Shortages of pharmaceuticals, intravenous fluids, and hospital nutrition products are becoming a way of life for healthcare providers. The FDA lists 79 current medication shortages (http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm accessed Dec. 17, 2014). Many of these are extremely common, often life-saving injectable drugs, and a number of them have few substitutes. The recent shortages of normal saline help emphasize that no supply chain is safe from potential shortages. Though not a disaster, these shortages often prompt evaluation and adaptive strategies identical to Crisis Standards of Care processes and thus provide an opportunity to apply a structured response to coping with shortages as well as offer ethical and procedural guidance for allocation decisions. The following provides answers and discussion around common questions related to drug shortages.

1. **Why do drug shortages occur, and why do they seem so common?**

   A variety of factors contribute to shortages. Sometimes, the shortage is on the consumer end, as was the case with potassium iodide as fears of radioactive seawater from the Fukushima Daichi reactor caused spikes in demand in California. Shortages have resulted from manufacturers eliminating drugs from their product lines in order to increase business margins. More often, shortages of raw materials, contamination of product, limitation of production due to regulatory, maintenance, or other issues cause shortages to occur. Injectable generic medications are particularly at risk due to their slim profit margins, paucity of manufacturers, and compliance/sterility issues required for their production. Shortages are very common, with 79 shortages listed on the Food and Drug Administration (FDA) website as of December, 2014. The FDA estimates that through its actions over 170 additional shortages were prevented in 2013 as well.

2. **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 drugs 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 drug substitutions and 2/3 noted less serious adverse events. Increased cost of substitute drugs also has significant monetary consequences for patients, hospitals and payers.

3. **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.

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

Wholesalers (such as Amerisource/Bergin, Cardinal, and McKesson) also 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 quantity and being first in line 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.

5. **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 still fill orders as a percentage of usual use unless there were specific facilities that were impacted more.

6. **How can a hospital or health system cope most effectively with drug shortages?**

All facilities should have a structured process in place to address shortages. Principles of crisis standards of care / disaster resource allocation which may be familiar from the MDH Scarce Resources Cardset (particularly including conservation, and substitution) ([http://www.health.state.mn.us/oep/healthcare/standards.pdf](http://www.health.state.mn.us/oep/healthcare/standards.pdf)) 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 use
• 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 required to ordering process for alternative agents to assure safety (particularly if the dosing is unfamiliar)
• Determine clinical education and communication required to effect a safe process

A healthcare system may utilize a system-wide process rather than have each facility develop its own approach. Decisions may also be made to concentrate available drugs at certain facilities where they are most needed (e.g. in a 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:

Hospitals may have agreements directly with drug manufacturers, though this is uncommon (less than 10% of usual purchases, even in large systems). Absent this, unless the facility is willing to purchase ‘gray market’ drugs from an intermediary there is usually little advantage to be gained by contacting alternate wholesalers, since they are all subject to the same allocation constraints. 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.

Pharmacies can elect to compound medications themselves for internal use if they have the appropriate resources. There is always a risk, however, in doing this that needs to be balanced against having product available (e.g. contaminated parenteral feeds contributing to 9 parenteral feeding deaths in 2011\(^1\) and fungal contamination of intrathecal steroids caused 64 deaths in 2013\(^2\)).

In pervasive shortages, national guidelines may be developed. These may be led by professional societies (such as during the intravenous immune globulin shortage a few years ago) or by pharmacy and hospital groups (as with the recent normal saline shortage\(^3\)). Often, however, it is up to the facility or health system to determine the best strategies, though involvement of the regional healthcare coalition may occur when resource allocation / sharing is required to meet critical demand.

\(^1\) https://www.ismp.org/newsletters/acute/20110407.asp
\(^2\) http://www.cdc.gov/hai/outbreaks/meningitis.html
\(^3\) http://www.ashp.org/DocLibrary/Policy/Conservation-Strategies-for-IV-Fluids.pdf
7. **How can a hospital assure that adequate stocks of medications needed for a disaster will be there when they are needed?**

First, healthcare 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. Stockpiling of these drugs should be done in conjunction with the wholesaler prior to a shortage occurring.

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.

**For further information:**

1. FDA Drug Shortages Homepage
2. American Society for Healthsystem Pharmacists (ASHP) Drug Shortages Resource Center
   [http://www.ashp.org/shortages](http://www.ashp.org/shortages)
3. CDC Vaccine Shortages & Delays
4. FDA Registered Compounding Outsourcing Facilities
   [http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm378645.htm](http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm378645.htm)

**If your region has surpassed its capacity to provide care, please contact MDH Emergency Preparedness and Response at 651-201-5735.**