

The Effects of Drug Shortages on Unsafe Injection Practices



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INTRODUCTION

On July 9, 2012, President Obama signed into law the Food and Drug Administration Safety and Innovation Act of 2012. The US Food and Drug Administration (FDA) now has new authority to combat shortages of drugs in the United States and impose new requirements on manufacturers regarding early notification to FDA of potential shortages or disruptions of supplies. The legislation also requires FDA to develop a list of drug shortages, including the reason for and duration of the shortages.¹

National drug shortages have become a factor in safe injection practices in healthcare facilities. Due to the ongoing shortages of frequently used drugs, practitioners are finding ways to help ease the burden of not having enough of these critical frequently used medications. Unsafe practices, such as reuse of single-dose vials on multiple patients, are done with the notion that they reduce costs without an appreciation of the risks involved.² As a patient safety liaison for the Pennsylvania Patient Safety Authority sharing information on current drug shortages with my peers and facilities, some facilities have stated they are using single-dose vials for more than one patient in order to conserve resources and prevent waste. There are other rationalizations for the misuse of single-dose vials, including efficiency, time constraints, conservation of resources, avoidance of waste, and cost considerations.³

No matter what the rationalization is, the improper use of single-dose vials continues to result in infection outbreaks.⁴ This year, two outbreaks of invasive *Staphylococcus aureus* infections in Arizona and Delaware were associated with the reuse of single-dose vials.⁴ During the last five years, the Centers for Disease Control and Prevention (CDC) is aware of at least 19 outbreaks due to unsafe injection practices involving the use of single-dose or single-use medications for more than one patient.⁴ National drug shortage was a documented factor in the unsafe injection practices of an outbreak involving bupivacaine this year. To conserve resources, staff used each 30 mL vial of the anesthetic, as needed, for multiple patients until the vial contents were depleted. If the 30 mL vial was not used in a single day, the vial was not discarded but saved for use the following day.³

Vials intended for single use are labeled “single-use” or “single-dose” because these vials contain no preservatives or antimicrobials to prevent bacterial contamination. Because such contamination is not visible to the human eye, it must be assumed that once the stopper is penetrated or the ampule is broken, contamination occurs, posing a risk of infection to the patient who next receives contents withdrawn from the vial.³

Frequent drug shortages complicate this problem. In most cases, there are no warnings of upcoming drug shortages or how long the shortages may last. Approximately 280 drugs, almost all manufactured in the United States, remain in short supply because of factors such as a dwindling number of drug manufacturers, deteriorating conditions in factories, and low prices for generics leading to a lack of investment to upgrade plants.⁵ Propofol is another drug in particular that is on the list of drug shortages. This drug is commonly used both in hospitals and ambulatory surgical facilities. Propofol is formulated in a lipid emulsion that supports rapid bacterial growth. There have been numerous outbreaks of bacterial and viral infections as a result of reuse of single-dose vials of propofol on multiple patients.²

CDC and the Centers for Medicare and Medicaid Services (CMS) have recently reiterated their stance on the use of single-dose vials.^{6,7} Both organizations state that the practice of using single-dose vials for more than one patient is unacceptable. There is one exception to this policy in that single-dose vials may be split into multiple doses

when utilizing US Pharmacopeia (USP) chapter 797 guidelines. Strict adherence to these guidelines by qualified, trained personnel, and under no less than International Organization for Standardization (ISO) class 5 air quality conditions, is mandatory. Proper labeling of these medications is also required. Clinical units and operating rooms are not considered adequate for this purpose. CMS states that facilities that reuse single-dose vials for more than one patient without adhering to USP chapter 797 standards must be cited during regulatory survey.³

Despite the availability of guidance on best practices from CDC and other groups, there remains a lack of awareness and

implementation of these recommendations by many practitioners. Guidance on the issue of safe injection practices and drug shortages can be found from various organizations, including CDC, CMS, FDA, and the Authority (in articles published in June 2008 and June 2011^{8,9}). The Safe Injection Practices Coalition has joined in a partnership with healthcare organizations led by CDC in the One and Only Campaign to provide resources for safe injection practices for the healthcare community and patients. Information on this campaign can be found at <http://www.OneandOnlycampaign.org>.⁴ Clinicians and purchasing staff should consider purchasing the smallest-size vials to prevent

waste and avoid the misconception by clinical staff that there is enough medicine for more than one patient in the single-dose vials. Another alternative would be to use multidose vials when appropriate.

CONCLUSION

Outbreaks of infection resulting from unsafe injection practices are both unacceptable and preventable. Each time a healthcare professional does not adhere to safe injection practices, they endanger the very patient who they set out to help. Healthcare practitioners must not endanger patients due to these shortages and inappropriate workarounds. Single-dose vials are only meant for one patient.

NOTES

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8. Dangers associated with shared multidose vials. Pa Patient Saf Advis [online] 2008 Jun [cited 2012 Sep 8]. [http://patientsafetyauthority.org/Advisories/AdvisoryLibrary/2008/jun5\(2\)/pages/68.aspx](http://patientsafetyauthority.org/Advisories/AdvisoryLibrary/2008/jun5(2)/pages/68.aspx).
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