Inappropriate Use of Pharmacy Bulk Packages of IV Contrast Media Increases the Risk of Infections

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Problem: In 2012, the Centers for Disease Control and Prevention (CDC) reiterated its position calling for medications labeled as “single dose” or “single use” to be used for only one patient. Single-use medications typically lack antimicrobial preservatives; they can become contaminated and serve as a source of pathogens when used inappropriately. With costly medications or severe drug shortages encouraging the inappropriate reuse of single-dose vials, and with 6% of nurses admitting in a national survey to always or sometimes using this unsafe practice, hospitals may find it challenging to meet the CDC requirement. The Institute for Safe Medication Practices (ISMP) has learned of another challenge to assuring safe use of the product and information on proper techniques to prevent contamination and the spread of infection.

The U.S. Pharmacopeia (USP) provides a detailed definition of a PBP, which includes but is not limited to the following crucial parameters:

1. A PBP is a container of a sterile preparation for parenteral use that contains many single doses. The contents of PBPs are intended for use in a pharmacy admixture program and are restricted to the preparation of admixtures for infusion or, through a sterile transfer device, for the filling of empty sterile syringes.
2. The PBP closure shall be penetrated only one time after constitution with a suitable sterile transfer device or dispensing set that allows dispensing of the contents.
3. The PBP is to be used only in a suitable work area, such as a laminar flow hood (or an equivalent clean-air compounding area).
4. PBPs, although containing more than one single dose, are exempt from the multiple-dose container volume limit of 30 mL and the requirement that they contain a substance or suitable mixture of substances to prevent the growth of microorganisms.
5. When a container is offered as a PBP, the label shall contain or refer to information on proper techniques to assure safe use of the product and bear a statement limiting the time frame in which the container may be used once it has been entered, provided it is held under the labeled storage conditions.

The Food and Drug Administration (FDA) considers an aseptic area to be a suitable work area for using PBPs. The FDA defines an aseptic area as having engineering controls such as HEPA-filtered laminar air flow that meets the guidelines of International Standards Organization (ISO) Class 5, appropriate cleaning and disinfection procedures, and periodic microbiological monitoring of the area. The FDA does not regard PBPs as appropriate for use in a radiology suite unless the suite meets the criteria for a suitable work area as noted above. More information pertaining to a suitable work environment can be found in USP General Chapter 797.

Accordingly, package labeling for PBPs of IV contrast media recommends transfer of the contents in a suitable work area as defined above, penetration of the closure only one time, and immediate transfer of the contents using a suitable transfer device. However, the labeling suggests that if the content transfer cannot be accomplished immediately, it can be completed within a maximum of four to 10 hours (depending on the specific product) from initial closure entry as long as the PBP container is not removed from the aseptic area during the entire four- to 10-hour period.

Confusion regarding the proper transfer of IV contrast media from PBPs has been perpetuated by the labeling of some radiographic contrast injectors on the market that describe use with PBPs, which is inconsistent with the PBP labeling. The FDA is aware of these labeling issues and is in the process of resolving the inconsistencies in the device and drug labeling.

Another confounding factor is that some staff members erroneously believe that use of a sterile transfer set, as outlined in point 2 of the USP definition of a PBP, is all that is required to meet the standards of a “suitable work area.” In these cases, hospital staff members hang a PBP of IV contrast media with a sterile transfer set attached for the entire day in a radiology suite or other unsuitable environment. Staff members then withdraw multiple, individual patient doses from the PBP with a power injector (or by hand in cardiac catheterization and surgery units) by entering the container over and over again. Such practices, which are
inconsistent with FDA requirements for the proper use of PBPs, the Centers for Medicare and Medicaid Services Conditions of Participation for Hospitals, the CDC Injection Safety Guidelines, and the Joint Commission standards, expose patients to the risk of developing a potentially life-threatening infection.

In fact, serious and fatal infections from misuse of single-use vials of contrast media were reported in the July 13, 2012, issue of Morbidity and Mortality Weekly Report. According to the CDC, three patients in an Arizona pain management clinic who received contrast media injections from the same container during radiological imaging were admitted to the hospital for severe methicillin-resistant *Staphylococcus aureus* (MRSA) infections, including mediastinitis, bacterial meningitis, epidural abscess, and sepsis. Hospitalization ranged from nine to 41 days, with additional long-term care required for one patient. A fourth patient who received contrast from the same vial was found deceased at home. The cause of death was reported as a multiple-drug overdose; however, an invasive MRSA infection from cross-contamination of the contrast media could not be ruled out. In addition to identifying improper reuse of contrast media containers intended for single use, officials noted that health care staff members failed to wear face masks during the spinal injection procedures.

**SAFE PRACTICE RECOMMENDATIONS:** To reduce the risk of infections from contamination of IV contrast media, consider the following recommendations.

**Pharmacy oversight.** The pharmacy department should oversee the purchase, distribution, storage, and use of IV contrast media in all inpatient and outpatient clinical areas of the health care organization. Regular pharmacy monitoring of the storage and use of these products should become routine. Pharmacists should periodically attend departmental staff meetings for units where contrast media is used to discuss the safe use of IV contrast media, including the inappropriate handling of PBPs in such areas.

**Single-dose vials and syringes.** In patient-care units such as radiology, cardiac catheterization labs, and operating rooms, staff members should draw doses of IV contrast media from single-dose vials or use prefilled single-use syringes from the pharmacy or as available from most manufacturers. Any medication remaining in the vials or syringes should be discarded immediately.

**Proper use of PBPs.** The contents of PBPs of IV contrast media (or PBPs of any medication) should only be transferred to single-dose containers or syringes in the pharmacy under a laminar flow hood or other suitable ISO Class 5 environment according to USP 797. If the dose of contrast media in a single-use vial is insufficient for one patient, a PBP could be used for a single aseptic transfer to a sterile container or syringe for one patient only. The PBP should be treated as a single-use vial—the transfer set should be disconnected and any remaining drug in the PBP should be discarded immediately after the initial removal of the patient’s individual dose.

**REFERENCES**


