

Drug Shortages: A Complex Health Care Crisis

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Abstract

National tracking of drug shortages began in 2001. However, a significant increase in the number of shortages began in late 2009, with numbers reaching what many have termed crisis level. The typical drug in short supply is a generic product administered by injection. Common classes of drugs affected by shortages include anesthesia medications, antibiotics, pain medications, nutrition and electrolyte products, and chemotherapy agents. The economic and clinical effects of drug shortages are significant. The financial effect of drug shortages is estimated to be hundreds of millions of dollars annually for health systems across the United States. Clinically, patients have been harmed by the lack of drugs or inferior alternatives, resulting in more than 15 documented deaths. Drug shortages occur for a variety of reasons. Generic injectable drugs are particularly susceptible to drug shortages because there are few manufacturers of these products and all manufacturers are running at full capacity. In addition, some manufacturers have had production problems, resulting in poor quality product. Although many suppliers are working to upgrade facilities and add additional manufacturing lines, these activities take time. A number of stakeholder organizations have been involved in meetings to further determine the causes and effects of drug shortages. A new law was enacted in July 2012 that granted the Food and Drug Administration additional tools to address the drug shortage crisis. The future of drug shortages is unknown, but there are hopeful indications that quality improvements and additional capacity may decrease the number of drug shortages in the years to come.

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Drug shortages pose a significant threat to public health and safety and have affected multiple areas of medicine during the past several years, including oncology, anesthesia, emergency medicine, and nutritional support. These shortages have resulted in delayed treatment for patients, medication rationing, and in some cases treatment being denied because of unavailability of critically important drugs. Addressing shortages remains a top priority for the Food and Drug Administration (FDA); manufacturers and other stakeholders also have important roles to play in ensuring that critical drugs remain available for patient care.

Determining whether a drug shortage exists can be challenging. From a clinician's viewpoint, a shortage exists if a needed medication is not available for a patient. However, this situation is not necessarily always a shortage. The definition of a drug shortage varies, depending on perspective. The FDA defines a shortage as "a situation in which the total supply of all clinically interchangeable versions of an FDA-regulated drug is inadequate to meet the current or projected demand at the patient level."^{1, p.8} The American Society of Health-System Pharmacists

(ASHP) and the University of Utah Drug Information Service (UUDIS) define a drug shortage as "a supply issue that affects how the pharmacy prepares or dispenses a drug product or influences patient care when prescribers must use an alternative agent."^{2, p.1400} The slight differences between these definitions results in higher drug shortage totals provided by the ASHP and the UUDIS compared with those provided by the FDA.

Problems with local ordering, local or national distribution, or manufacturing can all result in supply problems that can lead to regional or national shortages. The medication distribution system in the United States is complex and generally operates on a just-in-time inventory system. Just-in-time inventory is a cost-reduction strategy used to avoid costs associated with carrying excess inventory. This means that, in general, there is not an excess of product anywhere in the supply chain.² Typically, the medications that manufacturers produce are distributed through wholesalers. The 3 largest wholesalers in the United States are AmerisourceBergen, Cardinal, and McKesson. These wholesalers have distribution centers located throughout the United States. A hospital



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or physician office staff typically orders medications through a wholesaler and receives a delivery from one of the distribution centers. If a problem occurs at any point in the distribution system, it can result in the situation of a clinician or patient not having access to a needed medication. For example, weather can delay shipments anywhere in the supply chain, hospitals or physician office staff can forget to order product, buyers may underestimate how much product is needed, or buyers may order more product than the distributor has on hand. These examples can create regional supply issues that are not problems at the manufacturer level.

If a manufacturer has a supply problem, however, it will often likely result in a national drug shortage, particularly if the manufacturer is the sole source for the medication or has a large share of the market. A given shortage is unlikely to occur at the same time and at the same rate across the country, though, because of varied distribution of product in the United States. The IMS Institute for Healthcare Informatics reviewed the drug shortage problem in 2011 and noted that 13 states (Arizona, Arkansas, Delaware, Florida, Hawaii, Kentucky, Nevada, Maryland, Massachusetts, Nevada, New Jersey, Ohio, and South Carolina) experienced more regional shortages than others; the IMS Institute for Healthcare Informatics could not identify the reason for the regional variation.³ Whether this trend is consistent for these states is unknown because this analysis has not been repeated.

Once a shortage begins, it is not uncommon for health care systems to order larger quantities than usual because it is virtually impossible in a shortage situation to know when additional supplies may again be available. Survey data from the American Hospital Association in 2011 reveal that 85% of hospitals purchase excess inventory in response to a shortage.⁴ This excess ordering can increase the duration of national shortages as manufacturers attempt to clear large backorders for product once their production lines are again operating. Excess ordering also means that some hospitals may have unnecessarily large inventories, whereas others may not have access to product.

Further complicating the issue is the fact that there are few situations when the entire supply of a given drug is completely unavailable. The

typical shortage situation is one where a purchaser can obtain some product but not enough to supply usual use. Health care organizations can choose to manage this type of situation in a variety of ways. One method is to continue using the product until supplies are exhausted. The most common method, however, is to ration or allocate the remaining product for specific clinical situations or defined patient populations where alternatives are not ideal. Rationing decisions, combined with differences in the types of patients treated, can lead to situations of local differences where one hospital is considerably affected by a given shortage but another may be seemingly unaffected. In addition, differences in communication about drug shortages may lead to perceived differences in effect. For example, some facilities may communicate about drug shortages early, whereas other facilities may choose to wait until a shortage worsens and requires immediate action.

DRUG SHORTAGE TRENDS

The UUDIS tracks national drug shortages and provides information on anticipated availability and clinical management strategies designed to minimize the effect of shortages on patients through a publicly available website offered through the ASHP (www.ashp.org/shortage; methods previously published).^{2,5} The FDA tracks national drug shortages and the number of shortages prevented each year. The number of new drug shortages identified by the UUDIS that have affected the US health care system in the past decade is shown in [Figure 1](#).⁶ These data reveal a decrease in the number of new drug shortages in 2012 and 2013 compared with the number of new drug shortages in 2010 and 2011, a promising figure that is likely due to prevention efforts by the Drug Shortage Program at the FDA. [Figure 2](#) illustrates the increasing number of drug shortages prevented by the FDA each year.⁷ Although the decreasing number of new shortages is good news, the number of active and ongoing shortages is at an all-time high: as of the end of the third quarter of 2013, the UUDIS was tracking 294 active drug shortages ([Figure 3](#)).⁶ For the past 4 quarters, active shortages have exceeded 290. These data, combined, indicate that although new shortages are being prevented by the FDA whenever possible, existing shortages are not resolving, often because many of the

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