DEPARTMENT OF HEALTH

EMERGENCY PREPAREDNESS AND RESPONSE
SCIENCE ADVISORY TEAM

Pharmaceutical Shortages for Minnesota Hospitals

FREQUENTLY ASKED QUESTIONS

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Shortages of pharmaceuticals, intravenous fluids, and hospital nutrition products are becoming a way of life for health care providers. The FDA lists 122 current medication shortages (FDA Drug Shortages (http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm) accessed July, 2026). Many of these are extremely common, often life-saving injectable medications, and several of them have few substitutes. The recent shortages of epinephrine, calcium, and other basic medications as well as administration bags help emphasize that no supply chain is safe from potential shortages. Though not a disaster, these shortages often require adaptive strategies identical to Crisis Standards of Care processes and thus provide an opportunity for a structured response in addition to ethical and procedural guidance for allocation decisions. The following provides answers and discussion to common questions related to drug shortages.

Why do medication shortages occur, and why do they seem so common?

A variety of factors contribute to shortages. Shortages have resulted from manufacturers eliminating medications from their product lines due to decreasing margins or due to consolidation of manufacturers. More often, shortages are due to lack of raw materials, contamination of product, limitation of production due to regulatory, maintenance, or other production issues**.** Damage to production facilities can also cause disruption as occurred in Puerto Rico after Hurricane Maria. Injectable generic medications are particularly at risk due to their slim profit margins, paucity of manufacturers, and compliance/sterility regulations required for their production. Rarely, the shortage is on the consumer end, as was the case with potassium iodide after the Fukushima Daiichi reactor meltdown caused spikes in demand in California. Even when product is available from alternate sources or suppliers the cost of those alternative medications may be prohibitive for both providers and patients. Despite the large number of medications in shortage the FDA estimates that over 132 additional shortages were *prevented* in 2017 alone due to its actions.

How big an impact do these shortages have?

Unfortunately, when certain medications aren't available, this may compromise treatment. This is particularly a problem in oncology, where shortage of basic chemotherapy agents has led to delays or altered treatment plans. Since the most common medications affected (80%) are generic, injectable medications, the impact of most shortages is felt by the hospitals, where use of unfamiliar medications or concentrations can lead to dosing errors, inappropriate or inadequate treatment, and other problems. Though exact impact on care is difficult to quantify, a recent survey of oncologists found that up to half of patients had their chemotherapy modified due to shortages. An American Society of Anesthesiologists 2012 survey with 3,063 responders reported six deaths were suspected of being related to medication substitutions and 2/3 of providers noted less serious adverse events. The increased cost of alternative medications also has significant consequences for patients, hospitals and payers. This may result in inadequate treatment for acute and chronic conditions.

When a shortage occurs, what actions are taken to try to maintain supply?

Manufacturers may allocate stock by percentage of request and historical order volumes to distributors (or according to direct contracts, though these are less common), or the FDA may intervene to assure rapid correction of any regulatory issues or recalls that may have prompted the shortage. The FDA may also look to international markets temporarily to approve other products for US distribution.

When our regional distributor has more requests than available product what actions are taken?

Wholesalers (such as Amerisource/Bergin, Cardinal, and McKesson) may have to allocate supplies, generally preferentially filling orders from hospitals and health systems over retail pharmacies. The wholesalers will look at 'usual use' numbers for the facilities to determine the allocation amount and try to fulfill a percentage of the order amount for everyone, rather than filling some orders and not others. Building a strong relationship with the wholesaler is important for better accuracy of usual consumed quantities and for a higher priority to receive product. Regional distributors will also look to their national warehouses and supply lines for additional materials.

One thing that regional distributors will *not* do is buy back product from 'gray market' vendors or look for large-scale compounding pharmacies to fulfill orders.

What if hospitals try to 'game the system' by ordering more than they need during a shortage?

Because the wholesalers know their customers and usual orders, orders that are inconsistently high would be flagged for review and if there was not a specific reason for the increase, would be filled according to usual order volumes. If all hospitals were requesting larger amounts than usual due to demand, the wholesalers would fill orders as a percentage of usual use unless there were specific facilities that were more impacted by an event.

How can a hospital or health system cope most effectively with medication shortages?

All facilities should have a structured process in place to address shortages. MDH has created Patient Care Strategies in Scarce Resource Situations available on the website (https://www.health.state.mn.us/communities/ep/surge/crisis/index.html) for all health care facilities to use in these situations. Principles of crisis standards of care/disaster resource allocation can be used to determine the response necessary. Sample actions may include:

- Designate a lead (incident manager) for shortages.
- Develop a process for recognizing and categorizing shortages based on usual use, product on hand, likely delivery, and clinical indications.
- For each shortage, assure that a lead pharmacist works with clinical staff to determine any restrictions on use and work with vendors to determine alternative available agents.
- Determine the degree of impact on clinical care.
- Determine changes to ordering and administration process for alternative agents to assure safety (particularly if the dosing is unfamiliar).
- Provide clinical education and communication required to affect a safe process change.

A health care system may utilize a system-wide process rather than have each facility develop its own approach. Decisions may also be made to concentrate available medications at certain facilities where they are most needed (e.g., during a recent shortage of intravenous nitroglycerine, one system restricted stocking to the hospital that did the highest volume of cardiac care and surgeries).

Further information on a structured response is available at: EMS.gov (http://www.ems.gov/pdf/2013/ASTHO_Shortages_of_Emergency_Meds.pdf)

Hospitals may have agreements directly with drug manufacturers, though this is uncommon (less than 10% of usual purchases, even in large systems). The only exception to this is some generic tablet manufacturers have preferred contracts with certain vendors, in which case that vendor may have priority for available product. Alternate wholesalers are all subject to the same manufacturer allocation constraints, therefore may not be adequate suppliers in a shortage. 'Gray market' medications from alternate suppliers may be available but are subject to concerns about storage and safety. Additionally, pharmacies can elect to compound medications themselves for internal use or utilize compounding pharmacies. Use of compounding pharmacies requires due diligence due to historical adverse outcomes from contamination.

In pervasive shortages, national guidelines may be developed by state or federal agencies and professional societies, or by pharmacy and hospital groups (as with the 2018 normal saline shortage). Often, however, it is up to the facility or health system to determine the best strategies, though involvement of the regional health care coalition may occur when resource allocation / sharing is required to meet critical demand.

How can a hospital assure that adequate stocks of medications needed for a disaster will be there when they are needed?

First, health care facilities should determine which medications will be most important in a no-notice disaster and depending on their role in the community establish baseline par levels that will allow them to respond appropriately in the first hours to days after an event. Examples of such medications include narcotic analgesia, sedation, paralytics, and intravenous antibiotics. Sufficient inventory of these medications should be maintained *prior* to a shortage occurring, when possible. ASPR TRACIE has a calculator that may be helpful to determine categories of medications and goals (ASPR TRACIE Hospital Pharmacy Module (https://asprtracie.hhs.gov/dash-tool/pharmacy/)).

Second, the facility should determine the process for rapidly getting the medications to the areas in the hospital that need them.

Third, the facility should have a 'pull list' for their regional wholesaler that will be activated by their pharmacy when a disaster occurs, allowing for reinforcement and replenishment of stocks much more rapidly than if the wholesaler is contacted as products are running low and only as specific shortages are identified. Vendors can help arrange delivery, even if this has to occur by helicopter as happened after Hurricane Katrina. A proactive communication and request strategy with vendors is always preferred to a reactive one.

What is the role of MDH in a medication shortage?

The Minnesota Department of Health has two roles in a medication shortage. First, MDH will continue to support and monitor the needs of health care facilities through their regional health care coalitions (HCCs) and facilitate resource requests as appropriate to MDH scope. Second, MDH is a conduit for communications to federal partners. The Strategic National Stockpile (SNS) is a federal asset and cannot be requested for everyday drug shortages, however MDH expects HCCs to keep the state informed on the situation in case it progresses to a prolonged public health emergency.

For additional information:

1. FDA Drug Shortages Homepage http://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm
2. ASPR TRACIE Pharmacy Topic Collection https://asprtracie.hhs.gov/technical-resources/53/pharmacy/47
3. American Society for Health system Pharmacists (ASHP) Drug Shortages Resource Center http://www.ashp.org/shortages
4. CDC Vaccine Shortages & Delays http://www.cdc.gov/vaccines/vac-gen/shortages/

5. FDA Registered Compounding Outsourcing Facilities
   http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm378645.htm
6. MDH Crisis Standards of Care Homepage
   https://www.health.state.mn.us/communities/ep/surge/crisis/index.html

If your region has exceeded its capacity to provide care, please contact MDH Emergency Preparedness and Response at 651-201-5700.

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