

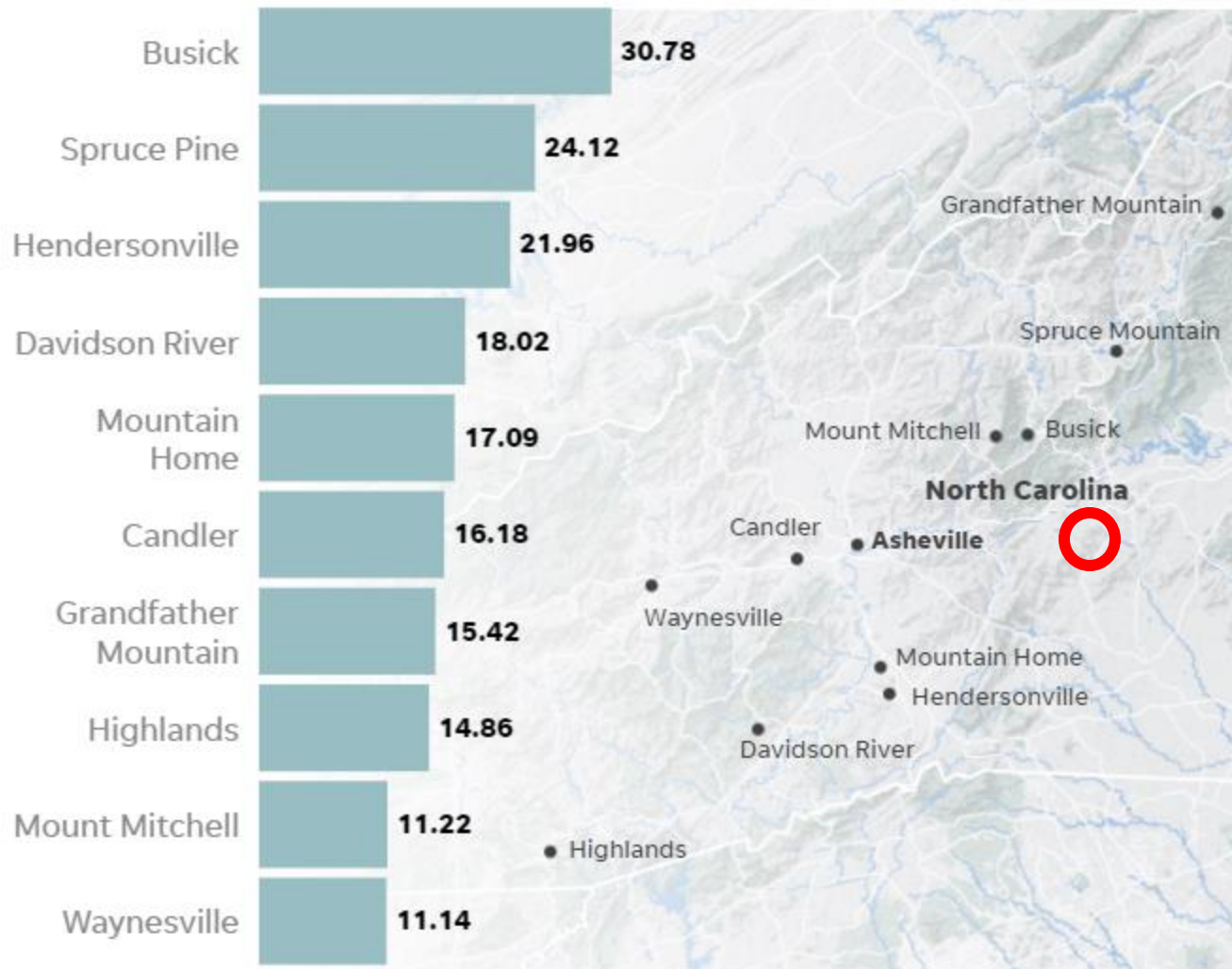
November 19th, 2024

- Announcements: No Sessions Next Week, Antibiotic Awareness Week, Bluesky (@uwcsim)
- John Lynch: *IV Fluid Stewardship*
- Facility Question

What Happened?



The National Weather Service released rainfall totals in inches for the following areas through 8 a.m. local time on Saturday.



SOURCES NWS, NOAA

GRAPHIC Jennifer Borresen/USA TODAY



Residents of Marshall, N.C. begin cleaning up businesses and the area around Main Street after catastrophic flooding of the nearby French Broad River caused by the remnants of Hurricane Helene destroyed much of the area. *Josh Morgan / USA TODAY*



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PERSPECTIVE

FACING THE SHORTAGE OF IV FLUIDS

Facing the Shortage of IV Fluids — A Hospital-Based Oral Rehydration Strategy

Andrés M. Patiño, M.D., Regan H. Marsh, M.D., M.P.H., Eric J. Nilles, M.D., Christopher W. Baugh, M.D., M.B.A., Shada A. Rouhani, M.D., M.P.H., and Stephanie Kayden, M.D., M.P.H.

Published March 21, 2018 | N Engl J Med 2018;378:1475-1477 | DOI: 10.1056/NEJMp1801772 | [VOL. 378 NO. 16](#)



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Puerto Rico produces 44% of the intravenous (IV) fluid bags used in the United States.¹ On September 20, 2017, Hurricane Maria struck the island, causing a humanitarian crisis and widespread devastation that escalated a critical shortage of IV fluids throughout the United States. Initially, small-volume bags — 50- and 100-ml bags used to dilute medications — became scarce. Today, the larger 500- and 1000-ml IV-fluid bags are also in short supply. U.S. hospitals are scrambling to develop strategies for rationing IV fluids to ensure availability for the patients who need them most.

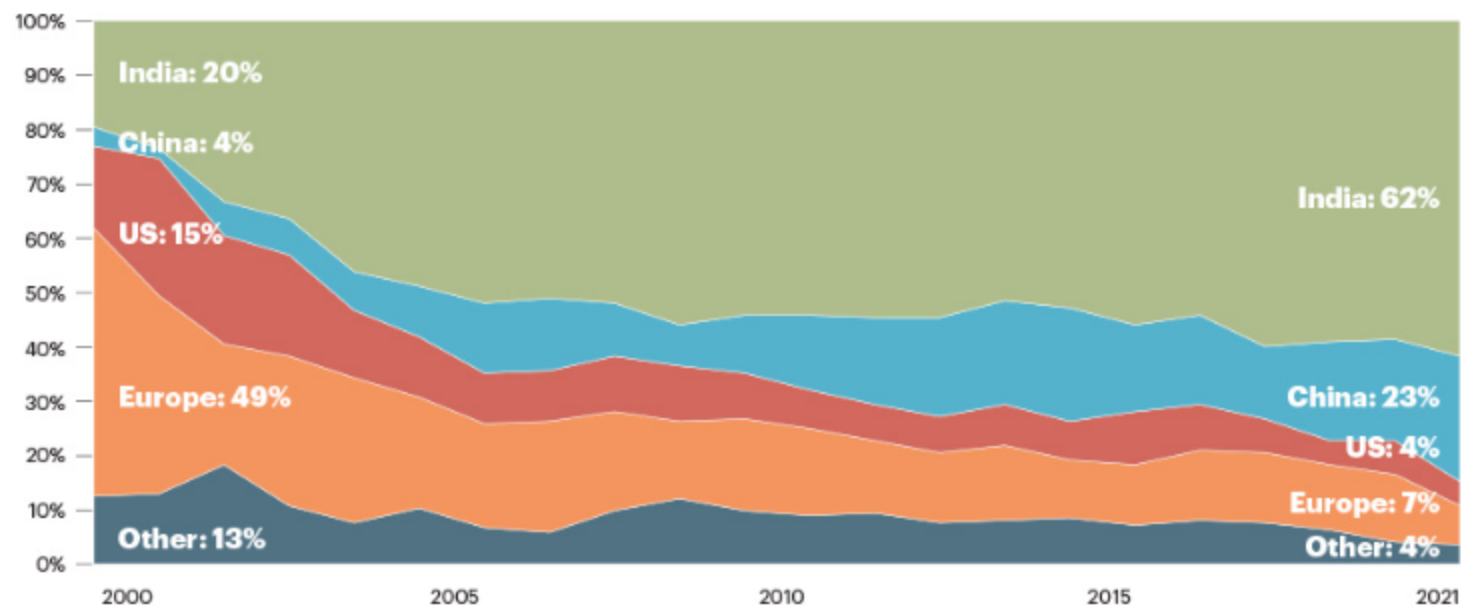
Hurricane Maria is only the latest challenge to the U.S. IV-fluid supply. Since 2014, U.S. hospitals have faced varying degrees of IV-fluid shortages, whose causes were multifactorial. IV-fluid production is complex and highly regulated in order to ensure quality and safety, which makes it expensive for hospitals and compounding pharmacies to produce their own. Most of the IV fluid used in the United States is produced by only three manufacturers, so availability is vulnerable to even small fluctuations in supply. In addition, hospitals buy IV fluids through large group-purchasing organizations representing hundreds of hospitals so that they can negotiate with manufacturers for lower prices or better access to scarce resources. Some observers argue that these organizations' market power keeps prices so low that they create a disincentive for manufacturers to increase production or for small producers to enter the market.²

Given these supply-side constraints, the U.S. IV-fluid supply will be vulnerable for the foreseeable future. It is therefore critical for U.S. hospitals to develop both short- and long-term alternatives to IV-fluid use.



Geographic concentration of pharmaceutical manufacturing: USP Medicine Supply Map analysis

Chart II: Active API Drug Master Files, by year of filing and country of manufacture



Source: US Pharmacopeia Medicine Supply Map

- India contributed 62% of active API DMFs filed in 2021, up from 20% filed in 2000. This increase is consistent with the country's well-publicized **national ambition** to enhance API manufacturing capabilities.
- Europe's contribution declined from 49% of active API DMFs filed in 2000 to 7% filed in 2021
- China contributed 18% of new API DMFs filed in 2019, and 23% filed in 2021
- U.S. contributed 4% of new API DMFs filed in 2019 and 2021



American Hospital
Association™

Advancing Health in America

AHA to President Urging the Administration to Take Action to Address IV Solution Supply Shortage as a Result of Helene

[Home](#) / [Advocacy](#) / [Letter/Comment](#)

October 7, 2024

President Joseph R. Biden
The White House
1600 Pennsylvania Avenue, NW
Washington, D.C. 20500

Dear President Biden:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, our clinician partners — including more than 270,000 affiliated physicians, 2 million nurses and other caregivers — and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the Administration's actions taken to date related to the devastating impact Hurricane Helene has had on individuals, communities and hospitals in the southeast.

The AHA and its members also are deeply concerned about the closure of Baxter's plant in Marion, N.C., due to damage caused by Hurricane Helene. This facility is a critical supplier of intravenous (IV) and peritoneal dialysis solutions, producing approximately 60% — or 1.5 million bags — of the IV solutions

Disruptions in Availability of Peritoneal Dialysis and Intravenous Solutions from Baxter International Facility in North Carolina

[Print](#)



Distributed via the CDC Health Alert Network

October 12, 2024, 8:30 AM ET

CDCHAN-00518

<https://emergency.cdc.gov/han/2024/han00518.asp>



System/Incident Command

- Communicate supply situation with providers and keep them updated with current strategies and expectations.
- Communicate with suppliers about ongoing needs/product availability.
- Establish a process to review current strategies and adjust to dynamic changes in product availability. This process should include pharmacy, clinician leaders, and leadership/incident command.
- Review/update treatment protocols.
- Reinforce provider and patient safety principles when not using usual products and procedures to prevent provider injury and medical errors.
- Share information with healthcare coalition, state, and other regional partners to ensure awareness of the severity of the shortage and currently implemented strategies.

General Strategies

- Maintain situational awareness of available formulations of fluids and use alternatives when available.
- Prioritize the use of crystalloid fluids for resuscitation/critical care and during major surgical procedures.
- Centralize stock of IV bags to the degree possible. Minimize par levels on units, particularly in non-critical care areas.
- **Transition as much fluid management as possible to oral and enteral forms.**
- Provide IV fluids in relation to need and acuity rather than empirically.
- Transition medications that require secondary IV fluids for administration to oral.
- Calibrate fluids to the type of bags available and the minimum necessary (e.g., if 500mL bags are in adequate supply, consider giving one of those rather than a 1000mL bag).
- Do not use IV fluids for non-IV use (e.g., irrigation).
- Reserve dextrose-containing IV fluids for patients who are hypoglycemic or at high risk (e.g., a pediatric patient unable to take oral fluids).
- Work with information technology to implement ordering alerts in the electronic health record (EHR) to prompt consideration of alternatives.

Oral Rehydration Therapy Protocol [304500]

[Expand All](#) [Collapse All](#)

General Instructions:

1. Age 13 or older and > 40 Kg
2. Mild dehydration
3. Blood Glucose < 150 and Creatinine < 1.5
4. Hemodynamically stable
5. Awake/alert/cooperative
6. Re-evaluate patient's ability to resuscitate volume orally & order IVF when appropriate
7. Target hydration goal: 1000 mL in about 2 hours (patients with vomiting can maintain a slower rate of intake)

Exclusion Criteria:

1. Moderate to severe dehydration
2. Inability to receive oral intake for another reason

Nursing [101336]

Notify Physician

☒ Notify Provider (Specify) [NUR183] 

Until discontinued, Starting today

Notify provider for the following:

1. Vomiting or pain not controlled by available supportive care medications.
2. Inability to drink prescribed volume of oral rehydration.

Medications [103192]

Rehydration Options [449565] (Selection Required)

☐ pediatric electrolyte replacement (Pedialyte) solution - for dehydration WITH vomiting [42866] 

1,000 mL, Oral, Once, For 1 Doses

Give 30 mL (2 large sips) PO every 5 minutes.

If patient tolerates intake of 250 mL without nausea/vomiting, intake can increase to 60 mL PO every 5 minutes.

===May substitute two 20 oz bottles of Gatorlyte for 1 L of Pedialyte, depending on availability ===

☐ pediatric electrolyte replacement (Pedialyte) solution - for dehydration WITHOUT vomiting [42866] 

1,000 mL, Oral, Once, For 1 Doses

Give 30 mL (2 large sips) PO every 3 minutes.

If patient tolerates intake of 250 mL without nausea/vomiting, intake can increase to 60 mL PO every 3 minutes.

===May substitute two 20 oz bottles of Gatorlyte for 1 L of Pedialyte, depending on availability ===

Antiemetics [449566]

Add antiemetic if oral intake is insufficient

☐ ondansetron (Zofran) injection [239706] 

4-8 mg, Intravenous, Every 8 hours PRN, nausea/vomiting

If PO not tolerated or ineffective

☐ ondansetron (Zofran ODT) disintegrating tablet [207795]  4-8 mg, Oral, Every 8 hours PRN, nausea/vomiting

Analgesics [449568]

Add pain control for pharyngitis

☐ phenol (Chloraseptic) mouth/throat spray [217757]  1 spray, Mouth/Throat, Every 1 hour PRN, sore throat

Pharmacy

- Review common infusion medications for potential conversion to push-dose (e.g., ceftriaxone).
- Consider changes to infusion concentrations to adapt to available bag sizes.
- Switch to oral antibiotics as soon as possible.
- Consider thresholds for repletion of electrolytes via intravenous route (e.g., intravenous potassium use restricted unless below a threshold value).
- Consider oral or IV alternatives to antibiotics that require large-volume IV fluids (e.g., vancomycin, trimethoprim/sulfamethoxazole).
- Use sterile water when appropriate for reconstitution and administration of medications.
- Consider allowing use of spiked/primed IV bags that were prepared but never connected to a patient for a short period of time (e.g., 12-24 hours).
- Use small-volume bags when appropriate for slow infusion rates.
- Use syringe pumps when appropriate for pediatric or other infusions obtaining sterile saline from vials rather than bags to fill syringes.
- Consider extending “hang times” beyond 24 hours for IV bags as appropriate.



Emergency Department

- Guide fluid resuscitation based on individual patient assessment rather than a protocol approach (e.g., consider whether a patient with potential sepsis but not signs of shock requires 30mL/kg IV fluids).
- Trial oral hydration whenever possible.
- Avoid use of medications that require IV bags when possible (e.g., antibiotics, electrolytes).
- Consider whether the patient is appropriate for non-invasive monitoring. Arterial lines require IV saline bags for circuit priming and pressurization.

Surgical Services

- Consider changing nothing by mouth (NPO) times prior to procedures to allow the ingestion of clear fluids closer to the time of procedure (e.g., up to 2 hours prior to procedure).
- Consider on an individual basis which patients require fluids based on the anesthetic, procedure, procedure duration, anticipated blood loss, patient medical history (e.g., renal function), and other factors.
- Consider whether the patient is appropriate for non-invasive monitoring. Arterial lines require IV saline bags for circuit priming and pressurization.

Inpatient Units

- Encourage oral or enteral fluids rather than IV; review IV maintenance fluids daily for discontinuation. Consider EHR prompts for alternatives to IV fluid orders.
- Consider removing maintenance fluids from order sets in the EHR and allow orders for 24-hour periods only.
- Do not use “keep open” lines or orders.
- Switch to oral/enteral alternatives as soon as possible from medications that require IV secondary administration bags.



DEERFIELD, Ill. - 2024-11-14

- All 2,500+ North Cove employees have been accounted for following Hurricane Helene. Employees have returned to work across the facility. Remediation contractors also remain engaged on a temporary basis to support site recovery.

- **NEW:** As previously projected, **Baxter restarted a second IV solutions manufacturing line this week.** Together with the line restarted the week of Oct. 28, these two lines represent – at their peak operation (prior to Hurricane Helene) – approximately 50% of the site’s total production and approximately 85% of the site’s production of one-liter IV solutions, the most commonly used size by hospitals and clinics.

- Barring any unanticipated developments, we currently expect that **peritoneal dialysis (PD) solutions and irrigation** will be the **next two manufacturing lines to restart in early December.**



DEERFIELD, Ill. - 2024-11-14

- Thanks to the support of ASPR, North Carolina Department of Transportation and our local team, the **second temporary bridge has been installed at the site and is officially in operation as of the week of Nov. 4.** This bridge enables additional truck and equipment traffic to enter and leave the site. Our first temporary bridge has already **transported more than 1,100 truckloads of finished product (manufactured pre-hurricane) off site and to customers.**

- **Global Manufacturing Network:** To date, we have activated nine plants across our global network to help increase available inventory, which is contemplated in current allocation levels.

- **U.S. Distribution for Products Authorized for Temporary Importation:** Baxter continues to carefully manage the availability of both previously finished goods coming out of North Cove and the import of product to the U.S., providing specific resources and training to those customers receiving product imported to the U.S.

- **U.S. Expiry Extensions for IV and Irrigation Products:** Baxter has received FDA authorization to extend the use dates of 50+ IV and irrigation codes to provide up to an additional 12 months of expiry. Products now have a 24-month expiry period from the date of manufacture. This extension only applies to products manufactured prior to the end of September 2024. Details have been communicated directly to customers.

- **IV Solutions Allocations:**

- On Nov. 11, Baxter further communicated with customers that, barring any unanticipated developments, we expect to reach 100% allocation across several IV product codes by the end of the year with additional details on planned, phased increases in allocations in late November, mid-December and end of year. This update is to help support customers' ability to plan for patient care, and is based on 1) the current and projected status of our North Cove remediation efforts, 2) our expectations regarding our ability to reallocate capacity from other Baxter facilities, and 3) temporary importation on certain products.
- Until the first planned increase for certain codes in late November, allocation levels for both direct customers and distributors remain as previously communicated by Baxter on Oct. 9.
- To date, we have evaluated and approved hundreds of allocation exception requests to help support neonatal and pediatric patient needs.

Resources

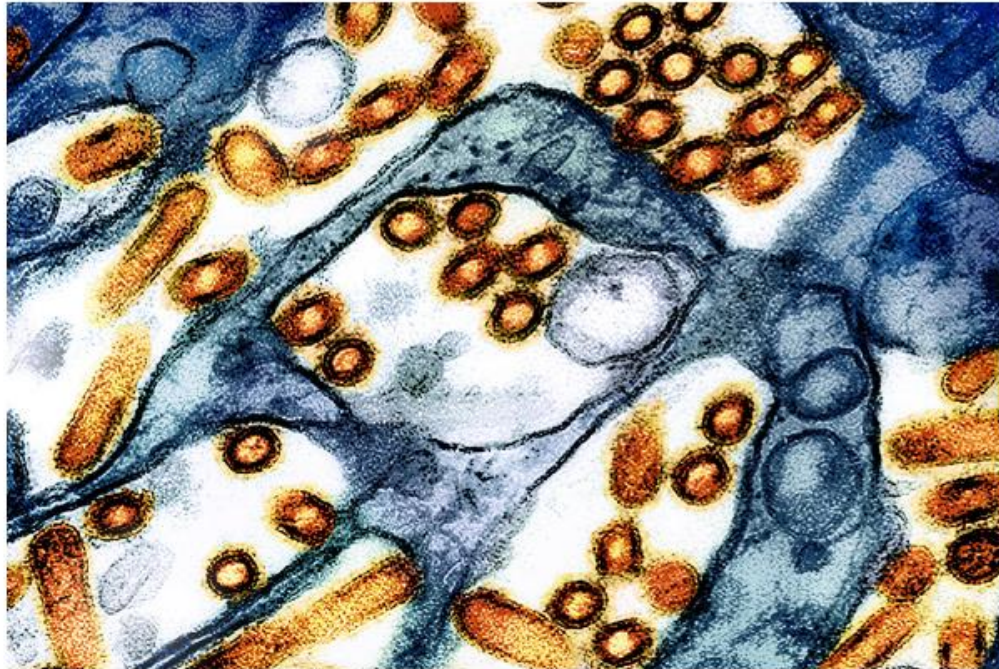
- <https://www.ashp.org/drug-shortages/shortage-resources/publications/fluid-shortages-suggestions-for-management-and-conservation?loginreturnUrl=SSOCheckOnly>
- <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/temporary-policies-compounding-certain-parenteral-drug-products>
- <https://files.asprtracie.hhs.gov/documents/iv-fluid-shortage-strategies.pdf>

Canada Detects Its First Human Case of Bird Flu

A teenager in British Columbia was hospitalized in critical condition with the disease, and officials were working to find out how the person was exposed to the virus.

▶ Listen to this article · 3:05 min [Learn more](#)

📺 Share full article



A colorized electron microscope image of avian influenza grown in cultured cells.
Centers for Disease Control

By [Vjosa Isai](#)

Reporting from Toronto

Nov. 13, 2024

First U.S. Case of Spreading New Mpox Type Reported in California

The unidentified patient had recently returned from Africa, where the virus has caused a deadly epidemic, health officials said.



Share full article



A health worker treated a mpox patient in the Democratic Republic of Congo in August. A person in California has tested positive for a type of mpox after returning from a recent trip to East Africa. Moses Sawasawa/Associated Press