Society of Interventional Radiology Position Statement on Injection Safety: Improper Use of Single-dose/Single-use Vials

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ABBREVIATIONS

CDC = Centers for Disease Control and Prevention, MDV = multidose vial, SDV = single-dose vial, USP = United States Pharmacopeia

Efficient health care delivery includes expense reduction, distribution of limited resources, and minimization of medical waste. These goals must be achieved without patient safety compromise. One challenging example is the administration of injectable medications. Some common procedures may require injection of only a small quantity of medication such as sodium tetradecyl sulfate (Sotradecol; AngioDynamics, Queensbury, New York), onabotulinumtoxinA (BOTOX Cosmetic; Allergan, Irvine, California), or radiocontrast agents for arthrography, myelography, or percutaneous pain management procedures. In a busy clinical setting, with several consecutive patients scheduled for similar procedures, it may be tempting to purchase a medication in a large "economy-size" container and split the doses into multiple syringes for administration to multiple patients.

An essential feature of injection practice involves the safe administration of a medication packaged in a single-dose vial (SDV) or single-use vial. The Centers for Disease Control and Prevention (CDC) note that improper use of a medication packaged in an SDV can place a patient at increased risk for acquiring a health care–related infection (1). Medication from an SDV is intended for parenteral administration for a single patient during a single procedure. SDVs are labeled as such in the manufacturer's package insert. The CDC states that SDVs must not be used for multiple patients. Even if an SDV contains more medication than is needed for a single patient, that vial should not be used for more than one patient nor stored for future use in the same patient.

In contrast with an SDV, a multidose vial (MDV) of a medication contains more than a single medication dose. MDVs are labeled as such by the manufacturer and typically contain an antimicrobial preservative agent to help prevent bacterial growth. The preservative agent has no effect on viruses and does not protect against contamination when health care personnel fail to follow safe injection practices. MDVs are discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial. An MDV used for more than one patient is required to be kept in a centralized medication area and not accessed in the immediate patient treatment area (eg, procedure room, patient room). If MDVs enter the treatment area, they should be dedicated for single-patient use and discarded immediately after use (2).

A medication in an SDV can become contaminated and act as an infection source if administered to multiple patients. The infection outbreak risk is particularly increased with repeated SDV access with more than one needle whenever an SDV is used for more than one patient. Since the CDC safe injection guidelines were published in 2007, the CDC has reported 21 outbreaks associated with SDV medications administered for multiple patients: seven outbreaks involved infections transmitted through contamination by blood, and 14 involved bacterial infections (3–7). Two recently reported outbreaks of invasive *Staphylococcus aureus* infection were confirmed in 10 patients being treated for pain in outpatient clinics in Delaware and Arizona, in which SDVs were reused for multiple patients (7). Transmission of life-threatening but preventable bacterial infections by failing to follow safe-injection recommendations can result in an infection outbreak that causes unnecessary morbidity and draws attention of the media and regulatory agencies (8).

Concerns have been raised about whether these guidelines and related policies contribute to drug shortages and increased medical costs to health care providers. On May 2, 2012, the CDC restated its 2007 position regarding the use of SDVs in response to "inaccuracies" being disseminated to health care providers (9). The CDC recognized the problem of drug shortages; however, such shortages are noted to be the result of manufacturing, shipping, and other issues unrelated to the guidelines. The CDC noted that lowering safety standards will not address the problem of drug shortages (10).

Under certain conditions, however, such as during limited drug availability, it is permissible for health care facilities to repackage SDVs into smaller doses, each intended for a single patient use. Repackaging is allowable if performed by qualified health care personnel under specific conditions according to standards in United States Pharmacopeia (USP) General Chapter 797, Pharmaceutical Compounding–Sterile Preparations (11), as well as the manufacturer's recommendations pertaining to safe storage of that medication outside of its original container (11). On June 15, 2012, CMS issued a memorandum that stated that health care providers that do not comply with USP standards for SDVs may be cited for deficiencies under applicable federal infection control standards (12).

SVDs must never be used for multiple patients unless specific conditions allow repackaging by qualified health care personnel under USP standards. It is the responsibility of interventional radiologists and other licensed personnel to adhere to best care practices for the safe performance of minimally invasive treatments.

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