Ambulatory Surgery Infection Control Workshop: Disinfection, Sterilization, and Safe Injections

Sharon Bradley RN, CIC
James Davis, BSN, RN, CCRN, CIC
Senior Infection Prevention Analysts

© 2013 Pennsylvania Patient Safety Authority
Objectives

• Recognize unsafe injection practices
• Select approaches to integrate safe injection strategies into clinical practice
• Identify areas for improvement specific to ambulatory surgical facility (ASF) practices related to sterilization and disinfection
• Possess a working knowledge of acceptable sterilization and disinfection practices in the ASF environment
Recognizing Unsafe Injection Practices

- Outbreaks
- Breaches
- Misperceptions
- Safe injection practices
- Single-dose/multidose vials
- Contamination
- Aseptic technique
## Injection Safety Questions

<table>
<thead>
<tr>
<th>Question</th>
<th>N = 134</th>
<th>%</th>
<th>#</th>
</tr>
</thead>
<tbody>
<tr>
<td>A new syringe and needle is used each time a multidose vial is entered.</td>
<td></td>
<td>19</td>
<td>25</td>
</tr>
<tr>
<td>A system is in place to monitor safe injection practices.</td>
<td></td>
<td>60</td>
<td>81</td>
</tr>
<tr>
<td>Multidose vials are used for only one patient and discarded.</td>
<td></td>
<td>85</td>
<td>114</td>
</tr>
<tr>
<td>Multidose vials used for more than one patient are dated when first opened.</td>
<td></td>
<td>86</td>
<td>115</td>
</tr>
<tr>
<td>The facility uses multidose injectable medications.</td>
<td></td>
<td>87</td>
<td>116</td>
</tr>
<tr>
<td>Multidose vials used for more than one patient are discarded after 28 days or per manufacturer instructions.</td>
<td></td>
<td>88</td>
<td>118</td>
</tr>
</tbody>
</table>
Los Angeles County
Department of Public Health
2010 Pain Clinic
Hepatitis Investigation Report
Acute Communicable Disease Program

May 2008:
Coming Soon to a Clinic Near You—Hepatitis C. When Basic Infection Control Practices Are Ignored, Misunderstood

July 2012:
Lab Tech Charged in N.H. Hepatitis C Outbreak Worked in Six Michigan Hospitals

October 2009:
Endoscopy Center of Southern Nevada: More Hepatitis C Tests Positive

April 2011:
Children Told to Be Tested for HIV after Flu Vaccines Reused

September 2011:
N.J. Doctor Loses License after Hepatitis B Outbreak

July 2012:
HHS Has Taken Steps to Address Unsafe Injection Practices

August 2012:
First Victim of Las Vegas Hepatitis Outbreak Dies

© 2013 Pennsylvania Patient Safety Authority
Injection Safety Breaches

• Same syringe used to administer medication to more than one patient
• Medication vial or bag accessed with syringe previously used to administer medication to a patient, then contents reused for another patient
• Single-dose medications used for more than one patient
• Failure to use aseptic technique when preparing and administering injections

(CDC “Injection Safety”)
Injection Pathways to Infection

- Sedative and analgesic administration
- Intravenous (IV) medication administration
- IV line and catheter flushes
- Intramuscular injections

(CDC “Injection Safety”)
Pennsylvania Serious Event Reports

• IV propofol was injected into the IV tubing of two patients using the same syringe. Rationale was that the probability of communicable disease is extremely low due to the IV port location high away from the IV site.

• Patient received IV propofol from a syringe used on the previous patient. Patient and source patient tested for HIV, hepatitis.
Pennsylvania Serious Event Reports

• The same syringe from another patient’s IV line was used to draw fluid from a patient's IV bag and then reused to flush the other patient’s IV.

• Additional fentanyl was injected into a catheter using the same syringe that had not been capped and without cleaning the infusion port.
What Is a “Safe” Injection?

• Does not harm the recipient
• Prevents transmission of infectious disease
• Does not expose the provider to any avoidable risks
• Does not result in dangerous waste for the community

(CDC “Injection Safety”)
A syringe or insulin pen can be reused if the needle is changed.

**FALSE**

- Contamination extends to the syringe or cartridge.
- Small amounts of microscopic blood are aspirated into the syringe due to negative pressure generated when removing the needle.

(CDC “Medication Administration”; “Prevent the Occurrence”)
The same syringe can be used to inject more than one patient \textit{if} the user only pushes the syringe plunger and does not draw back before injecting.

\textbf{FALSE}

• Application of positive pressure does not prevent backflow of microscopic amounts of blood containing viral particles into the needle and syringe.

• Microscopic quantities of blood are sufficient to infect subsequent patients.

(CDC “Medication Administration”; “Prevent the Occurrence”)
True or False

A syringe used only to inject medication into an IV port several feet away from the insertion site can be reused for another patient.

FALSE

- Separation from the patient’s IV by distance, gravity, and/or positive infusion pressure does not ensure that small amounts of blood are not present.

(CDC “Medication Administration”; “Prevent the Occurrence”)
True or False

A syringe and/or needle can be reused to enter a vial for the same patient if the vial and syringe will be discarded at the end of the procedure and not used for subsequent patients.

**SOMETIMES—if:**

- Administration of incremental doses for a single patient or procedure is handled with strict adherence to aseptic technique.
- The syringe is never left unattended and is discarded at the end of the procedure.

(CDC “Medication Administration”; AORN)

Analyzing, Educating and Collaborating for Patient Safety
Direct Syringe Reuse

NEVER USE A SYRINGE ON MORE THAN ONE PERSON!
Unsafe Injection Practices and Disease Transmission

(CDC “Acute Hepatitis”)

Analyzing, Educating and Collaborating for Patient Safety
© 2013 Pennsylvania Patient Safety Authority
What Is a Single-Dose Vial (SDV)?

- A vial of liquid medication
- Intended for injection or infusion
- Meant for use in a single patient
- For a single case or injection

(CDC “Questions about Single-Dose”)
USP Definition of SDVs

Single Dose Container USP 10.20.70

- Single unit container for article intended for parenteral administration only
- Prefilled syringes, cartridges, fusion and closure sealed container when so labeled

Single Unit Container USP 10.20.60

- Holds a quantity of drug product intended for administration as a single dose – or
- A single finished device intended for use promptly after the container is opened

United States Pharmacopeia and the National Formulary General Notice and Requirements Nov 2012
Single-dose or single-use vials can be used for more than one patient.

**FALSE**

- Once an SDV is entered, contents support microorganism growth.
- SDVs have no antibacterial preservative.
- Adherence to single entry into SDVs prevents inadvertent contamination of the vial.

(CDC “Questions about Single-Dose”)
Propofol

- Lipid emulsion supports rapid bacterial growth
- Bacteriostatic preservative—not bactericidal
- Single patient use of vial and prefilled syringes
- Complete anesthesia administration within six hours of opening vial

© 2013 Pennsylvania Patient Safety Authority
True or False

Individual SDVs can be entered multiple times for a single patient.

**SOMETIMES:**

- If it is for a single patient, case, procedure, or injection.
- If SDV must 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.
- Prevent inadvertent contamination of vial.
- Safest practice: enter SDV only once.

(CDC “Questions about Single-Dose”)

Analyzing, Educating and Collaborating for Patient Safety

© 2013 Pennsylvania Patient Safety Authority
Opened, unused medication from SDVs can be combined or stored for future use.

**FALSE**

- SDVs have no antibacterial preservative.
- Potential for unrecognized contamination exists.
- SDVs should be discarded unopened by expiration date.

(CDC “Questions about Single-Dose”)
DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Office of Clinical Standards and Quality/Survey & Certification Group

DATE: June 15, 2012
TO: State Survey Agency Directors
FROM: Director
Survey and Certification Group
SUBJECT: Safe Use of Single Dose/Single Use Medications to Prevent Healthcare-associated Infections

Memorandum Summary

- Under certain conditions, it is permissible to repackage single-dose vials or single use vials (collectively referred to in this memorandum as “SDVs”) into smaller doses, each intended for a single patient: The United States Pharmacopeia (USP) has established standards for compounding which, to the extent such practices are also subject to regulation by the Food and Drug Administration (FDA), may also be recognized and enforced under §§501 and 502 of the Federal Food, Drug and Cosmetics Act (FDCA). These USP compounding standards include USP General Chapter 797, Pharmaceutical Compounding - Sterile Preparations (“USP <797>”). Under USP <797>, healthcare facilities may repackage SDVs into smaller doses, each intended for use with one patient.

(CMS “Safe Use”)
United States Pharmacopeia (USP)

- International Organization for Standardization (ISO)
- ISO class 5 clean air quality conditions
  - Limits in level of particulate matter in room air
  - Filtered unidirectional airflow
- ISO class 7 buffer area
  - For repackaging CSP supplies
  - Laminar airflow workbench
  - Biological safety cabinets
- SDV opened or punctured in ISO may be used up to six hours, then must be discarded.

(USP “Environmental”)

Analyzing, Educating and Collaborating for Patient Safety

© 2013 Pennsylvania Patient Safety Authority
SDV Use Time Limits

USP (USP 797 standards)
• SDVs or ampules opened or punctured in non-ISO may be used up to one hour and then discarded.

Centers for Medicare and Medicaid Services (CMS)
• Improper repackaging: syringe with a single dose from an SDV prepared on the patient care unit that will be administered more than one hour after preparation.

Centers for Disease Control and Prevention (CDC)
• Discard opened or accessed SDVs as per manufacturer specification or at the end of the case or procedure (whichever is first).

(CDC “Injection Safety”; CMS “Safe Use”; USP “Pharmaceutical Compounding”)

Analyzing, Educating and Collaborating for Patient Safety

© 2013 Pennsylvania Patient Safety Authority
What is a Multidose Vial (MDV)?

- **Vial of liquid medication**
- **Intended for parenteral administration**
- **Contains more than one dose**
- **Contains antimicrobial preservative**

(CDC “Medication Administration”; AORN)
MDVs can be used for more than one patient.

**TRUE**

- Preferable to dedicate an MDV to a single patient because there is the potential for breaches in aseptic technique.
- Necessary reentries require a new sterile needle and syringe.
- Restrict to centralized clean medication area.
- Dedicate to single patient if used in treatment rooms, bays, or operating room suites, then discard.

(AORN; Perz et al. “US Outbreak”)
A syringe and/or needle can be reused to access an MDV.

SOMETIMES—if:

• Necessary for reconstituting medications—use strict aseptic technique.
• Never use a syringe from another patient (“double dipping”).
  – Can result in transfer of contaminants to the vial or fluid.
  – Has repeatedly been shown to result in transmission of hepatitis B and C.

(CDC “Medication Administration”; “Prevent the Occurrence”)
The same syringe can be used to withdraw medication from two different MDVs.

**FALSE**

- Use a separate needle and syringe for each vial.

- Breaches in aseptic technique between doses increase the risk of particulate matter being transferred from one vial or stopper to another vial.

(AORN)
Leftover contents from MDVs can be pooled to obtain a sufficient dose.

**FALSE**

- This practice increases the risk of serial contamination of additional vials.
- Bacteriostatic agents used in MDV are not effective against hepatitis and other viruses.

(“Prevent the Occurrence”; Pugliese et al.)
MDV Expiration Dates

• Manufacturer expiration date
  – Unopened products
  – Expiration date on label

• Beyond-use date (BUD)
  – Open products
  – Vial cap removed or punctured
  – Label and discard after open 28 days

Expiration date  
Do not use after  
4/1/13

Opened 4/1/13
Initials __________
Discard 4/29/13

(AORN; CDC “Medication Administration”)
Contamination of IV Fluids

- Using common bag of saline or other IV fluid on more than one patient
- Accessing IV bag with syringe previously used to flush a patient's catheter
- Transmission of hepatitis B and/or hepatitis C virus

(Dolan et al.; “Prevent the Occurrence”; CDC “Injection Safety”)

Analyzing, Educating and Collaborating for Patient Safety

© 2013 Pennsylvania Patient Safety Authority
USP ISO Class 5 Exempt

• Immediate-use non-nutrient sterile injections
• Dilute, dissolve, measure, or mix of sterile solutions
• Use sterile devices
  – Spikes, filter straws, needles, or syringes
• One-hour limit
  – Begin infusion of spiked IV solutions
  – Discard open, unused vials, bottles, bags, or syringes
• Precludes rapid microbial population increase

(AORN; Dolan et al.)
Contamination of Shared Medical Equipment
Injectable medications can be prepared in a workspace where needles and syringes are dismantled and discarded.

**FALSE**

- Items that could have come in contact with blood or body fluids should not be in the clean medication prep area.
- Ensure clear demarcation of clean and dirty areas in confined workspaces.

(AORN; CDC “Frequently Asked Questions”; “Prevent the Occurrence”)
Reusable fingerstick devices, insulin pens, and lancets can be used on more than one patient.

**FALSE**

- Microscopic blood in pen cartridge may contain infectious viral particles.
- Can be inoculated into patient fingerstick wound.
- Multiple outbreaks of hepatitis B and C.

(CDC “Infection Prevention”; “Prevent the Occurrence”)
BE AWARE
DON’T SHARE

Insulin pens that contain more than one dose of insulin are only meant for one person.

They should never be used for more than one person, even when the needle is changed.

ONE INSULIN PEN, ONLY ONE PERSON

The One & Only Campaign is a public health campaign aimed at raising awareness among the general public and healthcare providers about safe injection practices.

For more information, please visit: www.ONEandONLYcampaign.org

Analyzing, Educating and Collaborating for Patient Safety
© 2013 Pennsylvania Patient Safety Authority
A blood glucose meter can be used on multiple patients.

**TRUE**—if:

- Cleaned and disinfected between every use.
- A new lancet is used with every use.
- Fresh clean gloves are used for each patient.
  
  — There is a risk of indirect transfer of virus from microscopic amounts of blood on a clinician’s hands or gloves after contact with a contaminated monitoring device.

(CDC “Infection Prevention”; “Prevent the Occurrence”)
Needles, cannulas, and spiking devices can be left inserted into a medication vial rubber stopper for multiple medication draws. **FALSE**

- Vial contamination occurs due to the collection of environmental microorganisms on the spiking device or needle.
- Sterile solutions can also be contaminated when withdrawn or poured from the stopper or spout.

(CDC “Medication Administration”; “Prevent the Occurrence”)
Aseptic Technique

- Perform hand hygiene prior to medication handling or administration.

- Disinfect skin and septum with alcohol and let dry before each entry.

- Use sterile needleless entry or transfer devices to withdraw medications from MDVs.

- Use a new needle, syringe, or needleless device immediately before every vial or bag access.

- Store and prepare medications and supplies in a clean area on a clean surface.

- Do not store unwrapped needles and syringes.

(AORN; CDC “Frequently Asked Questions”)
Safe Injection Learning Objective

Select approaches to integrate safe injection strategies into clinical practice.
Safe-Practice Adoption Barriers

Awareness of performance gaps before practice adoption

Resource investment and capacity to make changes

Leadership directly responsible for closing gaps

Define targets to close performance gaps

Awareness
ACCOUNTABILITY
ACTION
ABILITY

(AORN; Denham)
Approaches to Integrate Safe Injection Strategies into Clinical Practice

• Increase awareness
  — Engage
  — Educate
• Oversee compliance
  — Execute
  — Evaluate

(Perz et al. “A ‘Never’ Event”; “Prevent the Occurrence”)
Increase Safe Injection Awareness

• Engage stakeholders
  – Share stories about actual patient harm
  – Recognize clinicians following safe practices

• Education
  – Small group of clinicians/leaders
  – All-staff campaign kickoff

• Survey clinicians
  – Ask how they would respond to behaviors that have potential or actually cause harm
  – Actual practices (anonymous)
Increase Safe Injection Awareness
Educational Focus

• Describe safe injection and basic aseptic practices.

• Include hand hygiene, glove changing, and avoidance of cross-contamination.

• Recognize the basics of indirect contact transmission of infectious agents.

(“Prevent the Occurrence”)
Increase Safe Injection Awareness Educational Focus

• Recognize the potential consequences of syringe reuse and other unsafe practices.

• Detect and correct unsafe practices.

• Understand the need for monitoring practices related to injection safety and basic infection control.

(“Prevent the Occurrence”)
Identify Infection Control Guidelines and Educational Materials

CDC guidelines and recommendations are available at http://www.cdc.gov/hai/prevent/prevent_pubs.html.

Analyzing, Educating and Collaborating for Patient Safety

© 2013 Pennsylvania Patient Safety Authority
To Prevent Transmission of Infections in Healthcare

1 ONE NEEDLE, ONE SYRINGE, ONLY ONE TIME.

Safe Injection Practices Coalition
www.ONEandONLYcampaign.org

Injection Safety is Every Provider’s Responsibility
Anesthesia Injection Practice Survey

• 200 providers in Florida, 2009
• Syringe or needle reuse acceptable
  – Anesthesiologists (82%), certified registered nurse anesthetists (CRNAs) (67%), student registered nurse anesthetists (SRNAs) (80%)
• Reused needles or syringes on same patient
  – Anesthesiologists (83%), CRNAs (67%), SRNAs (33%)
• Only 50% would allow needles or syringes to be reused on themselves or their family.
• 88% were aware of the Nevada outbreak.

(Barton et al.)
2010 Injection Practice Survey

• 5,446 clinician responses
• 30% sometimes or always entered SDVs multiple times for the same patient.
• 15% reuse syringe to enter MDVs.
  – 6.5% saved vial for use on another patient.
• 9% used a bag or bottle IV solutions for multiple patients.
• 6% sometimes or always use SDVs for multiple patients.
• 0.9% sometimes or always reused syringes with a new needle for a second patient.

(Pugliese et al.)
Increase Safe Injection Awareness

• Tailor written infection control policies to the individual practice setting.

• Build principles into daily work processes.

• Investigate the feasibility of implementing a satellite pharmacy.

• Implement forcing functions.
  — Purchase single-dose medications and flush vials whenever possible.
  — Use auto-destruct syringes/plungers.
Safe Injection Reminders

• Posters for staff lounges and waiting rooms
• Brochures, pocket cards, and videos
• Frequently asked questions (FAQ) pamphlets for hard copy distribution at staff meetings or training seminars
• List of truths and myths uploaded to the facility intranet or screensavers
• Safety checklists for monitoring individual practices
• Support documents from administration
Oversight of Compliance with Safe Injection Practices

• Employ a licensed healthcare professional qualified through training in infection control.

• Provide job-specific infection control training, competency validation, and at least an annual review of staff practices.

• Implement policies and processes that support safe injection practices.

(CMS “Infection Control Surveyor”; “Prevent the Occurrence”)
Infection Control
Conditions for Coverage

42 CFR § 416.51
• “Maintain an infection control program that seeks to minimize infections and communicable diseases.”

42 CFR § 416.44
• “The ASC must have a safe and sanitary environment, properly constructed, equipped and maintained to protect the health and safety of patients.”

(CMS “State Operations Manual“)
17. Does the ASC have a licensed health care professional qualified through training in infection control and designated to direct the ASC’s infection control program?

- YES
- NO

NOTE: If the ASC cannot document that it has designated a qualified professional with training (not necessarily certification) in infection control to direct its infection control program, a deficiency related to 42 CFR 416.51(b)(1) must be cited. Lack of a designated professional responsible for infection control should be considered for citation of a condition-level deficiency related to 42 CFR 416.51.

17a. If YES, Is this person an:

(Fill in only ONE bubble)

- ASC employee
- ASC contractor

17b. Is this person certified in infection control (i.e., CIC)?

(Note: §416.50(b)(1) does not require that the individual be certified in infection control.)

- YES
- NO

17c. If this person is NOT certified in infection control, what type of infection control training has this person received?

17d. On average, how many hours per week does this person spend in the ASC directing the infection control program?

[ ] [ ] hours per week
<table>
<thead>
<tr>
<th>EDUCATION QUESTIONS</th>
<th>N = 134</th>
<th>%</th>
<th>#</th>
</tr>
</thead>
<tbody>
<tr>
<td>The facility has a designated licensed staff member directing infection control.</td>
<td></td>
<td>91</td>
<td>122</td>
</tr>
<tr>
<td>The infection control education includes all licensed medical-surgical staff.</td>
<td></td>
<td>88</td>
<td>90</td>
</tr>
<tr>
<td>The staff receives ongoing infection control education.</td>
<td></td>
<td>73</td>
<td>98</td>
</tr>
<tr>
<td>The staff directing infection control has received formal training in infection control.</td>
<td></td>
<td>65</td>
<td>87</td>
</tr>
<tr>
<td>Infection control education is provided for all contractual employees.</td>
<td></td>
<td>38</td>
<td>35</td>
</tr>
</tbody>
</table>
Oversight of Compliance with Safe Injection Practices

• Clearly designate responsibility for oversight and monitoring.

• Conduct quality assurance assessments.

• Establish procedures and responsibilities for reporting and investigating breaches in infection control policy.

(Perz et al. “A ‘Never’ Event”)

© 2013 Pennsylvania Patient Safety Authority
# Sample Safe Injection Assessment Tool

### (2) 100% Implemented  (1) Partial implementation  (0) Not implemented

<table>
<thead>
<tr>
<th>Best Practice</th>
<th>IC Plan / Goals</th>
<th>Process Policy and Procedures</th>
<th>Education</th>
<th>Accountability</th>
<th>Process and outcomes</th>
<th>Remediation Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Item can be evaluated by clinical observation</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I SAFE INJECTIONS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 Injections are prepared using aseptic technique.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 Injections are prepared in a clean area free from contamination or contact with blood, body fluids or contaminated equipment.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 Needles and syringes, prefilled syringes and insulin pen cartridges are used for only one patient.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4 Vials are always entered with a new needle and a new syringe, even for the same patient.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 Single dose vials, ampoules, iv solutions are used for only one time, for one dose for one patient.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6 Medication administration tubing and connectors are used for only one patient.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7 MDV are dated when opened – discarded within 28 days or manufacturer instructions.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8 MDV used on multiple patients are kept in a centralized clean med area and do not enter the immediate patient treatment area (OR, cubicle.)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9 Rubber septum is scrubbed with alcohol and dried prior to puncture.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10 SDV are discarded within one hour of opening or puncture.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

**Analyzing, Educating and Collaborating for Patient Safety**

© 2013 Pennsylvania Patient Safety Authority
### INJECTION SAFETY CHECKLIST

The following injection safety checklist items are a subset of items that can be found in the [CDC Infection Prevention Checklist for Outpatient Settings: Minimum Expectations for Safe Care](http://www.cdc.gov/injectionsafety/PDF/SIPC_Checklist.pdf).

The checklist, which is appropriate for both inpatient and outpatient settings, should be used to systematically assess adherence of healthcare personnel to safe injection practices. (Assessment of adherence should be conducted by direct observation of healthcare personnel during the performance of their duties.)

<table>
<thead>
<tr>
<th>Injection Safety</th>
<th>Practice Performed?</th>
<th>If answer is No, document plan for remediation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injections are prepared using aseptic technique in a clean area free from contamination or contact with blood, body fluids or contaminated equipment.</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Needles and syringes are used for only one patient (this includes manufactured prefilled syringes and cartridge devices such as insulin pens).</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>The rubber septum on a medication vial is disinfected with alcohol prior to piercing</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Medication vials are entered with a new needle and a new syringe, even when obtaining additional doses for the same patient.</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Single dose (single-use) medication vials, ampules, and bags or bottles of intravenous solution are used for only one patient.</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Medication administration tubing and connectors are used for only one patient.</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Multi-dose vials are dated by HCP when they are first opened and discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial. Note: This is different from the expiration date printed on the vial.</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Multi-dose vials are dedicated to individual patients whenever possible.</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Multi-dose vials to be used for more than one patient are kept in a centralized medication area and do not enter the immediate patient treatment area (e.g., operating room, patient room/cubicle). Note: If multi-dose vials enter the immediate patient treatment area, they should be dedicated for single-patient use and discarded immediately after use.</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>
II. Injection Practices (injectable medications, saline, other infusates)
Observations are to be made of staff who prepare and administer medications and perform injections (e.g., anesthesiologists, certified registered nurse anesthetists, nurses).

<table>
<thead>
<tr>
<th>Practices to be Assessed</th>
<th>Was Practice Performed?</th>
<th>Manner of Confirmation</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Needles are used for only one patient</td>
<td>☐ Yes</td>
<td>☐ Observation</td>
</tr>
<tr>
<td></td>
<td>☐ No</td>
<td>☐ Interview</td>
</tr>
<tr>
<td></td>
<td>☐ N/A</td>
<td>☐ Both</td>
</tr>
<tr>
<td>B. Syringes are used for only one patient</td>
<td>☐ Yes</td>
<td>☐ Observation</td>
</tr>
<tr>
<td></td>
<td>☐ No</td>
<td>☐ Interview</td>
</tr>
<tr>
<td></td>
<td>☐ N/A</td>
<td>☐ Both</td>
</tr>
</tbody>
</table>

(CMS “Infection Control Surveyor“)
Reporting: Event Types

• Incident
  – “An event, occurrence, or situation involving the clinical care of a patient in a medical facility which could have injured the patient but did not either cause an unanticipated injury or require the delivery of additional health care services to the patient.”

• Serious Event
  – “An event, occurrence or situation involving the clinical care of a patient in a medical facility that results in death or compromises patient safety and results in unanticipated injury requiring the delivery of additional health care services to the patient.”

(Commonwealth of Pennsylvania Patient Safety Authority)
<table>
<thead>
<tr>
<th>Code</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Circumstances that could cause adverse events (e.g., look-alike medications, confusing equipment, etc.)</td>
</tr>
</tbody>
</table>

**Event, No Harm**

<table>
<thead>
<tr>
<th>Code</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>B1</td>
<td>An event occurred but it did not reach the individual (&quot;near miss&quot; or &quot;close call&quot;) because of chance alone.</td>
</tr>
<tr>
<td>B2</td>
<td>An event occurred but it did not reach the individual (&quot;near miss&quot; or &quot;close call&quot;) because of active recovery efforts by caregivers.</td>
</tr>
<tr>
<td>C</td>
<td>An event occurred that reached the individual but did not cause harm and did not require increased monitoring (an error of omission such as a missed medication dose does reach the individual).</td>
</tr>
<tr>
<td>D</td>
<td>An event occurred that required monitoring to confirm that it resulted in no harm and/or required intervention to prevent harm.</td>
</tr>
</tbody>
</table>

**Event, Harm**

<table>
<thead>
<tr>
<th>Code</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>E</td>
<td>An event occurred that contributed to or resulted in temporary harm and required treatment or intervention.</td>
</tr>
<tr>
<td>F</td>
<td>An event occurred that contributed to or resulted in temporary harm and required initial or prolonged hospitalization.</td>
</tr>
<tr>
<td>G</td>
<td>An event occurred that contributed to or resulted in permanent harm.</td>
</tr>
<tr>
<td>H</td>
<td>An event occurred that resulted in a near-death event (e.g., required ICU care or other intervention necessary to sustain life).</td>
</tr>
</tbody>
</table>

**Event, Death**

<table>
<thead>
<tr>
<th>Code</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>An event occurred that contributed to or resulted in death.</td>
</tr>
</tbody>
</table>
## Event Type Taxonomy

<table>
<thead>
<tr>
<th>Event Type</th>
<th>Event Type Sub1</th>
<th>Event Type Sub2</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Equipment, supplies, or devices</strong></td>
<td>Sterilization problem</td>
<td></td>
</tr>
<tr>
<td><strong>Error related to procedure, treatment, or test</strong></td>
<td>Surgery or invasive procedure problem</td>
<td>Break in sterile technique</td>
</tr>
<tr>
<td><strong>Complication of procedure, treatment, or test</strong></td>
<td>Maternal complication</td>
<td>Infection</td>
</tr>
<tr>
<td></td>
<td>Nosocomial Infection</td>
<td>Intravascular catheter infection</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wound or surgical site infection</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Nosocomial pneumonia</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sepsis 48 hours post-admit</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Antibiotic-associated diarrhea</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Antibiotic-resistant organism</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Urinary tract infection</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Other nosocomial infection</td>
</tr>
</tbody>
</table>

(Canmonwealth of Pennsylvania Patient Safety Authority)

Analyzing, Educating and Collaborating for Patient Safety

© 2013 Pennsylvania Patient Safety Authority
Exercise: Reporting Unsafe Injections

IV propofol was injected into IV tubing of two patients using the same syringe. Rationale: probability of communicable disease is extremely low due to the IV port location high away from the IV site.

- Incident—required monitoring to confirm no harm
- Error related to procedure, treatment, or test

Patient and source patient tested positive for HIV and hepatitis.

- Serious Event—contributed to or resulted in permanent harm
- Complication of procedure, treatment, or test
Infection Event Description Elements

• Information sources include:
  – Verbal or surveillance tool
  – Physician, patient, lab, or hospital
• Surgical procedure/date
• Event type—description of error
• Infection site, labs, or organism
• Symptoms or treatment
  – Antibiotic, hospitalization, or surgery
• Outcome
  – Resolved, loss of function, or death
Investigating Breaches—Root Causes

1. **Why** was the SDV reused?
2. **Why** did the clinician think it was within safe injection standards?
3. **Why** was the clinician not aware?
4. **Why** was the education not done?
5. **Why** does the facility allow clinicians to practice without assuring knowledge or competency of safe practices?
Investigating Events—Just Culture

• Human error
  – Unaware of the safe injection policy
  – Not able to comply with the policy
  – Intended to use safe practice—made a mistake

• At-risk behavior
  – Knows safe practice—didn’t see risk
  – Mistaken belief that violation was insignificant or justified
  – Check behavioral choice—are others following policy?

• Reckless
  – Known risk was consciously disregarded

© 2013 Pennsylvania Patient Safety Authority
Bottom Line: Patient Safety

• Risk of negative outcomes versus cost or convenience
• Multifaceted approach
  – Awareness: engage, educate
    • Plan, policy, and surveillance
    • Dashboards and scorecards
    • Education and competency assessment
  – Oversight: enforce, evaluate
    • Ensure safe practices, proper handling of injection equipment, and good aseptic technique
    • Assessment, monitoring, and reporting
    • resources
Prevent the Occurrence of Bloodborne Disease Transmission Associated with Unsafe Injection Practices

Questions?
References


References

• Centers for Disease Control and Prevention (CDC). Medication administration questions [online].

• Centers for Disease Control and Prevention (CDC). Questions about single-dose/single-use vials [online].


References


References

• Marx D. Patient safety and the “just culture” [slide presentation online]. 2007 [cited 2013 Mar 25].


References


Safe Injection
Interactive Session
Activity #1
Test Your Knowledge
Breaches in the principles of infection control associated with unsafe injection practices include all of the following EXCEPT:

a. Changing the needle on a used syringe or device prior to injecting medication to more than one person
b. Accessing a common bag of sterile IV solution to flush IV lines of multiple individuals
c. Wiping the glucometer with a disinfectant in between testing blood sugar levels on multiple patients
d. Preparing IV medication in the dialysis patient treatment area
Which statement LEAST accurately describes the misperceptions associated with unsafe injection practices?

a. The risk for syringe contamination in an IV line is eliminated by distance, gravity, and positive infusion pressure.

b. Reusing a syringe for additional doses of medication for the same patient is considered safe.

c. Secondary use of a syringe is considered safe, as contamination is limited to the needle device.

d. Preparation of injectable medications is appropriate in a confined workspace with a clear demarcation of clean and dirty areas.
All of the following practices may contribute to contamination of injection equipment and medication vials EXCEPT:

a. Administering propofol from the contents of a combined vial stored in a lab coat pocket.
b. After flushing an IV, using a second syringe to draw a blood specimen.
c. Accessing a vial of medication using a syringe from a previous case with a clean needle.
d. Inserting a fresh needle and syringe into a medication vial and storing on the anesthesia table for the next case.
Which system-level intervention would NOT be appropriate to prevent an unsafe injection practice?

a. Develop protocol to change needles on all syringes used for multiple patients.

b. Unpackage syringes as close to administration time as possible.

c. Purchase single-dose medication and flush vials whenever possible.

d. Label individual insulin pen devices for each patient using them.
Which recommendation is MOST appropriate regarding awareness and oversight of safe injection practices?

a. Empower patients to speak up about unsafe injection practice for patients.

b. Write a policy outlining safe injection practice requirements.

c. Require periodic injection practice education, competency assessment, and monitoring for all clinicians in healthcare facilities.

d. Present a business plan to the chief executive officer supporting the facility’s safe injection policy.
Activity #2
Case Scenarios
Case Study A

Patient #4 of the day was brought to the procedure room at 2 p.m. for a hernia repair. The procedure room nurse inserted an IV prepared from an IV bag spiked earlier that morning in the medication prep room.

The CRNA opened a new SDV of sedation medication. Using a new sterile needle and syringe, he withdrew sedation medication from the vial. The CRNA injected IV sedation into the patient’s IV port and then used the same needle and syringe to access an MDV of sterile saline. He withdrew saline from the MDV and flushed the IV port using the same patient’s needle and syringe.
Case Study A

The RN placed the MDV back onto a medication cart in the procedure room. The additional content in the 50 mL sedation and flush vials were used for three additional patients that afternoon in sequential order.

The vial of saline was discarded at the end of the day. The unused portion of the vial of sedation was dated and stored in the refrigerator for the next day.
Case Study B

A patient was brought to the procedure room to receive a steroid injection to his right knee. The physician preferred to draw up medications for the procedure himself. He asked the nurse to bring one vial of lidocaine, one vial of kenalog, and one syringe to the procedure room.

The physician accessed the MDV of lidocaine, injected the lidocaine, changed the needle, and then drew up the kenalog from the MDV. When the nurse objected to the process, stating it was unsafe, the physician replied that it was OK, as he made sure not to aspirate to avoid syringe contamination.