

## Infection Prevention: Single- and Multidose Vial Management

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Since the Centers for Disease Control and Prevention's (CDC's) *Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings* was published in 2007, there have been numerous outbreaks identified from the mishandling of medication and the reuse of syringes (CDC, 2013). These guidelines include a section on safe injection practices as a component of standard precautions and are not new, although compliance with the use of single-dose vials (SDVs) and multidose

vials (MDVs) continues to be problematic.

In 2008, the United States Pharmacopeia (USP) revised USP General Chapter <797> and its standards for the pharmaceutical compounding of sterile preparations. USP Chapter <797> requirements must be met in *all* healthcare settings (not just pharmacies), and by *all* clinicians involved in sterile compounding, including home care and hospice staff. Pharmacies compound sterile preparations in at least an International Organization for Standardiza-

tion (ISO) class 5 environment with primary engineering control devices, personal protective equipment, and personnel and surface sanitation requirements. Staff who prepare medications outside of ISO class 5 settings (e.g., in general room air) put the patient at risk for infection as the environment contains particulates and microorganisms that can cause contamination of the vials from both airborne and direct contact sources (USP, 2011).

All stored medications must be labeled with an expiration date. The manufacturer's expiration date refers to the date after which an unopened MDV should not be used. Once the vial cap is removed or the vial is punctured, the manufacturer's expiration date is no longer valid and the vial must be relabeled with a revised date (also called the "beyond use date" [BUD]). The BUD refers to the date after which an opened MDV should not be used. The BUD should never exceed the manufacturer's original expiration date (USP, 2011). USP Chapter <797> recommends the following for SDVs and MDVs:

- If a MDV has been opened or accessed (e.g., needle-punctured), the vial should be dated and discarded within 28 days, unless the manufacturer specifies a different (shorter or longer) date for that opened vial.
- If a MDV has not been opened or accessed (e.g., needle-punctured), it

**Table 1. Differences Between a Single- and a Multidose Vial**

Single-Dose Vial (SDV)	Multidose Vial (MDV)
Bottle of liquid (injectable) medication that is approved by the Food and Drug Administration for use on one person.	Bottle of liquid (injectable) medication that is approved by the Food and Drug Administration for use on multiple persons.
Contains one dose of a medication and no antimicrobial preservative.	Contains more than one dose of a medication and a bacteriostatic preservative.
Discard immediately after a single use.	Dedicate MDV to a single patient whenever possible. If MDVs are used for more than one patient, they must not enter the immediate treatment area (e.g., patient room in a facility-based hospice care setting).
Use within 1 hour when opened in less than International Organization for Standardization class 5 air quality (general room air) with any remaining contents discarded.	May be used up to 28 days of opening or puncture (except for vaccines or when original manufacturer's expiration date is shorter) or when the manufacturer's expiration date is reached.
	Label with a revised expiration date once the MDV is opened or punctured.
Dedicate to a single patient. Use a new needle and new syringe for each entry if a SDV must be entered more than once during a single procedure for a single patient to achieve safe and accurate titration of dosage.	Dedicate to a single patient whenever possible. If MDVs are used for more than one patient, they should not be stored or accessed in the immediate patient treatment area (e.g., patient room in a facility-based hospice care setting). If a MDV enters the immediate patient treatment area, it should be dedicated to that patient only and discarded after use.

Medicare-certified home healthcare agencies and hospices that do not adhere to United States Pharmacopeia <797> standards, and reuse single-dose vials for multiple patients, will be cited for deficiencies under the applicable infection control standard(s).

should be discarded according to the manufacturer's expiration date.

- If a SDV is opened or punctured in less than an ISO class 5 environment (room air), the contents must be used within 1 hour or discarded.
- Single-dose ampoules must be discarded after opening and may not be stored for any period of time (USP, 2011).

Vaccines stored in MDVs are exempt from the 28-day beyond use dating requirement and can be used until the manufacturer's expiration date when the integrity of the vaccine has been maintained through proper storage and handling (i.e., the correct temperature has been maintained, temperature checks have been conducted

twice a day, etc.) or there is a BUD noted in the package insert. The Food and Drug Administration allows manufacturers to provide extended dating in the package insert only if they have conducted testing beyond the 28 days. For example, tuberculin purified protein derivative products used for skin testing (Aplisol, TUBERSOL) and Byetta (exenatide) may be used up to 30 days per the manufacturers' recommendations, and Levemir stored in a MDV and a Levemir FlexTouch pen may be used up to 42 days after opening. Therefore, it is important to check the manufacturer's recommended storage time frames.

Medicare-certified home healthcare agencies and hospices that do not adhere to USP <797> standards, and reuse SDVs for multiple patients, will

be cited for deficiencies under the applicable infection control standard(s) (Centers for Medicare and Medicaid Services, 2012). Often staff is not familiar with the differences between a SDV and MDV vial. Table 1 includes a summary of these differences. Medication in either a SDV or MDV and the associated injection equipment/supplies must be handled, prepared, and stored using aseptic technique in a sub-ISO 5 environment to prevent microbial contamination. Table 2 contains important strategies for the staff to consistently manage SDVs and MDVs in an aseptic manner. ■

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**Table 2. Aseptic Technique Using Single- and Multidose Vials**

- Perform hand hygiene.
- Check the single- or multidose vial or container before each entry for:
  - Visible turbidity, leaks, cracks, or particulate matter, and
  - Whether the expiration or beyond use date has passed.
- Store and prepare medications and supplies in a clean area, on a clean surface.
- Affix a new needle to a new syringe without contact contamination, for each entry into a vial.
- Disinfect the vial's septum prior to entry by wiping with at least 70% isopropyl alcohol before each piercing of the septum. Assure the septum's surface is wet with the isopropyl alcohol and allow the wet surface to air dry for 10 seconds before piercing the septum.
- Spike the vial with a needle or one-way device without direct contamination and remove it after use.

Source: Adapted from McGoldrick, M. (2015). Patient care practices. In *Home Care Infection Prevention and Control Program* (pp. 26-27). St. Simons Island, GA: Home Health Systems, Inc.