



**Centers for Disease Control and Prevention
National Center for Emerging and Zoonotic Infectious Diseases
Division of Healthcare Quality Promotion
Single-dose/Single-use Vial Position and Messages
May 1, 2012**

CDC is aware of confusion about and misrepresentation of guidelines protecting patients from disease that occurs when clinicians use single-dose/single-use vials for more than one patient. In an effort to ensure clinicians are clear about CDC guidelines, the agency is restating its position on the use of single-dose/single-use vials and also seeks to dispel inaccuracies being disseminated to healthcare providers.

CDC's Position

Protect Patients Against Preventable Harm from Improper Use of Single-dose/Single-use Vials

The Centers for Disease Control and Prevention's guidelines call for medications labeled as "single dose" or "single use" to be used for only one patient. This practice protects patients from life-threatening infections that occur when medications get contaminated from unsafe use. Concerns have been raised about whether these guidelines and related policies contribute to drug shortages and increased medical costs to healthcare providers. CDC recognizes the problem of drug shortages; however, such shortages are a result of manufacturing, shipping, and other issues unrelated to the above guidelines (www.fda.gov/DrugShortageReport). CDC's priority is protecting patients from harm. CDC routinely investigates and is apprised of infectious disease outbreaks involving single-dose/single-use vials being used for multiple patients. These outbreaks cause extensive harm to patients, and they are associated with significant healthcare and legal expenses. Therefore, CDC continues to strongly support its current policies regarding single-dose/single-use vials. It is imperative that drug shortages and drug waste concerns are dealt with appropriately and do not lead to unsafe medical practices that impose increased disease risk on patients. Shortages of some essential medications may warrant implementation of meticulously applied practice and quality standards, as stated in United States Pharmacopeia General Chapter <797> Pharmaceutical Compounding – Sterile Preparations, to split doses under sterile conditions.

General Messages

- Vials labeled by the manufacturer as "single dose" or "single use" should only be used for a single patient. These medications typically lack antimicrobial preservatives and can become contaminated and serve as a source of infection when they are used inappropriately.
- Ongoing outbreaks provide ample evidence that inappropriate use of single-dose/single-use vials causes patient harm.
- In times of critical need, contents from unopened single-dose/single-use vials can be repackaged for multiple patients. However, this should only be performed by qualified healthcare personnel

in accordance with standards in [United States Pharmacopeia](#) General Chapter <797> Pharmaceutical Compounding – Sterile Preparations. 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. Healthcare facilities can proactively arrange for these doses to be split, in accordance with USP standards, when necessary.

- Lowering safety standards will not address the problem of drug shortages.

Basic Safe Injection Practice Messages

1. CDC evidence-based guidelines define safe injection practices under Standard Precautions. These include one-time use of needles and syringes and limiting sharing of medication vials. Vials labeled as “single dose” or “single use” should not be used on multiple patients.
 - a. A large single-dose/single-use vial may appear to contain adequate drug to treat more than one patient. However, this does not change the fact that the vial is not intended for such use and, therefore, it should only be used for a single patient and a single procedure.
2. Unsafe injection practices include, but are not limited to, reuse of syringes for multiple patients or to access shared medications, administration of medication from a single-dose/single-use vial to multiple patients, and failure to use aseptic technique when preparing and administering injections.
3. Injection safety is every provider’s responsibility. It is especially important to remember that when injecting medications into sterile sites, such as the spine, there is no margin for error.
4. When providers deviate from CDC’s safe practice guidelines, they are imposing risks on their patients. Since the CDC Guidelines were published in 2007, CDC is aware of at least 19 outbreaks associated with single-dose/single-use medications:
 - a. 7 outbreaks involved bloodborne pathogen infections and 12 involved bacterial infections (with a majority of affected patients requiring hospitalization)
 - b. All of these outbreaks involved outpatient settings, with the majority occurring in pain remediation clinics (n=8).
5. Healthcare providers should consult with pharmacy professionals and USP 797 standards when there is a need to subdivide contents of single-dose/single-use vials.

Misperceptions vs. Facts

CDC is aware of a number of misinterpretations or misrepresentations of CDC’s guidelines regarding single-dose/single-use vials. CDC outlines below some of these issues and provides more explanation of the agency’s position.

Misinterpretation/Misperception	Fact
Improper use of single-dose/single-use vials puts patients at risk of infection with only bloodborne pathogens such as hepatitis C virus.	Infection risk is not just limited to bloodborne pathogens. Outbreaks from improper use of single-dose/single-use vials have resulted in life-threatening bacterial infections including bloodstream infections, meningitis, and epidural abscesses. Many of these infections have occurred following injection procedures performed in pain remediation clinics.
Guidance regarding safe handling of single-dose/single-use vials is new and has only been in place since 2010.	CDC injection safety guidelines are not new. They have been part of Standard Precautions since 2007 (http://www.cdc.gov/injectionsafety/IP07_standardPrecaution.html).
According to CDC, there is never a circumstance when contents from a single-dose/single-use vial may be used for more than one patient.	CDC recommends that providers limit the sharing of medications whenever possible. In certain instances, qualified healthcare personnel may repackage medication from a previously unopened single-dose/single-use vial into multiple single-use vehicles (e.g., syringes). This should only be performed under ISO Class 5 conditions in accordance with all standards in the United States Pharmacopeia General Chapter 797, Pharmaceutical Compounding – Sterile Preparations, as well as the manufacturer’s recommendations pertaining to safe storage of that medication outside of its original container.
There is no evidence that single-dose/single-use vials used for multiple patients are responsible for infections if “proper infection control measures” are applied.	Dedicating a single-dose/single-use vial to one patient is, in and of itself, a critical element of proper infection control. CDC continues to see outbreaks in healthcare settings where providers thought they were preparing and administering injections safely. In the last 5 years alone, CDC is aware of at least 26 outbreaks due to unsafe injection practices. These outbreaks resulted in more than 95,000 patients being referred for testing after potential exposure to infectious diseases. 73% (n=19) of these outbreaks involved use of single-dose/single-use medications for more than one patient. Several of these outbreaks are listed here . All of the outbreaks associated with improper use of single-dose/single-use medications occurred in outpatient settings, with pain clinics (n=8, 42%) representing the most common facility type. These and other suboptimal practices are common, as reported by numerous studies about infection control compliance rates. In fact, in one study published in the Journal of the American Medical Association, CDC and Centers for Medicare and Medicaid Services colleagues reported that two-thirds of the outpatient facilities

	<p>inspected had lapses in basic infection control practices (http://blogs.cdc.gov/safehealthcare/?p=419). Moreover, infection surveillance is lacking in most outpatient settings; thus it is likely that outbreaks are occurring at a higher frequency, but going undetected.</p>
<p>CDC’s recommendations regarding single-dose/single-use vials are flexible. In 2002 the agency issued a communication to the Centers for Medicare and Medicaid Services (CMS) regarding how to safely use contents from single-dose/single-use vials for more than one patient in a dialysis setting. If they allowed use of single-dose/single-use vials for more than one patient in dialysis clinics, why can’t it be applied to other patients?</p>	<p>The current injection safety guidance is part of CDC’s 2007 Guideline Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings. This guidance supersedes all other formal and informal guidance on this topic and was developed to reflect accumulating evidence, including bloodborne pathogen risk, gathered from outbreaks caused by unsafe injection practices.</p> <p>In 2002, an informal communication to the Centers for Medicare and Medicaid Services (CMS) suggested that certain medications packaged in a single-dose/single-use vial could be used for more than one patient in dialysis settings, assuming that certain criteria were followed. In 2008, CDC issued a formal clarification specifically to dialysis providers stating that the 2007 guidance superseded the 2002 CDC communication to CMS (http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5732a3.htm).</p>
<p>Considerable healthcare savings could be achieved if less stringent policies were in place.</p>	<p>Any potential savings from stretching the contents of single-dose/single-use vials by healthcare providers can be quickly offset by the costs associated with viral hepatitis, bloodstream infections, meningitis, epidural abscesses and other infectious complications. These costs are primarily borne by patients and their families. In addition, clinicians could face legal costs and potentially lose their medical licenses if basic safe practices are not followed and patients are harmed.</p>

FAQs About Single-dose/Single-use Vials

What is a single-dose or single-use vial?

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.

Can single-dose or single-use vials be used for more than one patient?

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.

In critical situations, is there any option for medication from a single-dose/single-use vial to be used for more than one patient?

It is optimal for the medication to be used for just one patient. Shortages of some essential medications may warrant implementation of meticulously applied practice and quality standards to split doses under sterile conditions. In these cases, qualified healthcare personnel may repackage medication from a previously unopened single-dose/single-use vial into multiple single-use vehicles (e.g., syringes). This should only be performed under ISO Class 5 conditions in accordance with standards in United States Pharmacopeia General Chapter 797, Pharmaceutical Compounding – Sterile Preparations, as well as the manufacturer’s recommendations pertaining to safe storage of that medication outside of its original container.

Is it acceptable to combine (pool) leftover medication from single-dose or single-use vials?

No. Do not combine (pool) leftover contents of single-dose or single-use vials or store single-dose or single-use vials for later use. Single-dose or single-use vials are intended for use on a single patient for a single case/procedure. There have been outbreaks resulting from pooling of contents of single-dose or single-use vials and/or storage of contents for future use.

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.

For more information, please see:

CDC Injection Safety Website: <http://www.cdc.gov/injectionsafety/>

- Free CME
- [Injection Safety Guidelines as part of Standard Precautions](#)
- Checklists/CDC Guide to Minimum Expectations for Safe Care
- Medscape expert commentary videos
- Recent Publications
- Educational materials for patients and clinicians

Safe Injection Practices Coalition Website: <http://www.oneandonlycampaign.org/>

- Clinician tools
- Patient information
- Educational materials

CDC Safe Healthcare Blog Entries Related to Injection Safety:

<http://blogs.cdc.gov/safehealthcare/?cat=164>

CDC Outpatient Settings Website: www.cdc.gov/HAI/settings/outpatient/outpatient-settings.html