Webinar

The Misuse of Vials
A Follow-Up to the Sentinel Event Alert

September 11, 2014
Hosted by The Joint Commission

Featured Presenters:

Ana McKee, M.D. (The Joint Commission)
Jerod Milton, R.Ph., M.B.A. (Children’s Hospital Colorado-Denver)
Joe Perz, DrPH, M.A. (Centers for Disease Control and Prevention)
Mike Cohen, R.P.h., M.S., Sc.D. (Institute for Safe Medication Practices)
Mark Singleton, M.D. (American Society of Anesthesiologists)
The Misuse of Vials
A Follow-Up to the *Sentinel Event Alert*

Ana McKee, M.D., Chief Medical Officer
The Joint Commission
Preventing Infection from the Misuse of Vials

Jerrod Milton, RPh, MBA
Vice President, Professional Services & Chief Pharmacy Officer
About Children’s Hospital Colorado

*Private, nonprofit pediatric system of care*
- 5 hospital system and 12 off campus specialty care centers

**593 Inpatient Beds**
- Main campus - 444
- Memorial Central, Colorado Springs - 113
- North Campus – 6
- South Campus - 16
- Parker Adventist - 6
- St. Joseph – 8

**Facilities**
- 2.4 million s.f. of occupied physical plant in network of care
Scope of Pharmacy Services

• 104 FTE throughout system of care

• Patient-specific unit-dose distribution 24x7
  • Decentralized clinical services
  • Supported by Omnicell automation
  • Robotics for solid dosage forms

• Medium-level risk aseptic compounding
  • 5 fully operational ISO7 clean rooms
  • Plus 2 new clean rooms nearly operational

Goal to provide patient-specific medication to bedside in as ready-to-administer form as possible.
Dispensing Stats

Managing Risk of Infection

• 1.65 million doses annually
  • 636,307 parenteral doses

• 65% of all parenteral doses dispensed from central pharmacy fill (prepared in USP 797 compliant clean room)

• Remaining 35% through Automated Dispensing Device
  • 21% dispensed by anesthesiologists (mobile workstation)
  • 14% dispensed from Omnicell Cabinet
Saline and Heparin Flush Solutions

- When available, prefilled saline and heparin flush solutions are provided as floorstock.
- Prefilled flush solutions are treated as single dose devices and any remaining volume after port access is to be discarded.
Floorstock Limitations

• An objective scoring system is employed by pharmacy management prior to approval of any floor stock medication requests
• Medication stability is a factor considered
Guiding Principles

Preventing Infection from the Misuse of Vials

Principles for All Vial Types

• Disinfect the vial’s septum by wiping before piercing.
  • The vial cap does not ensure the vial septum is sterile
  • At least 70% isopropyl alcohol swab
  • Use friction (i.e., scrub the hub)
  • Septum should be visibly wet, then allowed to air dry for 10 seconds before piercing
  • Unless clearly specified, do not assume a multiple-dose vial
• Do not leave needles or other objects in vial septum between uses as this may contaminate the vial’s contents.
Policy Statements

Preventing Infection from the Misuse of Vials

Single-dose / Single-use Vials

• Generally, single dose vials are used only one time (discard after entered once).
  • Practical exceptions would include reconstituting medications or vaccines

• Multiple doses for a single patient may be drawn from a single dose vial during emergency situations

• Single-dose/single-use vials opened in less than ISO Class 5 air quality must be used within one hour, with any remaining contents discarded

No re-use of syringe or needle

If a single-dose/single-use vial must be entered more than once during a single procedure for a single patient, in order to achieve safe, timely, and accurate titration of dosage staff are to use a new needle and new syringe for each entry into vial.
Multiple-dose Vials

- Multi-dose vials expire 28-days after opening or when the manufacturer’s expiration date is reached, whichever is sooner
- Avoid using MDVs on multiple patients
- Strict aseptic technique should be used when removing a dose (discard if uncertain or questionable)

Floor Stock Limitations

- Influenza virus vaccine
- Short-acting insulin (and vial is labeled for patient-specific use only)
- Few exceptions by location
  - Anesthesia (local anesthetics, neostigmine)
  - Crash carts (flumazenil, naloxone)
Aseptic Technique 101 (for Sub-ISO5)

- Perform proper hand hygiene
- Use aseptic technique in all aspects of parenteral medication administration, medication vial use, injections, and glucose monitoring
- Store and prepare medications and supplies in a clean area, on a clean surface
- Never store needles and syringes unwrapped (sterility must not be compromised)
- Discard all opened vials, IV solutions, and related paraphernalia involved in an emergency situation
- Avoid contacting sterile drugs, sterile areas of devices and containers with non-sterile objects (including secretions or particles shed from personnel).

Training and Orientation

• Didactics
  • Medication safety class for new graduate nurses and new hire nurses

• e-Learning
  • Policy Pearls
  • Annual competency assessment requirement

• Competency On-the-Fly
  • Regulatory readiness approach (leader rounding)
Challenges / Opportunities for Improvement

Our Medication Safety Committee convened after the recent SEA to discuss this subject matter.

• Identified Opportunities
  • More rigorous education and competency assessment
  • Closer monitoring of floor stock by pharmacy personnel (including review & approval process, closer screening of substitute products)
  • Package labeling (e.g. auxiliary labeling SDV, MDV 28 day, MDV #day)
  • Continue to unit-dose and dispense medication from central pharmacy where feasible (i.e. to perioperative services / anesthesia)
  • Targeted communication concerning principles presented
Thank you!
Preventing infection from the misuse of vials: the view from CDC

Joe Perz, DrPH MA

Team Leader, Quality Standards & Safety (proposed)
Prevention and Response Branch
Division of Healthcare Quality Promotion
Centers for Disease Control and Prevention

September 11, 2014
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Injections and Infusions are Central to Healthcare Delivery

- Injections and infusions of parenteral medications likely represent the most common invasive procedure across all the healthcare continuum
  - Chemotherapy
  - Intravenous antibiotics
  - Vaccination
  - Sedation/anesthesia for surgical procedures, endoscopy, and imaging/diagnostic studies
  - Joint injections
  - Cosmetic procedures
  - Alternative medicine
Injection Practices Among Clinicians in United States Health Care Settings

• Survey of 5,500 U.S. healthcare professionals
• 1 percent “sometimes or always” reuse a syringe on a second patient
• 1 percent “sometimes or always” reuse a multidose vial for additional patients after accessing it with a used syringe
• 6 percent use single-dose/single use vials for more than one patient

Unsafe Injection Practices Can Lead to Transmission of Life-Threatening Infections

SOURCE
Infectious person, e.g., chronic, acute

CONTAMINATED INJECTION EQUIPMENT OR MEDICATION

HOST
Susceptible, non-immune person
Summary of US Experience

• Since 2001, >50 outbreaks due to mishandling of injections at the “point of care” (extrinsic contamination)
  • ~ 40/60 split between hepatitis and bacterial infections
  • ~90% of outbreaks occurred in outpatient settings
• Since 2007, at least 20 of the outbreaks involved multi-patient use of single dose vials/containers
• Over 150,000 patients have required notification advising them to seek testing after a potential exposure to an unsafe injection
Recognize the differences between single-dose and multiple-dose vials and understand appropriate use of each container type.

View graphic
Click Link Below To View Video

http://Check Your Steps! Make Every Injection Safe
SAFETY STEPS
FOLLOW THESE INJECTION SAFETY STEPS FOR SUCCESS!

BEFORE THE PROCEDURE
Carefully read the label of the vial of medication.
- If it says single-dose and it has already been accessed (e.g. needle-punctured), throw it away.
- If it says multiple-dose, double-check the expiration date and the beyond-use date if it was previously opened, and visually inspect to ensure no visible contamination.
- When in doubt, throw it out.

DURING THE PROCEDURE
Use aseptic technique.
- Use a new needle and syringe for every injection.

- Be sure to clean your hands immediately before handling any medication.
- Disinfect the medication vial by rubbing the diaphragm with alcohol.
- Draw up all medications in a clean medication preparation area.

AFTER THE PROCEDURE
Discard all used needles and syringes and SDVs after the procedure is over.
MDVs should be discarded when:
- the beyond-use date has been reached
- doses are drawn in a patient treatment area
- any time vial sterility is in question

FAQs Regarding Safe Practices for Medical Injections:
www.oneandonlycampaign.org/content/healthcare-professional-faqs

ONEANDONLYCAMPAIGN.ORG
Thank You

www.cdc.gov/HAI

For more information please contact Centers for Disease Control and Prevention

1600 Clifton Road NE, Atlanta, GA 30333
Telephone, 1-800-CDC-INFO (232-4636)/TTY: 1-888-232-6348
E-mail: cdcinfo@cdc.gov    Web: www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.
Safety issues involving medication vials

Mike Cohen
Institute for Safe Medication Practices
Safety issues involving medication vials

- People using multiple dose vials (MDVs) and not dating them or using MDVs and dating them with the date opened instead of the beyond use date (BUD) of 28 days (or sooner if specified by manufacturer).
- Single dose vials (SDVs) not discarded after volume has been withdrawn
- People not understanding the difference between SDV and MDV
- Syringes pre-drawn (OR/anesthesia) and stored somewhere (e.g., anesthesia cart), possibly without dating.
- Vials with syringe/needle or transfer device remaining in vial septum
Safety issues involving medication vials

- Pharmacies using pharmacy bulk packages and saving them for reuse. (must be punctured once and remain in ISO Class 5 environment)
- In ambulatory care settings, drawing flush solutions from bags of NSS (this is rare in inpatient areas but seen now and then in ambulatory care - observed just recently so safety folks should be aware).
- Use of a SDV in the pharmacy clean room more than 6 hours after initial puncture.
- Insulin pen issue in inpatient areas.
AVOIDING MISUSE OF VIALS:
A follow-up to the Sentinel Event Alert

September 11, 2014
Mark Singleton, M.D.
Use and Administration

- Use single-dose vials for parenteral medications whenever possible rather than multi-dose vials.
- Use antiseptic (e.g., alcohol wipes) on the access surface prior to penetration.
Use and Administration

Do not administer medications from SDVs or ampules to multiple patients.

Do not combine leftover contents for later use.
Multi-Dose Vials (MDVs)

Use and Administration

- Use sterile needle or cannula and syringe each time

- Use antiseptic (e.g., alcohol wipes) on the access surface prior to penetration
Multi-Dose vials (MDVs) cont.

Storage and Disposal

- Store in accordance with the manufacturer’s recommendations
- Dispose of all syringes, needles, and medication vials at the end of an episode of care
- Discard if sterility is compromised or questionable
Multi-Dose Vials (MDVs) cont.

- Use manufacturer prepared syringe packages whenever possible rather than medication vials
- Select the smallest or most clinically appropriate sized vial available when making purchasing and treatment decisions to reduce waste
Multi-Dose Vials (MDVs) cont.

- Urge manufacturers to produce vials in appropriate sizes to reduce waste.
- Do not use MDVs on multiple patients
On The Line To Answer Questions:

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  Branch Chief, Infection Control Devices Branch
  FDA

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