutions to the Strategic National Stockpile, recognizing the size of these products may limit the ability to stockpile large amounts.
· Provide governmental incentives to manufacturers who add additional manufacturing sites, expand capacity at existing facilities, and those that diversify production or fortify facilities to withstand severe weather challenges.
· Legislation should enhance the Food and Drug Administration Safety and Innovation Act (FDASIA)requirements for notification of drug shortages to include reasons for shortages, as well as estimated timelines and durations.
· Modify labeling requirements to change the labeling laws to establish a rating system for manufacturers based on quality (similar to hospital star ratings).
· Require manufacturers to maintain stability data to allow for extension of expiration dates when necessary.
· The Department of Justice and Federal Trade Commission should consider potential public health impact to pharmaceutical supply when reviewing healthcare industry mergers and acquisitions.
· The Department of Health and Human Services and the Department of Homeland Security should review drug supply as a part of national security measures.
· Proactively develop importation protocols to minimize delays when importation is required.
· Institutions should develop protocols to prepare for shortages and enact conservation measures when alerted of a potential shortage.
· Promote communication and transparency with regards to available supply to frontline purchasers and clinicians.

References:

1. Mazer-Amirshahi M, Fox ER, Zocchi MS, Pines JM, van den Anker JN. Longitudinal trends in U.S. shortages of sterile solutions, 2001-17. Am J Health Syst Pharm. 2018 Dec 1;75(23):1903-1908.
2. Mazer-Amirshahi M, Fox ER. Saline Shortages - Many Causes, No Simple Solution. N Engl J Med. 2018 Apr 19;378(16):1472-1474.
3. U.S. Food and Drug Administration. Hurricane Helene: Baxter's manufacturing recovery in North Carolina. https://www.fda.gov/drugs/updates-2024-hurricane-season/hurricane-helene-baxters-manufacturing-recovery-north-carolina. Accessed December 15, 2024.
4. Hick JL, Hanfling D, Courtney B, Lurie N. Rationing salt water--disaster planning and daily care delivery. N Engl J Med. 2014 Apr 24;370(17):1573-6.
5. Woodcock J, Wosinska M. Economic and technological drivers of generic sterile injectable drug shortages. Clin Pharmacol Ther. 2013 Feb;93(2):170-6. doi: 10.1038/clpt.2012.220.