



ACMT Position Statement on Prescription Drug Shortages

The position of the American College of Medical Toxicology, is as follows:

Prescription drug shortages have become a major public health problem. Shortages have not only impacted antidotes, but also drugs across a wide range of specialties as well as basic medical supplies. These shortages may compromise the quality of care and pose a threat to patient safety. ACMT calls upon stakeholders to implement measures to ensure patient safety in the setting of severe and long standing drug shortages.

Background

Prescription drug shortages have become severe and long in duration in recent years.¹ Shortages have impacted several important antidotes used in the treatment of poisoned patients, such as fomepizole, naloxone, and sodium bicarbonate.² Drug shortages have impacted a wide range of medications used across medical specialties, including emergency and critical care, infectious diseases, and oncology.³⁻⁵ In addition, shortages have also impacted the most basic medical supplies, such as saline solutions, dextrose, sodium bicarbonate, and sterile water.⁶

Prescription drug shortages have impacted primarily generic injectable products.^{1,3-7} The reasons for shortages are multifactorial, however; quality problems at production sites are the most commonly cited problem by the US Food and Drug Administration (FDA).^{1,7} In addition, other factors, such as a lack of redundancy and transparency in manufacturing systems and supply chains, contribute to shortages.⁷ Increased demand for a particular product may precipitate a shortage, as well as business decisions to discontinue a product.⁷ Natural disasters may precipitate shortages. Severe shortage of saline solution occurred when a Puerto Rico manufacturing plant that produced sodium chloride was damaged during Hurricane Maria.^{8,9}

Ongoing efforts to mitigate drug shortages have resulted in overall fewer numbers of shortages; however, shortages continue to be a major public health problem. Prior to the Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012, manufacturers were under no obligation to notify the FDA of a drug shortage.¹⁰ FDA notification is important, because the agency can work to approve new products, ask other suppliers to increase production, or even secure imported products. The FDA prevents hundreds of shortages each year due to the enhanced notification requirements of FDASIA. At the same time, there are some limitations to FDASIA. For example, there are no penalties for drug manufacturers who do not provide notification to FDA. Suppliers are also under no obligation to provide the actual reason for the shortage to FDA. This is important, because FDA can assist suppliers

with approvals to move production to other facilities, or approve other sources of raw materials. If FDA is not provided a reason for shortages, they cannot assist in mitigation efforts.¹⁰

Widespread drug shortages have the potential to impact patient care in a variety of ways.^{9,11} Patients risk delayed, inadequate, or omitted treatment, additional or increased patient monitoring, and incorrect medication administration. Patient outcomes may suffer when less efficacious or more toxic therapeutic alternatives are substituted for unavailable first-line agents. Medication errors may occur when providers are forced to use less familiar therapeutic alternatives. Medication errors can also occur when different concentrations or formulation are stocked when the usual concentration is unavailable.¹¹⁻¹³ Compounding errors may result when pharmacies must compound products that were traditionally available as pre-mixed products.¹⁴ Compromised sterility and microbial contamination have been reported when using vials multiple times to minimize waste of products in short supply.¹⁵ Lastly, drug substitution might require alternative rescue agents or antidotes. Although data regarding outcomes are lacking, several deaths have been attributed to drug shortages.¹⁶

In addition to the impact on patient care, drug shortages increase healthcare costs and consume valuable healthcare resources. Data from 2011 estimate the annual labor costs to manage drug shortages at over 200 million dollars.¹⁷ Additional data from 2014 estimate over 200 million dollars per year to simply purchase additional products to mitigate shortages.¹⁸ The current environment of electronic health records, smart pumps, and bar code administration, relies on using a consistent product. Most hospitals spend hundreds of hours per shortage to make necessary informatics changes. In many cases, changes cannot be made quickly enough in the electronic environment, risking patient safety.

Given the impact drug shortages have on patient safety and the healthcare system as a whole, ACMT calls upon stakeholders to implement measures to mitigate the impact of drug shortages.

Methodology

We performed a literature search when drafting this position statement. A PubMed and Medline search was performed using the terms “prescription drug shortages” and “drug shortages.” Only articles written in English were reviewed. All relevant articles were reviewed as well as any applicable references in the bibliography.

This document was reviewed and approved by the ACMT Position Statement and Guidelines Committee, was sent to the ACMT Board of Directors, and then sent to the entire College membership for review.

Recommendations

Government

- Congress should enhance FDASIA requirements for notification of drug shortages to include reasons for shortages, as well as estimated timelines and durations.

- Congress should change the labeling laws to require disclosure of the actual manufacturer(s) of a drug and establish a rating system for manufacturers based on quality (similar to hospital star ratings).
- The Department of Justice and Federal Trade Commission should consider potential public health impact to pharmaceutical supply when reviewing healthcare industry mergers and acquisitions.
- The Department of Health and Human Services and the Department of Homeland Security should review drug supply as a part of national security measures.

Manufacturers/Distributors

- Manufacturers should establish business continuity plans and redundancy in manufacturing for critical and life-saving products.
- Suppliers should provide transparency around which manufacturers are producing products or product elements, as well as the location.

Hospitals and Healthcare Systems

- Hospitals and healthcare systems should work to purchase high quality products and be willing to pay additional costs for products with proven track records of availability and quality.

Health Care Providers

- Healthcare providers should establish interprofessional committees to manage drug shortages.
- Providers should establish protocols for use of therapeutic alternatives during shortages to ensure patient safety.
- Hospitals should establish protocols to minimize waste and optimize limited supplies.
- Providers should adhere to a transparent, ethical framework for rationing limited supplies.
- Providers should document and report medication errors and patient safety events that occur as a result of drug shortages.

Disclaimer

While individual practitioners may differ, these are the positions of the American College of Medical Toxicology (ACMT) at the time written, after a review of the issue and pertinent literature.

Compliance with Ethical Standard

Conflict of Interest: None

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