

The Society of Critical Care Medicine Expresses Concerns for Patient Safety due to Ongoing Drug Shortages in the United States

Critically ill and injured patients in the field or in the nation's hospitals frequently require immediate intervention with pharmacologic agents. Trauma, medical and surgical emergencies, and other urgent medical events in both adults and children can lead to further harm and possibly death when drug shortages exist. Some recent shortages have involved drugs for life-threatening conditions and, in some cases, the product in shortage has been the only one for the patient's condition.

- A patient with ovarian cancer was only able to receive one dose of doxorubicin liposomal because this drug has been on protracted shortage and is not expected to be available until 2012; her subsequent treatments are on hold. The long-term impact on her cancer is unknown.
- A patient with thyroid cancer had sodium iodide I 131 treatment delayed this summer until it became clear the radiopharmaceutical wasn't going to become available. Alternative, less effective, and more toxic regimens had to be utilized.
- In many centers, labetalol – widely used in the intensive care unit for management of uncontrolled hypertension – is available only to patients with brain hemorrhage. Less reliable, less effective, less familiar regimens, and those potentially more prone to toxicity and error, become the only alternative treatments.

These shortages now involve a wide range of medications, impacting nearly every aspect of acute care: cancer chemotherapy agents, anesthetics, antibiotics, electrolytes for nutrient solutions, and dozens more.

The US Food and Drug Administration (FDA) reported a record 178 drug shortages in 2010, with the numbers already over 200 in 2011. The Society of Critical Care Medicine (SCCM) is aware of these shortages and has taken steps to inform both the FDA and the Subcommittee on Health, U.S. House Committee on Energy and Commerce, of the implications of these shortages on intensive care unit patients.

The Impact of Drug Shortages

The need for healthcare institutions to effectively manage drug shortages (often with little notice) has markedly impacted the ability of the multiprofessional care team to function effectively.¹ Coordination of a response is multifaceted, necessitating healthcare providers to address both operational and clinical issues. Considerations include evaluation of the drug supply and need for centralization (e.g., removal from automated dispensing machines), convening workgroups to establish conservation and allocation strategies, determining therapeutic alternatives, communicating with healthcare providers, and providing education.^{2,3} Existing order sets, protocols, and technology, such as bar coding and computerized prescribing systems, may need to be updated.^{2,3} Additional resources are needed to effectively manage the increased workload associated with drug shortages, yet maintain the existing level of patient care. The estimated labor cost associated with managing drug shortages in the United States is \$216 million annually, with pharmacists spending an average of 9 hours each week on this activity.³ Medication use processes are complex and involve a systematic approach to the incorporation of new medications into hospital formularies. When drug management strategies require deviation from established processes in an emergent fashion, the potential for error is introduced at multiple levels.

Drug shortages have had an alarming impact on patient care, particularly patient safety, clinical outcomes, and cost of care. In a national survey of more than 1,800 healthcare practitioners, more than 1,000 errors and adverse patient outcomes were described secondary to shortages over the past year.⁴ In fact, approximately one in three respondents (35%) reported that their facility had experienced a near miss (i.e., an error that occurred but did not reach the patient); one in four cited an actual error (one that did reach the patient); and one in five reported adverse patient outcomes in the past year due to a drug shortage.⁴ In many of these cases, the drug became unavailable abruptly, leaving little time to plan for an

alternative solution. Nevertheless, even with adequate warning, clinical outcomes can be affected by the use of an alternative agent. Generally, a given drug is an “alternative” for a specific reason: inferiority to the primary agent, increased adverse effect profile, or higher acquisition cost. In one analysis, it was suggested that drug shortages necessitating the use of therapeutic alternatives (either more expensive generic drugs or therapeutic substitutes) could cost US hospitals at least \$200 million annually.⁵ On average, providers are paying 11% more for medications affected by shortages, a figure likely to increase if medications are obtained on the “gray market” (i.e., secondary markets that advertise availability of scarce drugs at exorbitant prices). This increase does not include the indirect costs associated with labor or the implementation of a therapeutic interchange program. In some cases, a therapeutic alternative may not exist. For example, infections caused by multidrug-resistant organisms could not be treated (ultimately causing death in at least one patient) because the only effective agent was unavailable due to a shortage.⁴ These scenarios illustrate the extreme consequences of any short supply of common everyday medications.

Recommendations

The Society recognizes the need for swift action to correct the increasing frequency and severity of drug shortages. Senators Amy Klobuchar (D-MN) and Robert Casey (D-PA), and Representatives Diane DeGette (D-CO) and Tom Rooney (R-FL) have introduced to the Senate and House of Representatives, respectively, the Preserving Access to Life-Saving Medications Act (S.296 and H.R.2245). These bills – in conjunction with President Obama’s executive order on October 31, 2011, instructing the FDA to take steps to address the issue – implement a number of recommendations put forth by a Drug Shortage Workgroup Summit of stakeholders, which included providers, drug manufacturers, the FDA, as well as a number of organizations, including SCCM. Collectively, key provisions of these efforts would: 1) require manufacturers to provide advance notice of a supply interruption, thereby enabling the FDA to prevent or mitigate the severity of a shortage; 2) expedite the FDA’s regulatory review of new drug suppliers, manufacturing sites, and manufacturing changes as practicable to prevent a shortage; and 3) require the FDA to communicate with the Department of Justice (DOJ) in relation to any stockpiling or “price-gouging” occurring in the gray market, and for the DOJ to take appropriate action where indicated. Although these efforts do not address all of the multifaceted causes of this complex problem, SCCM believes they represent important first steps to solving this crisis. These actions have the potential to reduce and/or mitigate shortages and improve patient safety by means of advance notice, allowing time for critical care professionals to appropriately and safely implement alternatives where possible. SCCM members, patients, and other stakeholders should advocate for the passage of the Preserving Access to Life-Saving Medications Act by contacting their congressional representatives and expressing their support.

As efforts to prevent or mitigate the impact of drug shortages continue, practitioners, patients, and caregivers should recognize the very real safety risks and quality-of-care implications inherent in this ongoing crisis. Drug shortages introduce a significant complicating factor into the care of critically ill patients, who already require the most complex care. As such, a proactive, patient-centered, multiprofessional approach, as advocated by SCCM and best exemplified in the critical care community, is required to optimize patient outcomes and prevent harm.

Summary and Closing

With the accelerating incidence of drug shortages, patients are being denied medications that may be the only effective choices for their illness, resulting in suboptimal therapy or no therapy at all. Healthcare institutions are being forced to spend extra resources on restructuring existing processes to adjust for sudden drug shortages. Patient safety and quality of care are directly affected, while the cost of healthcare is increased through ineffective therapeutic alternatives or “gray market” acquisitions. SCCM endorses the Preserving Access to Life-Saving Medications Act (S. 296/H.R.2245) as an important initial step to mitigating drug shortages and their consequences for the critically ill.

References

1. Hill JM, Reilly C. Can the United States ensure an adequate supply of critical medications? *FDLI's Food and Drug Policy Forum*. 2011;1(16):1-10.
2. Federico FA, Benjamin B, Cohen M. Drug shortages: a patient safety crisis. Leaders must plan ahead to address this critical issue. *Healthcare Executive* 2011;26(5):80, 82-83.
3. Kaakeh R, Sweet BV, Reilly C, et al. Impact of drug shortages on U.S. health systems. *Am J Health-Syst Pharm*. 2011;68:1811-1819.
4. Institute for Safe Medication Practices. ISMP survey on drug shortages. *ISMP Med Saf Alert* 2010;15(15):4.
5. Cherici C, Frazier J, Feldman M, et al. Navigating drug shortages in American healthcare: A Premier healthcare alliance analysis. March 2011. <http://www.premierinc.com/about/news/11-mar/drug-shortage-white-paper-3-28-11.pdf>. Accessed November 11, 2011.