Critical-Care Drug Shortages Continue, Despite FDA Action

By Lila Abassi — May 4, 2016

Shortage of drugs needed in acute and critical-care facilities are still widespread, despite federal regulation to curb the problem. In 2012, the Food and Drug Administration passed the Safety and Innovation Act (FDASIA), which was designed to give administrators greater authority to respond to crisis situations involving drug shortages.

In a report [2], published in Health Affairs, Yale University researchers sought to assess the impact that this legislation has had since its implementation. According to the authors, despite early evidence that there were reductions in total drug shortages, there still remains, however, reports of shortages in many drugs used in acute and emergent situations.

The authors used data collected between 2001 to 2014, provided by the University of Utah’s Drug Information Service, to show that despite overall reductions in drug shortages since the legislation was enacted, still half of all the shortages were drugs needed in critical settings. These shortfalls, they report, have become increasingly frequent and prolonged, as compared to non-acute drugs (median of 242 days versus 173 days).

“Our key finding was that up to 2012, shortages were rising for both non-acute and acute drugs,” according to senior author of the paper, Dr. Arjun Venkatesh [3], assistant professor of emergency medicine. “The shortages for non-acute drugs are decreasing and getting shorter but the shortages for acute drugs are increasing and getting longer,” he added.
Needless to say, these drug shortages can significantly compromise patient care and safety. Careful allocation and rationing by healthcare professionals has been one way to cope with shortage of critical medicines; another has been attempts to find alternative therapies. These shortages can delay important, time-sensitive treatments for patients and they also can result in medication errors.

Some institutions have seen delays or cancellations of procedures, prolonged hospital stays, serious medication errors or adverse drug reactions. These issues do not reflect the time spent by either pharmacists and other healthcare personnel in dealing with the management of drug shortages.

A complete list of all shortages is made available by the FDA and the American Society of Health-System Pharmacists (ASHP). Some examples of acute-care medications that are in short supply include commonplace drugs such as antibiotics to intravenous saline, as well as naloxone, which reverses overdoses due to heroin use – clearly ever more important as the opioid abuse pandemic plagues the nation.

Some reasons for drug shortages include the following:

- Unavailability of bulk and raw materials, of which 80 percent come from outside the U.S.
- A delay, or halt of production, regarding noncompliance of good manufacturing practices
- Voluntary recall of a drug after a problem surfaces with the medication, such as inadvertent bacterial or fungal contamination
- Change in the manufacturer or product formulation that delays production
- Manufacturer's business decision to halt production of a drug
- Manufacturer mergers that narrow the focus of product lines, causing discontinuation or shift in production to a new facility, resulting in production delays
- Poor inventory-ordering practices, stockpiling before price increases, and hoarding caused by rumors of an impending shortage
- Unexpected increases in demand for a drug
- Natural disasters that involve manufacturing facilities, or incidents that lead to having treat disaster victims

If these shortages of critical medications are not resolved, the future is grim. It seems that despite being handed broader reign, the FDA has not been able to address all classes of shortages, which points to the need for reconfiguring core strategies in order to minimize this problem.

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