

Recommendations for Ethical Allocation of Sterilized Fluids

NOVEMBER 15, 2024

Disclaimer: This document summarizes recommendations to ethically address a critical sterilized fluid shortage. **It does not carry the force or effect of law, and it should not be construed as a statement of legal or regulatory requirements and protections.** Health care facilities or systems implementing strategies to manage resource shortages and other crisis situations are strongly encouraged to consult with their legal counsel, and coordinate their efforts with health system leadership, Health Care Coalition (HCC) partners, and MDH.

Background

There is a national shortage of IV fluids and other fluid products that will likely last through 2024 due to the Baxter manufacturing outage related to Hurricane Helene.¹ These shortages have affected the ability of providers in Minnesota to provide resources consistently and reliably to all patients. Updates on this shortage are maintained by the U.S. Food and Drug Administration online: [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).

This document provides a voluntary framework for the ethical allocation of these resources; it is intended to assist providers in their care delivery and organizational response during this period of shortage. It also aims to provide a basis for consistent response to this situation among institutions and systems across the State of Minnesota, to promote transparency, fairness, and equity to provide the best care possible to all patients throughout the state of Minnesota. It is based on common ethical values that have been affirmed in Minnesota through a public engagement process regarding crisis

¹ US Food and Drug Administration (FDA) Hurricane Helene: Baxter's manufacturing recovery in North Carolina. October 2024. <https://www.fda.gov/drugs/updates-2024-hurricane-season/hurricane-helene-baxters-manufacturing-recovery-north-carolina>

response,² bioethics literature,^{3,4} and guidance from state⁵ and national^{6,7,8,9} groups. It incorporates the input of a statewide expert panel of physicians with expertise in pediatric and adult medicine, pharmacists, ethicists, MDH’s Science Advisory Team and Minnesota Department of Health (MDH) staff, convened by the Metro Health & Medical Preparedness Coalition in collaboration with the other health care coalitions in the state, at the request of health professionals involved in managing the shortage.

This framework recommends conservation and substitution strategies to preserve supply of IV fluids and other sterile fluid products in shortage (for simplicity, hereafter referred to as “fluids”) due to the Baxter Manufacturing outage. It also recommends strategies for prioritizing allocation of these resources, if, despite an organization’s best efforts to mitigate the shortages, supplies are insufficient to meet the needs of all patients. **The goal is to manage the shortages while preventing adverse outcomes for patients, if possible.** Systems/facilities should implement all available measures that can mitigate the shortages while preventing adverse outcomes for patients. This may include postponing non-emergent procedures if other mitigation strategies will be insufficient to preserve supplies for patients in need. **Systems/facilities should transition to prioritized allocation only if aggressive implementation of mitigation strategies (including postponing procedures) does not preserve sufficient supplies to meet the needs of all patients, and other systems/facilities are similarly situated so sharing supplies is not possible.** Prioritized allocation may result in adverse outcomes for patients even while maximizing benefits and minimizing harms across the population of patients needing the resources.

Ethical criteria for the allocation of fluids during the shortage

The following recommendations apply to the context of the shortage of fluids. They do not necessarily capture best practices in conventional conditions – that is, in the absence of these resource shortages.

Responsibly steward supplies of fluids:

Adopt strategies to mitigate the shortages so that, as far as possible, care provided can be functionally equivalent to that delivered in conventional (normal) conditions. This means that, while care provided will be different, patient outcomes will be substantially comparable (even if not identical) to those achieved in conventional conditions. Serious adverse outcomes should not be expected due to altered care delivery. For more information on transitions between conventional, contingency and crisis conditions,

² Minnesota Department of Health (MDH). Minnesota Crisis Standards of Care Framework: Ethical Guidance. Updated: 01/10/2020. Available at <https://www.health.state.mn.us/communities/ep/surge/crisis/framework.pdf>.

³ Michael Manolakis, Ethical integrity in managing drug shortages, *American Journal of Health-System Pharmacy*, Volume 69, Issue 1, 1 January 2012, Page 17, <https://doi.org/10.2146/ajhp110640>

⁴ Philip M. Rosoff. Unpredictable Drug Shortages: An Ethical Framework for Short-Term Rationing in Hospitals. *The American Journal of Bioethics* 12:1, 2012: 1-9. Available at <https://www.tandfonline.com/doi/full/10.1080/15265161.2011.634483?scroll=top&needAccess=true&role=tab>.

⁵ Minnesota Department of Health (MDH). Patient Care Strategies for Scarce Resource Situations: Medication Administration. August 2021. <https://www.health.state.mn.us/communities/ep/surge/crisis/standards.pdf> See section 5.

⁶ US Dept of Health and Human Services Administration for Strategic Preparedness and Response Technical Resources, Assistance Center, and Information Exchange (ASPR TRACIE). Intravenous Fluid Shortage Strategies. October 2024 <https://files.asprtracie.hhs.gov/documents/iv-fluid-shortage-strategies.pdf>.

⁷ US Food and Drug Administration (FDA) Hurricane Helene: Baxter’s manufacturing recovery in North Carolina. October 2024. <https://www.fda.gov/drugs/updates-2024-hurricane-season/hurricane-helene-baxters-manufacturing-recovery-north-carolina>

⁸ American Society of Hospital Pharmacists (ASHP). Small- and Large-Volume Fluid Shortages – Suggestions for Management and Conservation. October 2024. https://www.ashp.org/drug-shortages/shortage-resources/publications/fluid-shortages-suggestions-for-management-and-conservation?_gl=1*defqep*_gcl_au*MzczMzgzNDM2LiE3MjgwNjQwNjE.*_ga*MTgzNzQwMzgwNS4xNzI4MDY0MDYy*_ga_5WL5JPM7T0*MTcy0DY5MTUzNC40LjEuMTcyODY5MTCwNy4yNS4wLjA

⁹ Academic Life in Emergency Medicine (ALiEM). Strategies for Surviving the IV Fluid Shortage: Antibiotic IV to PO Conversions & First Dose via IV Push. December 13, 2017. <https://www.aliem.com/surviving-iv-fluid-shortage-antibiotic-po-conversions-and-iv-push/>

please see [Ethical Framework for Transitions Between Conventional, Contingency, and Crisis Conditions in Pervasive or Catastrophic Public Health Events with Medical Surge Implications](#).¹⁰

Mitigation strategies should be applied more aggressively as supply becomes more constrained.

Substitute:

- In the context of shortage of product supplied by one manufacturer, use alternative product brands if possible. Note that this may not be possible, given that alternatives may also be in short supply given protective allocations.¹¹ Further, similar isotonic crystalloids should be substituted for one another whenever possible, depending on availability.
- Use alternative therapies such as oral rehydration for non-critically ill patients, enteral feeding, and oral medications when doing so will not significantly impact patient outcomes.^{12,13,14,15}
- Temporary guidance from FDA on compounding fluids that are in shortage is available on the [FDA webpage](#)¹⁶.

Conserve:

- Evaluate protocols for fluid administration to conserve supplies, aiming to avoid significantly impacting patient outcomes. Conservation strategies include those listed in guidance from the following: [ASPR TRACIE](#)¹⁷, [American Society of Hospital Pharmacists](#)¹⁸, the [American Society of Nephrology](#) and the [American Society of Pediatric Nephrology](#)^{19,20}.
- Avoid, whenever possible, the use of fluids for TKO (to keep open) indications. Further, since it is customary to change from one fluid to another when the area of care changes (i.e., ED to an inpatient unit), this should be avoided until the bag of fluids being given is used.

¹⁰ Minnesota Department of Health (MDH). Ethical Framework for Transitions Between Conventional, Contingency, and Crisis Conditions in Pervasive or Catastrophic Public Health Events with Medical Surge Implications: MINNESOTA CRISIS STANDARDS OF CARE. 11/24.21. https://www.health.state.mn.us/communities/ep/surge/crisis/framework_transitions.pdf

¹¹ Xavier Becerra, US Secretary of Health and Human Services. Letter to Health Care Leaders and Stakeholders on Impacts of Hurricane Helene from Secretary Becerra. October 9, 2024. <https://www.hhs.gov/about/news/2024/10/09/letter-health-care-leaders-stakeholders-impacts-hurricane-helene-secretary-becerra.html>

¹² US Dept of Health and Human Services Administration for Strategic Preparedness and Response Technical Resources, Assistance Center, and Information Exchange (ASPR TRACIE). Intravenous Fluid Shortage Strategies. October 2024 <https://files.asprtracie.hhs.gov/documents/iv-fluid-shortage-strategies.pdf>.

¹³ Minnesota Department of Health. Patient Care Strategies for Scarce Resource Situations: Medication Administration. August 2021. <https://www.health.state.mn.us/communities/ep/surge/crisis/standards.pdf> See section 5.

¹⁴ Baxter. Medical Information Letter for Healthcare Facilities. September 30, 2024. https://www.baxter.com/sites/g/files/ebysai3896/files/2024-10/9-30_Medical%20Information%20Letter.pdf

¹⁵ American Society of Hospital Pharmacists (ASHP). Small- and Large-Volume Fluid Shortages – Suggestions for Management and Conservation. October 2024. <https://www.ashp.org/drug-shortages/shortage-resources/publications/fluid-shortages-suggestions-for-management-and-conservation?loginreturnUrl=SSOCheckOnly/>

¹⁶ US Food and Drug Administration (FDA). Temporary Policies for Compounding Certain Parenteral Drug Products. <https://www.fda.gov/media/182632/download>

¹⁷ US Dept of Health and Human Services Administration for Strategic Preparedness and Response Technical Resources, Assistance Center, and Information Exchange (ASPR TRACIE). Intravenous Fluid Shortage Strategies. October 2024 <https://files.asprtracie.hhs.gov/documents/iv-fluid-shortage-strategies.pdf>.

¹⁸ American Society of Hospital Pharmacists (ASHP). Small- and Large-Volume Fluid Shortages – Suggestions for Management and Conservation. October 2024. <https://www.ashp.org/drug-shortages/shortage-resources/publications/fluid-shortages-suggestions-for-management-and-conservation?loginreturnUrl=SSOCheckOnly/>

¹⁹ American Society of Nephrology. Interim strategies for peritoneal dialysis (PD) solution use for prevalent patients undergoing PD. https://www.asn-online.org/news/2024/1007-PD_Solutions.pdf

²⁰ American Society of Pediatric Nephrology. Interim Guidance on PD Solution Conservation During Supply Shortage. <https://aspneph.org/interim-guidance-on-pd-solution-conservation-during-supply-shortage/>

- Pause non-emergent procedures that may be postponed without significant risk of adverse outcomes related to the delay.
 - The [Appendix](#) provides recommendations about incorporating the pausing of procedures into mitigation strategies as supplies become more constrained.

Maximize benefit of these scarce resources while minimizing harms and promoting equity:

- **When the mitigation strategies noted above are insufficient to maintain functional equivalence to care during normal times, then the ethical objective of response shifts from a focus on patient-centered care to a focus on promoting overall benefit to the population while respecting rights and promoting fairness and equity.** This is a shift from *contingency conditions* to *crisis conditions*.²¹
- **Since there will be variation in supply of different fluid products, the appropriate timing for transitioning from mitigation to allocation that benefits the population overall will differ from product to product.** Systems/facilities should transition to prioritized allocation for a product only if there is insufficient supply of that particular product to meet patient needs, despite mitigation efforts, and it is not possible to secure additional supply from other facilities.
- When a system/facility determines that functional equivalence can no longer be maintained, then prioritized allocation strategies should be implemented by the system/facility. Healthcare systems/facilities are responsible for implementing strategies that are proportional to the shortage.²²
- **Clinical risks and benefits of treatment should guide treatment decisions.** If there is insufficient supply to treat all patients who need fluids, even after implementing the substitution and conservation strategies outlined above, prioritize patients at highest risk of poor outcomes if they do not receive fluids, [per the list of categories in the Appendix](#). **Prognosis should be understood in terms of likelihood to survive the current episode of acute illness or preventing a foreseeable episode of acute illness, not long-term survival or quality of life.**
 - Prioritize patients in the following groups: patients in Category 1 should be prioritized over those in Category 2 (and so on through the list of categories). All patients within each category should be taken to have equivalent priority - the bulleted list within each category does not present an ordering of priority for allocation.
 - Categories can be found in the [Appendix](#).
 - When allocation is required among patients with equivalent priority, use a randomization process. Healthcare systems/facilities should use a process that works for them (which may involve one of many online randomizers), and should decide how often to implement randomization based on their patient population and their capacity for managing this aspect of allocation. Randomization is the fairest process for allocating among patients who are similarly situated in terms of risk.
 - A facility's allocation and randomization process should include all eligible patients – those who normally receive care at the facility as well as new patients who do not normally access treatment through the facility and patients who are transferred to the facility.

²¹ Minnesota Department of Health (MDH). Ethical Framework for Transitions Between Conventional, Contingency, and Crisis Conditions in Pervasive or Catastrophic Public Health Events with Medical Surge Implications: MINNESOTA CRISIS STANDARDS OF CARE. 11/24/21. https://www.health.state.mn.us/communities/ep/surge/crisis/framework_transitions.pdf

²² Minnesota Department of Health (MDH). Ethical Framework for Transitions Between Conventional, Contingency, and Crisis Conditions in Pervasive or Catastrophic Public Health Events with Medical Surge Implications: MINNESOTA CRISIS STANDARDS OF CARE. 11/24/21. https://www.health.state.mn.us/communities/ep/surge/crisis/framework_transitions.pdf

to provide this information. While the Regional Healthcare Preparedness Coordinator (RHPC) who is working to facilitate sharing as outlined below may convey this request for information, it is not the RHPC's role to track the mitigation strategies used by different hospitals or to verify information provided. The RHPC's only role is to offer assistance in locating available supplies, if possible.

- If any hospital in the state has insufficient fluids to care for current or potential patients in Category 1, 2 or 3 within the next 48 or 72 hours based on supplies, it should utilize its normal processes, within its system and between healthcare systems, to secure supply. If the hospital is unsuccessful in accessing supply, they may reach out to their [Regional Healthcare Preparedness Coordinator \(RHPC\)](#) to help identify available supply. **Hospitals should not wait until they have a patient with urgent need, if possible, because the process to secure supply for sharing may take some time.**
 - The RHPC will coordinate the following decision-making process:
 - Identify whether another system or facility may be able to support the patient's needs.
 - Review the case with both facilities to determine the optimal strategy, either transferring the fluids across system/facilities, or transferring the patient's care to the accepting system/facility.
 - If both options are possible, it would be more equitable to transfer fluids between systems/facilities, since this will avoid unduly disadvantaging the patient by requiring travel, additional expense, or other burdens to access the resource.

In extreme shortages where there are multiple needs, there may be more patients in need than there are supplies of fluids to be shared. In these cases, MDH will follow their policy to facilitate a structured approach for scarce resource allocation.

Sample planning tools can be found in the [Appendix](#). Facilities/systems may adapt these planning tools to fit their particular circumstances (e.g., their specific practices for ordering/stockpiling supplies).

Appendix

Prioritization of patients for fluids

This prioritization was developed by an advisory group of subject matter experts in the state of Minnesota, in collaboration with the Minnesota Department of Health. This prioritization is based on expert opinion.

Category 1 (highest risk):

- Hemodynamically unstable patients requiring fluid resuscitation regardless of location
 - Hemodynamic instability characterized in terms of age-appropriate vital signs indicators of shock
- Hemodynamically stable patients with emergent surgical need (e.g., risk of death without surgical intervention)

Category 2:

- Hemodynamically stable patients with urgent surgical need (e.g., risk of harm without surgical intervention)
- Hemodynamically stable patients aged 3 years and younger at risk of hemodynamic instability
- Hemodynamically stable patients who require fluids based on their diagnosis or with evidence-based indication for fluids (for example, diabetic ketoacidosis, chronic TPN dependence)
- Hemodynamically stable patients currently unable to take PO and without enteral access (e.g., encephalopathic or stroke patient who cannot swallow safely currently without a feeding tube)

Category 3:

- Inpatients who cannot be discharged from the hospital without a surgical intervention
- Patients with conditions that would very likely necessitate hospital admission within 1-2 weeks without procedural intervention that requires fluids
- Ambulatory and in-home infusions being administered to prevent hospitalization within the next 1-2 weeks (e.g., IV antibiotics or biologics for autoimmune disease)
- Curative chemotherapy
- Inpatient and emergency department use for hemodynamically stable patients with other indications for use of fluids than Category 2
- Planned C-sections

Category 4:

- Ambulatory and in-home infusions being administered to prevent hospitalization

- within the next 2-4 weeks
- Infusions used with palliative chemotherapy infusions

Category 5:

- Non urgent ambulatory infusion services including routine hydration services

Category 6:

- Other indications for fluids

Planning tools

Facilities/systems may adapt the following planning tools to fit their particular circumstances (e.g., their specific practices for ordering/stockpiling supplies).

Strategy table

Tool for implementing a gradual transition across the continuum of care (Note: mitigation includes conservation and substitution strategies outlined above. Mitigation strategies should be applied more aggressively as supply becomes more constrained.)

Supply	Phase	Strategies
15-30 days' supply	Contingency	Mitigation Can share across systems to avoid preventable harm
10-14 days' supply with no or reduced resupply	Contingency	Mitigation Pause Tier 1 procedures Can share across systems to avoid preventable harm
7-10 days' supply	Contingency	Mitigation Pause Tier 2 procedures Stop sharing Deferral
3-7 days	Contingency Approaching Crisis	Mitigation Pause Tier 3 procedures
<3 days	Crisis	Implement Crisis Standards of Care

Additional guidance on pausing procedures

Procedures that can be done without fluids should continue and if any tiers are paused should be moved up if possible if they are scheduled out.	
Tier 1	Can safely delay for greater than 90 days <ul style="list-style-type: none"> • Low risk of long-term consequences • Low risk of disease progression • No or low risk of infection if not performed • No or mild impact on physical function and/or quality of life

Tier 2	Can delay for up to 90 days <ul style="list-style-type: none"> Low to moderate risk of long-term consequences Low to moderate risk of disease progression Low to moderate risk of infection if not performed Low to moderate impact on physical function and/or quality of life Includes non-urgent ambulatory infusion services including routine hydration services and office-based procedures requiring use of IV fluids
Tier 3	Can delay for up to 30 days <ul style="list-style-type: none"> Moderate risk of long-term consequences Moderate risk of disease progression Moderate risk of infection if not performed Moderate impact on physical function and/or quality of life Includes infusions administered to prevent hospitalization within the next 2-4 weeks

Tool for tracking degree of scarcity of specific product types

	LR	SOD Chloride	Plasma LYT	Dextrose 5%	Dextrose 10%	Sterile Water	Irrigation
Conventional (31 days or more of supply)							
Contingency (8-30 days of supply)							
Contingency Approaching Crisis (7 or fewer days of supply)							
Crisis (3 day supply)							

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