The Safe Injection Practices Issue

With medication shortages on the rise, it's important to reiterate best practice regarding drugs packaged in single- and multi-use vials. The chart below provides at-a-glance understanding of the differences between these packaging options and the resulting implications for patient safety based on the Centers for Disease Control and Prevention (CDC) guidelines.

<table>
<thead>
<tr>
<th>What is a single-dose vial?</th>
<th>What is a multi-dose vial?</th>
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</thead>
<tbody>
<tr>
<td>A single-dose or single-use vial is a vial of liquid medication intended for parenteral administration (injection or infusion) that is meant for use in a single patient for a single case/procedure/injection. Single-dose or single-use vials are labeled as such by the manufacturer and typically lack an antimicrobial preservative.</td>
<td>A multi-dose vial is a vial of liquid medication intended for parenteral administration (injection or infusion) that contains more than one dose of medication. Multi-dose vials are labeled as such by the manufacturer and typically contain an antimicrobial preservative to help prevent the growth of bacteria. The preservative has no effect on viruses and does not protect against contamination when healthcare personnel fail to follow safe injection practices.</td>
</tr>
</tbody>
</table>

Can single-dose or single-use vials be used more than once? No. | Can multi-dose vials be used more than once? Yes.

For an entertaining, interactive tutorial on single- and multi-use vials from the One & Only Campaign, click here.

AAAHC on the road
Attending a professional conference? Visit our booth at:

Great Lakes Medical/Dental Summit
May 9-10
Indianapolis, IN

ASCA 2014
May 14-16*
Nashville, TN

American College Health Assn. Annual Meeting
May 29-30*
San Antonio, TX

APIC
June 7-9
Anaheim, CA

US Public Health Service Scientific and Training Symposium
June 11-12
Raleigh, NC

Becker's 12th Annual Spine, Orthopedic and Pain-Management-Driven ASC Conference
June 12-14
Chicago, IL

*Dates reflect exhibit hall access only; conference dates are longer.

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### Use Vials Be Used for More than One Patient? Used for More than One Patient? How?

No. Vials that are labeled as single-dose or single-use should be used for a single patient and single case/procedure/injection. There have been multiple outbreaks resulting from healthcare personnel using single-dose or single-use vials for multiple patients.

Even if a single-dose or single-use vial appears to contain multiple doses or 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 on the same patient.

To prevent unnecessary waste or the temptation to use contents from single-dose or single-use vials for more than one patient, clinicians and purchasing personnel should select the smallest vial necessary for their needs when making treatment and purchasing decisions.

### When Should Single-dose or Single-use Vials Be Discarded?

Medication vials should always be discarded whenever sterility is compromised or questionable. In addition, the following recommendations are made for handling of single-dose or single-use vials:

- If a single-dose or single-use vial has been opened or accessed (e.g., needle-punctured) the vial should be discarded according to the time the manufacturer specifies for the opened vial or at the end of the case/procedure for which it is being used, whichever comes first. It should not be stored for future use.
- If a single-dose or single-use vial has not been opened or accessed (e.g., needle-punctured), it should be discarded according to the manufacturer’s expiration date.

### When Should Multi-dose Vials Be Discarded?

Medication vials should always be discarded whenever sterility is compromised or questionable.

In addition, the United States Pharmacopeia (USP) General Chapter 797 [16] recommends the following for multi-dose vials of sterile pharmaceuticals:

- If a multi-dose 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 multi-dose vial has not been opened or accessed (e.g., needle-punctured), it should be discarded according to the manufacturer’s expiration date.

NOTE: The manufacturer’s expiration date refers to the date after which an unopened multi-
The beyond-use-date refers to the date after which an opened multi-dose vial should not be used. The beyond-use-date should never exceed the manufacturer’s original expiration date.

For information on storage and handling of vaccines please refer to [the CDC Vaccine Storage and Handling Toolkit](http://www.e-affect.com/aaahc-email/email-5-14/email-3.html) or the manufacturer’s recommendations for specific vaccines.

The One & Only Campaign is a public health campaign, led by the Centers for Disease Control and Prevention (CDC) and the Safe Injection Practices Coalition (SIPC), to raise awareness among patients and healthcare providers about safe injection practices. The Campaign aims to eradicate outbreaks resulting from unsafe injection practices.

What do surveyors look for?

**Q&A on Multi-dose vials**

Safe injection practices touch on multiple topics covered by AAAHC Standards including Quality of Care Provided, Quality Management and Improvement and, most importantly, Infection Prevention and Control and Safety.

At its March 2014 meeting, the AAAHC Standards and Survey Procedures Committee addressed several questions about survey practices and the use of multi-dose vials (MDV).

**Q:** Would storing an unopened manufacturer-labeled and within current date range MDV in an anesthesia cart in the operating room result in a survey deficiency?

**A:** No, this would not result in a deficiency. It is acceptable to store an unopened MDV inside of the anesthesia cart or inside of the operating room. An example of such a practice would be an emergency drug used for patient rescue. However, once a MDV is opened and accessed in a direct patient care area, the vial is dedicated to use with that patient only. Any unused medication from this vial is discarded.

**Q:** Is it appropriate to prepare a medication by drawing it into a syringe aseptically in an operating room/procedure room/patient examination space, prior to a patient’s arrival or...
when no patient is present, with the intention of retaining the contents of the MDV for use with other patients?

**A:** No. This is not an appropriate use of a MDV. Once opened or accessed within a patient care area, MDV contents should not be retained for use on other patients.

**Q:** Please define ‘immediate treatment area.’

**A:** The CDC and WHO guidelines, and the Medicare requirements for ASCs, state: “If a MDV is opened and accessed in the immediate patient treatment area, it should be dedicated to that patient only and discarded after use.” These guidelines formally define a patient care area as “operating room, procedure room, and patient examination areas.” When medication from a MDV is drawn up in a space separate from the operating room, procedure room, or exam area, it is acceptable to securely store that syringe for up to one hour, assuming the dose is labeled with the date/time drawn and the name or initials of the health care worker (HCW) preparing the syringe. When such a dose is drawn up and immediately administered, it need not be labeled as long as the dose does not leave the oversight of the HCW preparing the dose.

**Additional resources:**

Safe Injection Practices to Prevent Transmission of Infections to Patients  See Recommendation IV.H.7, category IA.

Frequently Asked Questions Regarding Safe Practices For Medical Injections  See page 6

GUIDE TO INFECTION PREVENTION FOR OUTPATIENT SETTINGS: Minimum Expectations for Safe Care  See pages 10-11

WHO best practices for injections and related procedures toolkit  Page 21 of 69

ASC Infection Control Surveyor Worksheet  See page 9

APIC position paper: Safe injection, infusion, and medication vial practices in health care  See page 4

American Society of Anesthesiologists: Standards, Guidelines, Statements and Other Documents  See “Recommendations for Infection Control in the Practice of Anesthesiology,” see pages 11-17