Single Dose Vials and ASCs - Impact and Options

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• No disclosures
• NO steroid preparation is FDA approved for use in the epidural space

• History of the issues regarding Single Dose Vials (SDV)
  • CDC Position
  • Outbreaks
Single Dose Vials and ASCs - Impact and Options

• Impact
  • Providers
  • Direct costs
  • Legal costs
  • Patients

• Options
  • Dividing single dose vials
  • Multi-dose Vials
  • Compounding/Repackaging pharmacies
  • GPOs

Centers for Disease Control (CDC) 2007

• Issued the Standard Precautions section of the 2007 Guideline for Isolation Precautions
• Provides evidence-based recommendations for safe injection practices
• Reflects the minimum standards that healthcare personnel should follow to prevent transmission of infections in healthcare settings.
CDC Position on Single Dose Vials (SDV)

- Vials labeled by the manufacturer as "single dose" or "single use" should only be used for a single patient.
- Never administer medications from the same syringe to more than one patient, even if the needle is changed or you are injecting through an intervening length of IV tubing.
- Always use aseptic technique when preparing and administering injections.

2007 Guideline for Isolation Precautions

- Generally, one should enter a single-dose or single-use vial only once even on a single patient.
- In certain situations, healthcare personnel may believe that drawing the entire contents of the vial into a single syringe will not allow for safe and accurate titration of dosage.
- If the single-dose or single-use vial will be entered more than once for a single patient as part of a single procedure, it should be with a new needle and new syringe.

2007 Guideline for Isolation Precautions

- Generally not enforced.
- 2011- there was an attempt by certain societies within the pain management community to amend the Guideline as an unnecessary burden on providers.
- CDC reiterated its position.
- CMS announced facility inspections would monitor adherence to the guidelines.
CDC: Best Safe Injection Practice. Reiterated:

- No reuse of syringes for multiple patients or to access shared medications
- No administration of medication from a single-dose/single-use vial to multiple patients
- Use aseptic technique when preparing and administering injections.

2007 Guideline for Isolation Precautions

Did the guidelines work?

Since the CDC Guidelines were published in 2007, CDC reports at least 19 outbreaks associated with SDV by 2012.

- 7 outbreaks involved blood-borne pathogen infections
- 12 involved bacterial infections (with a majority of affected patients requiring hospitalization)
- All of these outbreaks involved outpatient settings, with the majority occurring in pain remediation clinics (n=8).
Why Didn’t the Guidelines Work?

They weren’t always followed.

Outbreaks Due to Single Dose Vials

- 8 patients who developed methicillin-susceptible *Staphylococcus aureus* infections following epidural steroid injection.
- 4 confirmed (and 8 suspected) cases of *Klebsiella pneumoniae* and *Enterobacter aerogenes* infections in patients receiving sacroiliac injections.
- Both attributed to the inappropriate re-use of single dose vials on multiple patients

What Happened?

- Primary Breaches
- Reinsertion of used needles into a vial or solution containers.
- Use of single needle or syringe to administer intravenous medication to multiple patients.
July 2012 Arizona, MRSA Outbreak

- All of the patients with infections received diluted contrast from the afternoon vial.
- 3 patients with infections went to a local hospital 4–8 days after their outpatient pain procedures.
- Severe infections, including acute mediastinitis, bacterial meningitis, epidural abscess, and sepsis.
- A 4th recipient of diluted contrast from the afternoon vial was found deceased at home, 6 days after treatment at the clinic. The cause of death was reported as multiple-drug overdose; however, invasive MRSA infection could not be ruled out.

CDC One and Only Campaign

In 2012, after those outbreaks, the CDC reiterated its position and CMS began enforcement.
CDC’s Position on SDV and Drug Shortages

• CDC recognizes the problem of drug shortages; however, such shortages are a result of manufacturing, shipping, and other issues unrelated to the guidelines.
• Critical shortages of some essential medications may warrant implementation of meticulously applied practice and quality standards to subdivide contents of single-dose/single-use vials, BUT

Sub Dividing Single Dose Vials

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.

Sub Dividing Single Dose Vials

Not allowed in order to save money!
WHY?

"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."

USP 797 Standards Apply To:

"...all persons who prepare compounded sterile preparations (CSPs) and all places where CSPs are prepared (e.g., hospitals and other healthcare institutions, patient treatment clinics, pharmacies, physicians' practice facilities, and other locations and facilities in which CSPs are prepared, stored, and transported.)"

CDC: USP 797 Standards

- Includes compounding of single dose vials and/or
- Separation of single dose vial contents to multiple vials or doses
Can My ASC Divide SDVs into Smaller Doses?

Yes, provided proper techniques are observed. These techniques must be in accordance with the United States Pharmacopeia (USP) Standards – Chapter 797 (USP797)

USP 797 Compliance Standards

- Requires Class 100 or ISO 7 (or greater) room
- Requires laminar flow workbenches
- Technicians must be wearing sterile gown, gloves, cap and booties.
- They are to enter the ISO Class 5+ room through a "clean" anteroom
USP 797 Compliance Standards
Requires compliance with:

- Specifications for cleaning and disinfecting the sterile compounding areas
- Personnel training and competency evaluation of garbing aseptic work practices and cleaning/disinfection procedures

Independent testing of these standards must be performed regularly and recorded for review

- Airborne particle sampling
- Surface sampling
- Gloved finger sampling

Failure to monitor or meet these standards

- May result in loss of accreditation from JCAHO and other certifying organizations
- Criminal or civil charges and loss of licensure for involved providers in the event of an infection
- FUGGEDABOUTIT!
“I can have my local hospital or compounding pharmacy divide larger single dose vials into multiple smaller doses on a monthly basis and bypass this issue.”

• Any facility that meets or exceeds the USP797 Standards for repackaging and compounding may perform this procedure.

But even if you do this...

• Once Isohexol (Omnipaque) has been repackaged, in the absence of sterility testing, it generally must be kept at controlled room temperature and used or disposed of within 48 hours.
• If it is kept in a controlled refrigerated temperature it may be kept for 14 days

How Does This Affect My ASC?

Pain Management Procedures -- epidural, facet joint, SI joint, use contrast media, steroids, local anesthetic
Joint Injections – Hip, knee, shoulder, carpal tunnel use local anesthetic, steroids
Anesthetization of skin – biopsy for mole/nevi removal (skin—HEENT, Plastic Surgery, Dermatology, etc.)
Single Dose Vials: Available Sizes

- Contrast Media -- 10cc, 20cc, 50cc+
- Local anesthetic -- 1cc, 2cc, 5cc, 10cc
- Steroids -- 1cc, 5cc, 10cc

Examples of Drugs Used in ASC

**ISOMENOL (OMNIpaque)**

- 10 cc -- $62
- 20 cc -- $68
- 50 cc -- $57

Medications for Injections-- Sacroiliac joint

- 0.2cc - 0.5cc contrast (49.5 – 49.8 cc/50 wasted)
- 1-2 cc local anesthetic (0 - 9 cc wasted)
- 0.2- 0.75cc steroid (0.8 - 9.25 cc wasted)
Medications for Injections– Epidural Steroid Injection

- 1-3 cc - contrast (47-49/50 wasted)
- 1-2 cc local anesthetic (0 - 8 cc wasted)
- 0.5-1.0 cc steroid (0.5 - 9 cc wasted)

What if we switch to Multi-dose vials?

Typically, multi-dose vials contain the addition of an anti-microbial agent to inhibit bacterial growth
CDC on Multi-dose Vials (MDVs)

Should be dedicated to a single patient whenever possible to prevent inadvertent contamination of the vial through direct or indirect contact with potentially contaminated surfaces or equipment.

• If a multi-dose has been opened or accessed (e.g., needle-punctured) the vial should be dated and discarded within 28 days unless otherwise specified by the manufacturer
• If a multi-dose vial enters the “immediate patient treatment area,” it should be dedicated to that patient only and discarded after (a single) use (i.e., de facto SDV)

MDV “Immediate Treatment Area”

• Immediate patient area– treatment room, procedure room, OR, recovery room, exam room, treatment bay, etc.
• Has to be drawn up (sterile) from a “non-treatment area” and transported to the treatment area.
• If not, it becomes a single dose vial.
“But we keep our vials and drawn-up syringes in a refrigerator.”

- Refrigeration has not been shown to decrease contamination of single dose vials.
- Refrigeration may actually inhibit the action of antimicrobial agents in multi-dose vials.

Do multi-dose vials protect patients from infection or potential outbreaks?

No...

Multi-dose Vial

While the multi-dose vial contains an antimicrobial preservative that inhibits the growth of bacteria, if there is a breach in sterile technique and the contents become contaminated, the patients are at risk for developing a bacterial infection.
Multi-dose Vial

In the event of *viral* or *fungal* contamination, there is no protection offered from a multi-dose vial and patients are at significant risk for infection.

So, what do we do...?

- You don’t split single dose vials...
- Let a retail compounding pharmacy do the repackaging and/or compounding

So Compounding Pharmacies Can Solve This Issue?

*Not always*...
September 2012 Fungal Meningitis Outbreak

- Multistate outbreak of fungal meningitis and other infections
- Patients who received contaminated preservative-free steroid injections from the New England Compounding Center in Framingham, Massachusetts.

Fungal Outbreak

- 751 total cases
- 384 meningitis
- 64 deaths
- Most cases in 5 states
  - 264 cases in Michigan
  - 153 in Tennessee
  - 93 in Indiana
  - 54 in Virginia
  - 51 in New Jersey

Outbreak

- Predominant fungus was Exserohilum rostratum.
- One patient, the index case, had a laboratory-confirmed Aspergillus fumigatus.
- Hundreds of patients developed localized spinal or paraspinal infections, such as epidural abscess and arachnoiditis, and infections associated with injections in a peripheral joint space, such as a knee, shoulder, or ankle.
Contaminated Drugs

- Infections during this outbreak were related to drugs compounded (not re-packaged) from one pharmacy, New England Compounding Center (NECC)
- No other compounding centers were implicated as having products that caused spinal/brain infections during this outbreak

Meningitis Outbreak

- Multiple products recalled
- The spinal infections were traced to contaminated lots of a preservative-free preparation of the steroid methylprednisolone acetate
Methylprednisolone Acetate

• Most providers using the NECC compounded steroid did so in order to obtain a specific preservative-free preparation
• Not commercially available without preservative
• Not purchased to lower costs or obtain single dose vials

What if that Steroid Had Preservative?

• Infections involved Exserohilum rostratum and Aspergillus fumigatus
• These are fungal infections
• Anti-microbial agents protect against bacteria, not fungi

Compounding Pharmacies

• Since the 2012 outbreak, multiple other compounding pharmacies had forced drug recalls due to the presence of suspected contaminants
• Thousands of compounding pharmacies did not...
• Even products from these pharmacies are subject to the disposal requirements after re-packaging.
Are There Other Options?

GPOs
- Allows large volume purchasing by bundling orders from individual providers
- Allows access to discounted rates similar to those negotiated by larger organizations

Single Dose Vials
- Direct costs are not very high (with volume purchases)
- There is a clear savings from avoiding the cost of an outbreak at your clinic or ASC
- Isohexatol (50cc)--$3.80-$6.50.
References


6. Fact Finder. Multi-Dose Vial. ISIS.
References


