Sentinel Event Alert

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Preventing infection from the misuse of vials

Published for Joint Commission accredited organizations and interested health care professionals, *Sentinel Event Alert* identifies specific types of sentinel and adverse events and high risk conditions, describes their common underlying causes, and recommends steps to reduce risk and prevent future occurrences.

Accredited organizations should consider information in a *Sentinel Event Alert* when designing or redesigning processes and consider implementing relevant suggestions contained in the alert or reasonable alternatives.

Thousands of patients have been adversely affected by the misuse of single-dose/single-use and multiple-dose vials. The misuse of these vials has caused harm to individual patients through occurrences and outbreaks of bloodborne pathogens and associated infections, including hepatitis B and C virus,[1,2] meningitis, and epidural abscesses.[3] Adverse events caused by this misuse have occurred in both inpatient and outpatient settings, according to the Centers for Disease Control and Prevention (CDC).

The misuse of vials primarily involves the reuse of single-dose vials,[3] which are intended to be used once for a single patient. Single-dose vials typically lack preservatives; therefore, using these vials more than once carries substantial risks for bacterial contamination, growth and infection.

Since 2001, at least 49 outbreaks have occurred due to the mishandling of injectable medical products, according to the CDC. Twenty-one of these outbreaks involved transmission of hepatitis B or C; the other 28 were outbreaks of bacterial infections, primarily invasive bloodstream infections. While many of these outbreaks occurred in inpatient settings, a high percentage occurred in pain management clinics, where injections often are administered into the spine and other sterile spaces using preservative-free medications, and in cancer clinics, which typically provide chemotherapy or other infusion services to patients who may be immuno-compromised. In addition, more than 150,000 patients required notification during this time frame to undergo bloodborne pathogen testing after their potential exposure to unsafe injections.[4]

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The CDC is aware of at least 19 bloodborne or bacterial infection outbreaks since 2007 associated with the misuse of single-dose/single-use vials. Seven involved bloodborne pathogen infections, and 12 were bacterial infections. All of these outbreaks occurred in the outpatient setting, with eight occurring in pain remediation clinics.[3] According to CDC officials, these examples likely underestimate the harm resulting from the misuse of single-dose/single-use vials. Due to the difficulty of tracing the misuse of vials to infections, the adverse impact of misusing a vial is typically not seen immediately.[5] Adverse events related to unsafe injection practices and lapses in infection control practices are underreported, and it remains a challenge to measure the true frequency of such occurrences.

While the misuse of disposable parenteral syringes and pen injectors also contribute to adverse events and outbreaks, this Alert will focus on the safe use of vials.

Causes and documentation of misuse

A significant contributing factor to the misuse of vials is the lack of adherence to safe infection control practices and to aseptic techniques within health care organizations. For example, a survey of 5,446 health care practitioners found lapses in basic infection control practices relating to vial use. The results included:

- For single-dose/single-use vials, 6 percent admitted to sometimes or always using vials for multiple patients.
- For multiple-dose vials, 15 percent reported using the same syringe to re-enter a vial numerous times for the same patient; of that 15 percent, 6.5 percent reported saving vials for use on another patient.
- Of the 51 professionals who reported reusing a syringe to obtain an additional dose from a multiple-dose vial and then leaving it for use on another patient, about half (52.0%) were from the hospital setting.[6]

A study by the CDC and the Centers for Medicare & Medicaid Services (CMS) published in the *Journal of the American Medical Association (JAMA*) found that two-thirds of inspected CMS-certified ambulatory surgical centers had lapses in basic infection control practices. Twenty-eight percent of these facilities used medications in single-dose vials for multiple patients.[7]

In addition, some providers compromise safe infection control practices in attempts to prevent waste.[5,6,8] The compulsion to prevent waste is sometimes exacerbated by medication shortages or costs.[3,5,9] However, any cost savings achieved by preventing waste can quickly be offset by one or more adverse clinical outcomes. The medical literature contains many examples of individuals who acquired preventable bloodborne and bacterial infections.[10-20] Some patients died from these infections, and many others required prolonged, sometimes life-long, treatment and follow-up care as a result. In other instances, underlying health conditions may have been exacerbated. In addition, there can be tremendous financial costs associated with treating infected patients or containing an outbreak, and providers causing harm face significant legal ramifications or disciplinary action.[3]

Recommendations and potential strategies for improvement

While organizations are required by Joint Commission standards to safely dispense and administer medications (see next section for all related Joint Commission requirements), the accomplishment of these goals depends on preventative action taken by clinical staff who administer injections. Staff should always follow safe injection and infection control practices – including correct aseptic technique, hand hygiene and the one-time-only use of needles and syringes – along with the specific recommendations for single-dose/single-use vials and multiple-dose vials in this alert. Safe infection control practices always apply when transporting, storing, preparing and administering medications, solutions and related supplies. See the CDC's comprehensive injection safety resource: http://www.cdc.gov/injectionsafety.

The following recommendations and potential strategies can be used to help prevent the misuse of vials, thereby preventing the spread of infection.

Effective processes and procedures

1. Develop and implement effective evidence-based organization-wide standardized policy and procedures for the prevention of the misuse of vials. The policy should apply to all staff who administer injections to patients, and should address the following:

Single-dose/single-use vials

- Use a single-dose/single-use vial for a single patient during the course of a single procedure. Discard the vial after this single use; used vials should *never* be returned to stock on clinical units, drug carts, anesthesia carts, etc. The One & Only Campaign from the CDC and Safe Injection Practices Coalition emphasizes ONE needle, ONE syringe, ONLY ONE time. Medications in single-dose/single-use vials lack antimicrobial preservatives and are therefore at greater risk to become contaminated and serve as a source of infection when used inappropriately. See campaign resources, including video.
- If a single-dose/single-use vial must be entered more than once during a single procedure for a single patient to achieve safe and accurate titration of dosage, use a new needle and new syringe for each entry.[21] Note: USP 797 states that single-dose/single-use vials opened in less than ISO Class 5 air quality be used within one hour, with any remaining contents discarded. Single-dose/single-use vials opened in ISO Class 5 air quality can be used up to six hours.[22]
- Do not combine or pool leftover contents of single-dose/single-use vials. Do not store used single-dose/single-use vials for later use, no matter what the size of the vial.[3]
- Unopened single-dose/single-use vials may be repackaged into multiple single-dose/single-use containers (e.g. syringes), which should be properly labeled, including the expiration date and a beyond-use date (which is different from the manufacturer assigned expiration date). This repackaging should be performed only by qualified personnel in ISO Class 5 air conditions in accordance with standards in the United States Pharmacopeia General Chapter 797, Pharmaceutical Compounding - Sterile Preparations. Also, follow the manufacturer's recommendations pertaining to safe storage of that medication outside of its original container.[3,22]

Multiple-dose vials

- Only vials clearly labeled by the manufacturer for multiple dose use can be used more than once.
- Limit the use of a multiple-dose vial to only a single patient, whenever possible, to reduce the risk of contamination.[23,24,25]
- When multiple-dose vials are used more than once, use a new needle and new syringe for each entry.[23] Do not leave needles or other objects in vial entry diaphragms between uses, as this may contaminate the vial's contents.[23]
- Disinfect the vial's rubber septum before piercing by wiping (and using friction) with a sterile 70 percent isopropyl alcohol,[22] ethyl/ethanol alcohol, iodophor,[26] or other approved antiseptic swab. Allow the septum to dry before inserting a needle or other device into the vial.[24]
- Once a multiple-dose vial is punctured, it should be assigned a "beyond-use" date. The beyond-use date for an opened or entered (e.g., needle-punctured) multiple-dose container with antimicrobial preservatives is 28 days, unless otherwise specified by the manufacturer.
- Store multiple-dose vials outside the immediate patient treatment area; observe the manufacturer's storage recommendations.[24]

All vials (single-dose/single-use and multiple-dose)

- Discard any vial if its sterility has been compromised or is questionable, including those having been placed on a used procedure tray or used during an emergency procedure – even if the vial is unopened/unused.[24]
- Select the smallest vial necessary when making purchasing and treatment decisions to reduce waste.[3]
- Urge manufacturers to produce vials in appropriate sizes to reduce waste.[27]

2. Conduct regular quality checks on clinical units to look for open vials.

Training and education

3. Provide annual education on injection safety and on preventing the misuse of vials for all staff who administer injections, including new or temporary staff. Education should include how to recognize and report known breaches of safe injection and infection control practices with vials, such as the use of a single-dose/single-use vial on more than one patient either accidentally (human error) or due to a mistaken belief that the breach was not significant or was justified (at-risk behavior). Staff education should aim to reduce gaps in knowledge regarding safe injection and infection control practices, and to reduce staff tolerance of behavioral choices that may place patients or others at risk of harm, such as using a single-dose vial of medication for multiple patients.

4. Before discharge, provide injection safety education to patients and caregivers who will use injectable medical products as part of a home health regimen. Use teach-back methods to assure understanding.

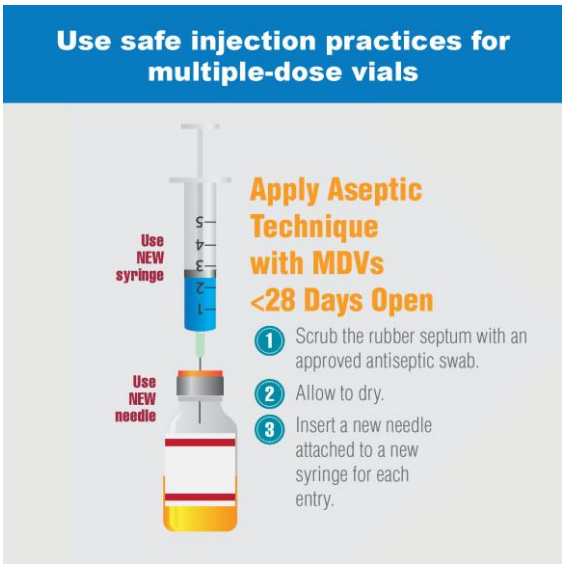
Safety culture

5. Emphasize that all staff are responsible for reporting risks, errors (including near misses), and adverse events. Create a culture within which the reporting of unsafe injection and infection control practices or near misses is viewed as a necessary step to improve safety.

6. Report clusters of infections or other adverse events to the appropriate local and state public health authorities. While reporting of adverse events is usually voluntary, outbreak reporting is typically required by state public health departments. Failure to report illness clusters to public health authorities can result in delays in recognition of disease outbreaks and in implementation of control measures. Incidents of adverse events associated with the misuse of vials can be reported to:

- The Joint Commission, in accordance with its Sentinel Event policy
- FDA Adverse Event Reporting System (FAERS)
- Appropriate state agencies (reporting may be mandatory in some states). See reportable conditions by state
- State health departments, if multiple patients are involved.
- Appropriate patient safety organizations (PSOs), such as ECRI Institute's or the Institute for Safe Medication Practices' (ISMP) National Medication Errors Reporting Program

7. When unsafe injection and infection control practices are identified, assess potential harm to patients and, if warranted, notify patients and test for bloodborne pathogens. Actions for notifying patients should be discussed with local and state public health authorities.



Related Joint Commission requirements

Reference the Standards FAQ for MM.03.01.01, Element of Performance (EP) 7, which requires organizations to re-label multiple-dose vials with a revised expiration date (that is, a beyond-use date) once staff opens or punctures a multiple-dose vial. Therefore, The Joint Commission requires a 28-day expiration date for multiple-dose vials from the date of opening or puncture, unless the manufacturer specifies otherwise (shorter or longer). In any case, the original expiration date printed on the vial cannot be extended. If the manufacturer's original expiration date is earlier than the revised expiration date, the earlier date must be used. *Note: Storage time limits for single-dose/single-use vials are defined by USP 797 (depending on the environment in which they are punctured) or the manufacturer – whichever is shorter.*[22]

See other relevant Joint Commission requirements: HR.01.05.03 (staff education and training), IC.01.04.01 (setting goals to minimize infection), IC.01.05.01 (infection prevention and control plan), IC.02.01.01 (infection prevention and control plan implementation), LD.04.04.05 (organizational patient safety program), MM.03.01.01, EP 10 (providing medications in the most ready-to-administer form)*, MM.05.01.11 (safe medication dispensing)*, MM.06.01.01 (safe medication administration), and MM.08.01.01 (medication management system evaluation).

* These requirements do not apply to some accreditation programs. MM.03.01.01 EP 10 does not apply to the Ambulatory Care or Nursing Care Center programs. However, MM.05.01.15 EP 1 does apply to the Nursing Care Center program, and it covers providing medications in the most ready-to-administer form. In addition, while MM.05.01.11 does not apply to most centers accredited under the Nursing Care Center program, it does apply to Veterans Affairs Community Living Centers (CLC), which are accredited under the Nursing Care Center program.

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