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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Addendum (June 2017):

Marge Gribogiannis, MPA, MT (ASCP) SM, CIC, Author/Reviewer, Chair, APIC Practice Guidance Committee

Infection control risk and use of imaging bulk packages (IBP) of IV contrast materials

The IBP was approved by the U.S. Food and Drug Administration (FDA) for the nonionic iodinated contrast medium ISOVUE in 2014. The USP now recognizes the IBP as the only contrast medium container suitable for multi-dose, multi-patient use directly in radiology rooms. The new definition of the IBP is now available online; the revised chapter will become official May 1, 2017. Some manufacturers have recently relabeled their products with FDA approval as imaging bulk package (IBP) versus the USP terminology of pharmacy bulk packaging (PBP). This label change appears to exempt the imaging bulk package from USP compounding standards for pharmacy bulk packaging.

Manufacturers of IBP do include the use of aseptic technique practices in their instructions for use (IFU). Infection preventionists should assess whether their facility is using PBP or IPB. When using items labeled IBP, IPs need to carefully observe and review the documented associated aseptic practices at their facility. In addition to monitoring for compliance with contrast media hang time and mandatory contrast material disposal and all associated disposables there needs to be review of any infection control breach in the automated contrast injection system. When using PBP, then it is important for IP to ensure it is not being used in the radiology/imaging area as PBP is solely intended for use by pharmacy.
A study published in 2015 by the *American Journal of Roentgenology* highlighted that the FDA approval of iopamidol as an imaging bulk package was based on manufacturer submission of both chemical and microbiologic studies. The study acknowledged that certain multi-patient doses of contrast bulk agents do not meet the USP definition of a pharmacy bulk package which led to FDA approval of a new USP category of multidose presentation—the imaging bulk package.¹