Drug Shortages: Causes, Impact, and Management

Shortages Drive Costs and Negatively Impact Patient Safety

What is the issue?

Over the past two decades, drug shortages have become commonplace. They affect basic necessities such as IV fluids and antibiotics, as well as life-saving drugs such as cardiovascular and anti-cancer agents.

The rate of new shortages has fallen since its peak in 2011, but many active shortages persist for years. While there were only 105 new shortages in 2017, there were a total of 175 ongoing shortages requiring active management by health systems.

In general, generic drugs, injectable drugs, and single-source products are the most vulnerable to shortages, though a variety of drugs have been affected. Generic drugs are susceptible because they are often manufactured at only a few plants, meaning that disruption at one site can compromise a significant portion of the total supply. For example, in 2017 the most wide-reaching shortage affected saline IV fluids and bags. It was caused, at least in part, by Hurricane Maria disabling two manufacturing plants in Puerto Rico, while a third plant was affected by production problems. The Department of Justice is also investigating possible collusion among manufacturers.

Injectable drugs are vulnerable to shortage because their manufacturers must maintain very high standards of sterility during production. These plants are monitored by the FDA and may be temporarily shut down due to non-compliance with good manufacturing practices.

Other commonly-cited causes of shortages include spikes in demand for specific drugs due to spread of disease, natural disaster, new indications, or changes in clinical guidelines; lack of availability of raw materials, often caused by global supply chain disruptions or reliance on sole source suppliers; FDA enforcement actions disrupting manufacturing; and manufacturers’ lack of incentive to produce drugs with low profit margin or small market sizes.

Why does it matter?

By one estimate, shortages cost US hospitals $446M annually—$230M generated by the need to purchase more expensive therapeutic substitutes, and $216M by increased labor costs. Additionally, shortages can have a profound and widespread effect on patient safety and outcomes and burnout. Specifically, shortages can:

- Necessitate rationing of drugs
- Require switching patients to a less effective alternative or one with known risks
- Compromise or delay procedures
- Increase risk of medication errors
- Disrupt clinical trials

Impact:

- Cause high levels of frustration among purchasing agents, pharmacists, nurses, physicians, and patients
- Contribute to burnout and strained professional relationships

Sources:


Even a single drug shortage can have major ripple effects estimated to increase medication error rates by 1%-5%. When a drug is no longer available from the health system’s usual supplier, pharmacy staff must spend time trying to find alternative sources, assessing inventory levels, and looking for opportunities to reduce utilization. If an alternative drug can be identified, often the P&T committee must convene on short notice to change prescribing protocols. Pharmacy and IT staff must integrate the new protocols into ordering, inventorying, and dispensing systems and account for any differences in dosing, packaging, and barcoding. Staff must be trained on the new protocols, especially when they require prescribing or administering unfamiliar alternative agents, product forms, or drug concentrations. In dire situations, the hospital may need to convene a multidisciplinary committee to determine how to ration limited drug supply and then communicate their decision to patients and families.

To illustrate the magnitude of the impact, one hospital that was forced to switch from IV bags to syringe administration of two drugs had to review and revise more than 700 order templates.

**How do pharmacists mitigate the effects of shortages?**

While a range of individuals within the hospital are affected, pharmacists bear the brunt of managing shortages and minimizing their impact. This includes determining which medications are in shortage, assessing the anticipated impact, identifying conservation strategies or alternative drug treatments, communicating with manufacturers and wholesalers, compounding and repackaging preparations, modifying policies and clinical protocols, updating medication administration systems, communicating with the health care team, and even establishing collaborative drug sharing arrangements with other institutions.

The time needed to complete these tasks has more than tripled since 2004, which many suggest necessitates adding at least 0.5 to 1 FTE to ensure patient safety and prevent burnout. Without adequate staffing, pharmacists often have to forgo patient care to rush to respond to impending crises.

**What else should health systems do?**

**Budget for shortages.** Drug acquisition costs and personnel costs increase when drugs are in shortage.

**Avoid stockpiling drugs** in anticipation of price increases and hoarding in response to rumors of impending shortages. These practices can trigger or exacerbate shortages.

**Develop a policy for managing drug shortages** that includes three phases: assessment, preparation, and contingency. The plan should outline responsibilities, communication channels, and decision making processes, and name a point person who takes the lead in implementing, coordinating, and monitoring response efforts.

**Consider becoming a 503B compounding pharmacy.** 503B certification enables compounding pharmacies to produce large batches of medication with or without prescriptions to be sold to other health care facilities. As a result, health systems with 503B status can often prepare drugs and IV fluids in-house when in shortage, providing advantages to both patients and the bottom line.

**Centralize your drug inventory or ensure cross-site inventory visibility.** Easy access to stock information promotes conservation and effective distribution and use of existing drugs.

**Educate your legislators on shortages and advocate for mitigation strategies.** Proposals may include requiring redundancy in production of critical products, requiring contingency plans for interruption in production of critical medications, and providing incentives for other manufacturers to increase production when shortages occur. Additionally, hospitals should notify the FTC of any price gouging concerns, the FDA of identified shortages, and the FDA Office of Criminal Investigations of gray market issues¹.

Sources:

¹) Gray markets are supply channels that are unofficial, unauthorized, or unintended by the original manufacturer and usually evolve as the sell items at any price the market will bear.

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