By Tyler A. Vest, PharmD, BCPS; Michelle A. Carrasquillo, PharmD; and Samuel M. Eberwein, PharmD, MS, BCPS

Strategies for Managing the IV Fluid Shortage

The US Commonwealth of Puerto Rico is known for its white sandy beaches and stunning landscapes; likewise, many pharmaceutical manufacturers call this paradise home. An estimated 10% of all pharmaceuticals used in the US are produced in Puerto Rico.[1,2] Small volume (<100 mL) IV fluids have been a commonly produced item by manufacturers on the island.[3]

When Hurricane Maria made landfall in Puerto Rico, on September 20, 2017, the result was widespread destruction to the island's infrastructure. In addition to destroying access to basic resources, including water, shelter, and power, the damages have caused massive disruptions in the manufacturing of multiple pharmaceutical products. Of particular concern is the production of small-volume IV fluids, including mix-on-demand systems. This substantial impact to the nation's drug supply chain has caused a critical shortage situation, leaving health care organizations without a critical component for patient care. These crucial IV fluids are regularly used for compounded sterile preparations (CSPs); without access, many institutions are facing unprecedented operational challenges to maintain care. To overcome the IV fluid shortage, health care organizations must identify and utilize alternative drug preparation and administration strategies.

Operational Strategies to Mitigate IV Fluid Shortages

Operational strategies do exist to ensure the maintenance of safe patient care during this shortage, including:

- Maximizing available IV fluid inventory
- Clinical interventions (IV to oral conversion, clinical alternatives)
- Prepared/mix-on-demand IV products
- Third-party purchases/utilization of imported IV fluids
- Alternative administration methods (IV push, elastomeric pumps, Buretrols)

Organizational alignment is key for implementing any of these strategies. Physicians, pharmacists, nurses, and supply chain leadership should connect early and often to determine which strategies are most effective for maintaining daily operations.

Maximize Available IV Fluid Inventory

Robust control of IV fluid inventory is critical for organizations addressing the shortage. Institutions may be unaware of the extent of their IV fluid use outside of the pharmacy, and communicating promptly with frontline staff to establish practice habits will assist in gaining an accurate understanding of how much IV fluid is used. Familiarity with practice will also help leadership determine the impact of any decisions related to changes made to address the shortage. Centralizing all IV fluid stock in one location is a quick approach for maintaining accurate inventory counts.[4]

Physicians, pharmacists, nurses, and supply chain leadership should connect early and often to determine which strategies are most effective for maintaining daily operations.

Once an institution has an accurate picture of IV fluid inventory, local allocation decisions can be made to determine which critical areas are to receive stock. This information is essential for pharmacy and nursing leadership to coordinate changes in drug preparation strategies to maximize IV fluid inventory. For example, an organization may have a larger stock of a certain size IV fluid bag (50 mL) compared to other sizes (25 mL, 100 mL, etc). Strategically converting drug preparation or fluid administration to the available quantities on hand is necessary to preserve the existing supply of IV fluids for as long as possible. As a last resort,

some organizations may be forced to repackage large-volume (>1000 mL) IV fluids into smaller volumes.

While each organization will have a different number of IV fluids on hand (and distribution of IV fluid bag sizes), appropriate allocation for drug preparation and critical patient care needs are integral considerations for organizational leadership in maintaining operations.

Clinical Interventions

Clinical interventions are a proactive method for health care providers to conserve IV fluids. Oral formulations are commonly available for a majority of medications, and are typically regarded as the safest and most convenient method of medication administration. Many organizations have an IV to PO policy for patients who qualify, which offers multiple benefits, including patient safety and conservation of IV fluid stock. In addition to pharmacist interventions, other health care providers must be diligent when reviewing patients each day to determine eligibility for receiving oral medications.

Pursue clinical alternatives to IV medications, especially when an equally efficacious oral medication option exists. For example, vancomycin is a commonly initiated empiric antibiotic requiring dilution in small-volume 250 mL and 500 mL fluid bags. Linezolid and daptomycin are clinical alternatives to vancomycin that can be administered orally and as IV push, respectively; many other IV anti-infectives have existing alternatives. Switch to clinically effective oral options as soon as possible.[5]

Premixed and Ready-to-Use IV Products

Utilizing already prepared IV products is an option for overcoming the IV fluid shortage. Multiple products are available in premixed formulations that can be stored at room temperature or frozen, depending on the product, including aztreonam, cefazolin, cefepime, penicillin, piperacillin/tazobactam, and vancomycin. Organizations pursuing these options will need to ensure that necessary storage space, especially for frozen products, is available to house this inventory.

Ready-to-use systems provide another alternative method of drug preparation pharmacies can implement to conserve IV fluid stock. While one ready-to-use system is severely affected by the shortage, similar systems remain available on the market. These ready-to-use systems can help with conserving IV fluids as they have specific IV fluid bags for connection or allow for IV fluid conservation until the medication is administered. However, introducing new drug delivery systems may require significant staff training and education to ensure proper use.

Ready-to-use systems provide another alternative method of drug preparation pharmacies can implement to conserve IV fluid stock. While one ready-to-use system is severely affected by the shortage, similar systems remain available on the market.

Third-Party Purchases/ Utilization of Imported IV Fluids

Partnering with a third-party supplier outside of an organization's normal drug supply channels is an additional method for obtaining IV fluid stock. Developing this strategy takes significant effort and time from a contracting and purchasing perspective; however, the FDA is expediting its reviews of new product applications to help address the shortage. This strategy can be highly effective if the third-party supplier has adequate inventory to meet the demand of current and future needs. Moreover, the relationships developed through this method may also serve the organization well in the event of future shortages.

The emergent nature of the IV fluid shortage may not allow sufficient time to vet third-party suppliers through an organization's normal processes. Thus, it is important to recognize the increased risks in expediting reviews of third-party suppliers, and to keep patient safety in the forefront when making decisions to introduce new fluid products.

In addition to expediting new product reviews, the FDA has temporarily approved the importation of IV fluids made in foreign facilities. Current importation sources include Australia, Canada, Ireland, and Mexico. These fluid products will be introduced into the supply chain through distribution channels as allocated by the manufacturer. Organizations will likely be placed on wait lists to gain access to these imported fluids, so anticipate implementing other operational strategies to manage the IV fluid shortage before these are readily available for use.

Alternative Administration Methods

Another strategy to reduce the amount of IV fluids being consumed is to convert medication administration to alternative methods that do not involve small-volume IV fluids. IV push is a

common, safe, and effective method of drug administration that organizations can implement quickly to conserve fluids. ISMP has developed best practices related to IV push medication administration, which institutions are advised to use as a model for implementing any IV push administration strategy.[6] Among the drugs which may be given as IV push, many are antibiotics, including: cefazolin, cefepime, cefotaxime, cefotetan, cefoxitin, ceftaroline, ceftazidime, ceftriaxone, cefuroxime, aztreonam, colistimethate, daptomycin, ertapenem, and meropenem.[7]

When converting to IV push, organizational leadership will need to work closely with pharmacy and nursing to determine where drug preparation should occur. Pharmacies will have the ability to prepare syringes for IV push; however, an individual organization's operational strategy may require nurse reconstitution of these drugs for immediate bedside administration. Organizations are encouraged to maintain preparation of medication in the pharmacy due to the engineering controls and staff expertise; however, resource limitations may necessitate nurse reconstitution of IV push medications. USP <797> includes vial reconstitution within its definition of what is considered a compounded sterile preparation (CSP). Therefore, organizations choosing to implement a nurse reconstitution strategy for drug preparation should be aware of the <797> guidelines related to immediate-use CSPs and the need for immediate bedside administration following reconstitution.[8] Additionally, The Joint Commission (TJC) standards related to medication management indicate nurse reconstitution of medications with immediate bedside administration is acceptable practice when delays in medication delivery could result in adverse patient outcomes.[9] If electing to move forward with the IV push strategy, detailed nursing instructions must be developed and distributed to ensure safe administration. Specific information must denote the following: IV push administration rate, reconstitution diluent, reconstituted solution stability, extended stability information, and any other relevant comments for medication preparation (eg, designated preparation areas).

Further conservation of IV fluids may be achieved by administering drugs through different types of delivery systems. Organizations may have the ability to prepare drugs in syringes and infuse them via syringe pumps. If syringe pumps are not available, adaptors for certain IV pumps may be available to facilitate syringe infusions. Elastomeric pumps provide another solution to conserve IV fluids. These types of pumps infuse medication at a set flow rate, and are prepared by inserting the medication into an elastic balloon contained inside a hard outer cover. The set flow rates of elastomeric pumps provide a high level of consistency and accuracy, and assist in infusing drugs not requiring titration.[10] Buretrols, commonly used drug delivery systems in the 1970s, use a sterile chamber that infuses medication in conjunction with a large-volume IV fluid solution. Consider Buretrols as a last resort due to the patient safety implications of the inconsistent infusion rates.[11]

The primary challenge associated with utilizing these alternatives is having the stock available to compound them. Organizations may not be equipped with sufficient syringe pumps, elastomeric supplies, or Buretrols to meet all patient needs with a single strategy. A combination of alternative administration methods, with other operational strategies, is likely necessary to successfully navigate the IV fluid shortage.

Implementation of Operational Strategies

The operational strategies described herein require careful attention to ensure safe implementation. As the shortage crisis continues to evolve, it is imperative that organizations consider the advantages and disadvantages associated with all of the available strategies. At a minimum, discussions for implementation of operational strategies should address:

- Operational strategy chosen
- Evaluation of the impact on practice change
- Electronic health record (EHR) changes needed
- Other technology system (eg, infusion pump libraries) changes needed
- Educational needs of all staff
- Policy/quick reference updates (eg, IV infusion guidelines)
- Additional changes anticipated following implementation

Developing a systematic approach to evaluate each strategy and establish an implementation plan is the first step toward an institution's success. Evaluate the practice impact to determine organizational priorities and the feasibility of local implementation. Some strategies may require approval from the P&T Committee or other institutional decision-making entities, which further necessitates early organizational alignment when undertaking any operational change.

Robust communication is imperative if organizations choose to pursue alternative operational strategies. Although email is a common methodology for communication, it can be unreliable. Follow up with organizational leadership and ensure information is shared in staff meetings and in routine, day-to-day conversations.

Changes to the EHR and other automation systems are often required to ensure safe, effective medication use when alternative strategies are utilized to mitigate a shortage. It is critical to understand how each operational strategy utilized will affect the systems in use. Go-live dates for operations need to be determined in conjunction with all required electronic changes to ensure appropriate safety checks are in place for facilitating drug preparation and administration.

Staff education is critical when any operational change occurs, but is even more vital in the event of a quickly paced change, as required to address the IV fluid shortage. Health care organizations may be unaccustomed to this rate of change, so it is beneficial to post educational documents in common areas. By clearly outlining the changes being made, and reinforcing these changes with communication strategies, staff will more easily adjust to the practice change. For example, the University of North Carolina Medical Center has developed a table describing our strategies for managing the IV fluid shortage (see **TABLE 1**).

Planning for the future has become increasingly important to manage the IV fluid shortage. The increased demand for products to facilitate alternative dispensing strategies has created additional shortages, further complicating an already dire situation. It is imperative for organizations to anticipate an environment of constant change during these unprecedented circumstances, and to have strategies in place for changing operations when the previous strategy is no longer an option.

Conclusion

The effect of Hurricane Maria on the production of IV fluids continues to weigh heavily on daily operational decisions. Estimates suggest that the IV fluid shortage may not be fully resolved until Fall 2018, although this date depends on how quickly manufacturers are able to return to pre-hurricane production levels. Thus, many organizations will need to use a combination of strategies to overcome the challenges presented by the shortages.

Operational strategies will need to change based on IV fluid inventories throughout the duration of the shortage, and health care organizations must be nimble in order to adapt to the many challenges that will arise. Proactive evaluation and implementation of operational strategies will ensure successful navigation of the IV fluid shortage and ensure high-quality, consistent patient care. ■

Tyler A. Vest, PharmD, BCPS, is a PGY2 health-system pharmacy administration resident at the University of North Carolina (UNC) Medical Center and a 2018 MS degree candidate at the UNC Eshelman School of Pharmacy in Chapel Hill, North Carolina. He earned his Doctor of Pharmacy from the University of Cincinnati James L. Winkle College of Pharmacy and is a board-certified pharmacotherapy specialist. Tyler serves as the resident manager for perioperative pharmacy services at UNC Medical Center. His professional interests include leadership development, practice advancement and pharmacy practice models, the medication-use process, and oncology.

Michelle A. Carrasquillo, PharmD, is a PGY2 health-system pharmacy administration resident at the UNC Medical Center and a 2018 MS degree candidate at the UNC Eshelman School of Pharmacy. She earned her Doctor of Pharmacy from the University of Florida College of Pharmacy and serves as the resident manager for investigational drug services at UNC Medical Center. Michelle's professional interests include practice advancement, evidence-based research, oncology, and specialty pharmacy operations.

Samuel M. Eberwein, PharmD, MS, BCPS, is the clinical manager of pharmacy for the sterile products area, perioperative services, and special formulations at UNC Medical Center. He earned his Doctor of Pharmacy from Campbell University and his Master of Science with an emphasis in health-system pharmacy administration from the UNC Eshelman School of Pharmacy while completing his 2-year health-system pharmacy administration residency at UNC Hospitals. Samuel is a board-certified pharmacotherapy specialist. He maintains active professional involvement in ASHP and the North Carolina Association of Pharmacists.

References

1. Hurricane Maria Updates: In Puerto Rico, the Storm 'Destroyed Us'. *New York Times*. www.nytimes.com/2017/09/21/us/hurricane-maria-puerto-rico.html. Accessed February 15, 2018.
2. U.S. Hospitals Wrestle With Shortages of Drug Supplies Made in Puerto Rico. www.nytimes.com/2017/10/23/health/puerto-rico-hurricane-maria-drug-shortage.html. Accessed February 15, 2018.
3. Baxter Provides Update on Puerto Rico Recovery Status Post Hurricane Maria. www.baxter.com/news-media/newsroom/press-releases/2017/10-12-17-baxter-provides-puerto-rico-update.page. Accessed February 15, 2018.
4. Small-Volume Parenteral Solutions Shortages. ASHP. www.ashp.org/Drug-Shortages/Shortage-Resources/Publications/Small-Volume-Parenteral-Solutions-Shortages. Accessed February 15, 2018.
5. Statement by FDA Commissioner Scott Gottlieb, MD, on efforts to address impact of IV fluid shortages following hurricane destruction and resolve manufacturing shortfalls. https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm585720.htm. Accessed February 15, 2018.
6. ISMP Safe Practice Guidelines for Adult IV Push Medications. www.ismp.org/Tools/guidelines/ivsummitpush/ivpushmedguidelines.pdf. Accessed February 15, 2018.
7. Trissel LA. *Handbook on Injectable Drugs.* 15th ed. Bethesda, MD: American Society of Health-System Pharmacists; 2009.
8. The United States Pharmacopeia, 35th rev, and the National Formulary 30th ed. USP General Information Chapter <797>. Pharmaceutical Compounding-Sterile Preparations. Rockville, MD: 2012.
9. Joint Commission International. Joint Commission International Standards for Hospitals, 6th ed. Oak Brook, IL: Joint Commission Resources, 2016.
10. Weisman RS, Missair A, Pham P, et al. Accuracy and consistency of modern elastomeric pumps. *Reg Anesth Pain Med.* 2014;39(5):423-428.
11. Nahata MC. Ensuring safe and effective medication use in pediatric patients. *J Pediatr Pharmacol Ther.* 2014;19(1):4-9.

TABLE 1

UNC Medical Center Strategies for Managing the IV Fluid Shortage

Drug	Current Process	Pharmacy Changes	Drug Preparation Notes	Nursing Changes
Ampicillin 1g	RTU Vial/ Bag System[1]	Compound in pharmacy with 50 mL bags.		Pump library will be updated with a new entry. Doses will be delivered to patient-specific area in medication room.
Ampicillin 2g	RTU Vial/ Bag System[1]	Compound in pharmacy with 50 mL bags.	Must reconstitute vials and inject into bag. No transfer needles.	Pump library will be updated with a new entry. Doses will be delivered to patient-specific area in medication room.
Ampicillin/ Sulbactam 1.5g	RTU Vial/ Bag System[1]	Compound in pharmacy with 50 mL bags.		Pump library will be updated with a new entry. Doses will be delivered to patient-specific area in medication room.
Ampicillin/ Sulbactam 3g	RTU Vial/ Bag System[1]	Switch to other RTU vial and bag system		No change.
Aztreonam 1g	RTU Vial/ Bag System[1]	Stock drug vials in ADCs.	N/A	Reconstitute vial with 9 mL Sterile Water for Injection. Administer via slow IV Push over 3-5 minutes.
Aztreonam 2g	RTU Vial/ Bag System[1]	Stock drug vials in ADCs.	N/A	Reconstitute vial with 17.8 mL Sterile Water for Injection. Administer via slow IV Push over 3-5 minutes.
Cefazolin 2g	Premade Bags	No change at this time.		No change.
Cefepime 1g	RTU Vial/ Bag System[1]	Compound in pharmacy with 50 mL bags.		Pump library will be updated with a new entry. Doses will be delivered to patient-specific area in medication room.
Cefepime 2g	Premade Frozen Bags[2]	Evaluating Shared Services Center (SSC) batching options.		Pump library will be updated with a new entry for the pharmacy compounded bags. Pharmacy compounded bags will be delivered to patient-specific area in medication room.
Cefoxitin	RTU Vial/ Bag System[1]	Compound in pharmacy with 50 mL bags.		Pump library will be updated with a new entry. Doses will be delivered to patient-specific area in medication room.
Ceftazidime 1g	RTU Vial/ Bag System[1]	Compound in pharmacy with 50 mL bags. Evaluating SSC batching.		Pump library will be updated with a new entry. Doses will be delivered to patient-specific area in medication room.
Ceftazidime 2g	RTU Vial/ Bag System[1]	Compound in pharmacy with 50 mL bags. Evaluating SSC batching.		Pump library will be updated with a new entry. Doses will be delivered to patient-specific area in medication room.
Ceftriaxone 1g	RTU Vial/ Bag System[1]	Switch to other RTU vial and bag system		No change.
Ceftriaxone 2g	RTU Vial/ Bag System[1]	Switch to other RTU vial and bag system		No change.
Cefuroxime 1.5g	RTU Vial/ Bag System[1]	Compound in pharmacy with 50 mL bags.		Pump library will be updated with a new entry. Doses will be delivered to patient-specific area in medication room.
Daptomycin	50 mL Bags	Volume increase anticipated.		No change.

Drug	Current Process	Pharmacy Changes	Drug Preparation Notes	Nursing Changes
Doxycycline 100mg	100 mL Bags	Encouraging the use of oral doxycycline instead of IV.		No change.
Ertapenem 1g	RTU Vial/ Bag System[1]	Compound in pharmacy with 50 mL bags.		Pump library will be updated with a new entry. Doses will be delivered to patient-specific area in medication room.
Meropenem 1g	RTU Vial/ Bag System[1]	Compound in pharmacy with 50 mL bags.		Pump library will be updated with a new entry. Doses will be delivered to patient-specific area in medication room.
Meropenem 2g	100 mL Bags	Compound in pharmacy with 50 mL bags.	Must reconstitute vials and inject into bag. No transfer needles.	Pump library will be updated with a new entry. Doses will be delivered to patient-specific area in medication room.
Meropenem 500mg	RTU Vial/ Bag System[1]	Compound in pharmacy with 50 mL bags.		Pump library will be updated with a new entry. Doses will be delivered to patient-specific area in medication room.
Metronidazole 500mg	Premade Bag	Encourage the use of oral metronidazole instead of IV.		No change.
Micafungin 100mg	100 mL Bags	Compound in pharmacy with 50 mL bags.	Must reconstitute vials and inject into bag. No transfer needles.	Pump library will be updated with a new entry. Doses will be delivered to patient-specific area in medication room.
Micafungin 150mg	100 mL Bags	No change at this time.	Must leave in 100 mL bags (cannot be >1.5 mg/mL for peripheral lines).	No change.
Oxacillin 2g	RTU Vial/ Bag System[1]	Compound in pharmacy with 50 mL bags.		Pump library will be updated with a new entry. Doses will be delivered to patient-specific area in medication room.
Phenytoin	100 mL Bags	Prepare doses < 250mg in syringes. Doses ≥ 250mg will be prepared in 50 mL bags.		Doses < 250mg should be pushed no faster than 50 mg/min.
Thiamine 500mg	100 mL Bags	Compound in pharmacy with 50 mL bags.		Pump library will be updated with a new entry. Doses will be delivered to patient-specific area in medication room.
Vancomycin 750mg	250 mL Bags	Pursuing clinical alternatives.	No change.	No change.
Vancomycin 1000mg	Premade Frozen Bags[2]	Pursuing clinical alternatives.	No change.	No change.
Vancomycin 1250mg	250 mL Bags	Pursuing clinical alternatives.	No change.	No change.
Vancomycin 1500mg	500 mL Bags	Pursuing clinical alternatives.	No change.	No change.
Vancomycin 1750mg	500 mL Bags	Pursuing clinical alternatives.	No change.	No change.
Vancomycin 2000mg	500 mL Bags	Pursuing clinical alternatives.	No change.	No change.

[1]RTU vial and bag systems are put together in pharmacy and are either stocked in ADCs or dispensed from central pharmacy for specific patient orders.
[2]Premade frozen bags are thawed in pharmacy and are either stocked in ADCs or dispensed from central pharmacy for specific patient orders.