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SBAR: Infection control risk with inappropriate use of pharmacy bulk packages (PBP) of IV contrast materials

Situation:

Reports of dangerous practices using bulk contrast material as a “multidose” container and dispensing from the same container to multiple patients throughout the day persist. Despite being labeled as pharmacy bulk packaging (PBP), reports of misuse have been reported in medical imaging departments, cardiac catheterization laboratories and outpatient surgery centers.

There are still reports of potentially dangerous practice of using bulk contrast material as “multidose” containers, and of dispensing from the same container to multiple patients throughout the day in medical imaging departments, cardiac catheterization laboratories, and outpatient surgery centers despite being labeled as pharmacy bulk packaging (PBP).

Background:

The Centers for Disease Control and Prevention (CDC) [“One and Only” Campaign](#), the [Institute for Safe Medication Practices \(ISMP\)](#), and [United States Pharmacopeia \(USP\) <797> Guidebook to Pharmaceutical Compounding-Sterile Preparations](#) create standards to inform key stakeholders regarding the safety aspects of single use medication.

The ISMP issued a medication safety alert on September 20, 2012 “[Inappropriate Use Of Pharmacy Bulk Packages Of IV Contrast Media Increases Risk Of Infections](#)” addressing concerns with the practice of administering PBP contrast materials to multiple patients throughout the day, i.e. using PBP as multi-dose containers. ISMP recommended the following safe practices:

- **Provide pharmacy oversight** in purchase, distribution, storage, and use of intravenous contrast media in all inpatient and outpatient clinical areas of the healthcare organization.
- **Use single-dose vials and syringes** in all patient care units and departments.
- **Ensure proper preparation of PBPs** by transfer 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>.

The USP <797> Guidebook to Pharmaceutical Compounding-Sterile Preparations outlines the proper environment for handling of sterile preparations, pre-administration manipulation of compounded preparations, storage, compounding, and transport. The guidelines state PBP:

- Refers to a container of a sterile preparation for parenteral use that contains many single doses.
- Are intended to be prepared directly for infusion, or to fill empty sterile syringes using a sterile transfer device per a pharmacy admixture program.



- Shall have its closures be penetrated only one time after constitution with a suitable sterile transfer device or dispensing set.
- Is to be used only in a suitable work area such as a laminar flow hood or an equivalent clean air compounding area.
- Contain a label with information on safe storage conditions and a statement limiting the time frame in which the container may be used once it has been entered.

Assessment:

There continue to be reports that PBP contrast materials are not being manipulated, stored, and dispensed using USP recommendations for safe infusion preparation. The misuse of PBP contrast materials (sometimes called “multi-pack”) as multi-dose containers is a dangerous practice as it has the potential for contamination that can lead to infection. Bulk contrast materials do not typically contain preservatives, therefore, should be handled in the safe manner prescribed for PBP products.

Recommendations:

Infection preventionists collaborate with pharmacy and user departments to verify that bulk packaging contrast material handling, storage, and dispensing conforms to standards outlined in the CDC "One and Only Campaign, the ISMP and the USP <797> for safe infusion. Bulk packaged contrast material should never be used as multi-dose containers in daily practice.

For questions, contact practice@apic.org

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