

## Managing Drug Shortages



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During my visits to regional healthcare facilities, I often ask the facility patient safety officers what challenges they face. One common frustration they mention is managing drug shortages. Drug shortages affect patient care. Not only are there clinical implications to drug shortages, such as having to use a less optimal medication or rescheduling procedures, there is a financial impact, and resources are required to manage the shortage. The patient safety aspect of drug shortages is not to be underestimated, either, as evidenced by these events reported to the Pennsylvania Patient Safety Authority.

*The pharmacist was working on an order for a brand new bag of D10/0.2%NS, as the premade bottles were on back order. The pharmacist had to start from scratch to prepare the solution. The pharmacist did his calculations and noted that he came up with something different than the pharmacist did the previous day. The pharmacist believed that the previous pharmacist had miscalculated and was low by a factor of ten of the sodium chloride. When the other pharmacist came into work on this day, this pharmacist discussed the miscalculation together. It was learned that the order from the previous day was correct, and the miscalculation for today resulted in the sodium chloride content of the IV [intravenous bag] to be ten times higher than what was ordered.*

*A patient [presented] to the ED [emergency department] for rabies vaccine; the pharmacy informed the ED that the vaccine was not available due to back order.*

*A patient required 71 mg tissue plasminogen activator (t-PA). [The patient] received 50 mg t-PA related to pharmacy shortage.*

### DRUG SHORTAGES AND PATIENT SAFETY

Results of a 2010 Institute for Safe Medication Practices (ISMP) survey of pharmacists and other healthcare providers<sup>1</sup> indicated that drug shortages present a clear patient safety threat. More than 1,800 respondents from across the country participated in the survey. Thirty-five percent of respondents indicated they experienced a near-miss event because of a drug shortage. One in four reported an error occurred that reached a patient, and one in five reported an adverse patient outcome occurred due to a drug shortage.

Many error examples included in the ISMP article discussing the survey results involve high-alert medications, which are medications that are more likely to cause harm when used in error. In one case, propofol was unavailable, and an alternative medication was not prescribed, leaving a paralyzed and ventilated patient with no sedation. Another patient received 10 mg of morphine instead of the 1 mg that was ordered. Another report indicated that a shortage of prefilled EPINEPHrine syringes may have contributed to a patient death during a code situation because healthcare providers were unable to keep up with the demand for EPINEPHrine when each ampul had to be diluted.

### WHY DRUG SHORTAGES OCCUR

Drug shortages occur for many reasons.<sup>2</sup> Raw materials used in manufacturing may be unavailable. Manufacturing disruptions could occur due to a change in formulation, manufacturer mergers, product discontinuation, or moving production to a new facility. Production line downtime due to maintenance, changes, or regulatory shutdowns will also adversely affect supply. A manufacturer may choose to eliminate a product due to small market size or unprofitability. Recalls may decrease a drug's availability. Natural disasters may disrupt production or increase demand. Drug demand may also increase because of a new indication, new guideline, a shift in clinical practice, or a disease outbreak. Hoarding of drugs can prematurely increase a shortage's impact or lead

to secondary shortages; for example, if morphine is in short supply, more people may be purchasing HYDROmorphone, leading to shortage of HYDROmorphone as well.

### MANAGING DRUG SHORTAGES

The American Society of Health-System Pharmacists (ASHP) identifies three main steps in managing a drug shortage in a healthcare facility:<sup>2</sup>

1. Identification and assessment
2. Preparation
3. Contingency

The first step in managing a drug shortage is to identify that there is a shortage. Often, a shortage is discovered when attempts are made to order a medication. How much medication is in stock will determine how much time a facility has to address the issue. ASHP and the U.S. Food and Drug Administration (FDA) have both created webpages to notify healthcare professionals when a drug shortage has been identified or is likely to occur. The FDA webpage (<http://www.fda.gov/drugs/drugsafety/drugshortages/default.htm>) lists only medically necessary drugs, while the ASHP webpage (<http://www.ashp.org/menu/PracticePolicy/ResourceCenters/DrugShortages.aspx>) is more comprehensive, with 199 medications listed in September.

Once a drug shortage has been identified, facilities need to assess the impact of the shortage on their practice. For example, how much of the drug is currently in

stock? How is the drug used and in what population? How long is the shortage expected to last?

After the impact has been assessed, facilities can begin to prepare to mitigate the effects of the shortage. This requires evaluating what concentrations, alternate packaging, or therapeutic alternatives are available. Therapeutic alternatives are rarely optimal choices, or they would be in use already. It is important to consider how the alternatives work. For example, are they appropriate for the population? Or, what are the dosing and prescribing parameters? There will likely be differences in the amount and frequency of dosing, side effects, and the onset and duration of the drug's effectiveness. Preparation, storage, and administration requirements are also important to examine. Certain populations may not be appropriate for use of these alternatives. Education and drug information about the alternatives is to be easily accessible to all staff. Facilities can also review the potential for look-alike or sound-alike confusion to arise whether utilizing an alternative drug or a different concentration of the drug in short supply.

The contingency step may involve the facility risk management or ethics departments if there is reason to believe that patient care could be delayed or compromised due to the shortage. Communication with staff and patients is also a component of this step.

### EFFORTS TO DECREASE SHORTAGES

Increasing attention has been paid to the impact of drug shortages. In November 2010, ISMP, ASHP, the American Society of Anesthesiologists, the American Society of Clinical Oncology, and representatives from other professional organizations, manufacturers, and healthcare facilities convened a summit to discuss the impact of drug shortages and create recommendations.<sup>3</sup>

In February 2011, the Preserving Access to Life-Saving Medications Act was introduced to the U.S. Senate and referred to committee.<sup>4</sup> This bill would require a drug manufacturer to notify the Secretary of Health and Human Services of a “discontinuance, interruption, or other adjustment of the manufacture of the drug that would likely result in a shortage of such drug” six months before a discontinuance or planned disruption, or “as soon as practicable” if the disruption is unplanned.

### CONCLUSION

Drug shortages can affect patient care and patient safety. While they are not preventable, they can be managed in a way that will decrease the likelihood of negative outcomes. This management includes identifying which drugs are likely to be unavailable or in short supply, assessing the utilization of those drugs in the healthcare facility, preparing for the shortage, and having clear policies for controversies that may arise.

### NOTES

1. Institute for Safe Medication Practices (ISMP). Drug shortages: national survey reveals high level of frustration, low level of safety. *ISMP Med Saf Alert* 2010 Sep 23;15(19):1-6.
2. Fox ER, Birt A, James KB, et al. ASHP guidelines on managing drug product shortages in hospitals and health systems. *Am J Health Syst Pharm* 2009 Aug 1;66(15):1399-406.
3. American Society of Health-System Pharmacists, American Society of Anesthesiologists, American Society of Clinical Oncology, et al. Drug shortages summit summary report, November 5, 2010 [online]. [cited 2011 Jul 27]. Available from Internet: <http://www.ashp.org/drugshortages/summitreport>.
4. S. 296—112th Congress: Preserving Access to Life-Saving Medications Act. (2011). In GovTrack.us [database of federal legislation]. [cited 2011 Jul 27]. Available from Internet: <http://www.govtrack.us/congress/bill.xpd?bill=s112-296>.

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