

AHC Media April 4, 2016

Safe Injection Practices and IV Push Guidelines: Compliance with CDC and CMS Standards




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Objectives

- Detail the 10 practices, appropriate for both inpatient and outpatient settings, on the CDC Injection Safety Checklist.
- Explain why every hospital should have a policy specific to safe injection practices.
- Explain new and revised standards, regulations, and laws put forth by CMS, TJC and the federal government.
- Evaluate compliance requirements and penalties.

Introduction and Safe Injection Practices



Safe Injection Practices

- This issue should be on the radar screen of every infection preventionist and hospital
- Do you know the **ten** requirements for safe injection practices by the CDC?
- Are you familiar with the provisions of the CMS hospital worksheet in infection control that includes questions that will be asked on safe injection practices by the surveyors?
- Are you familiar with the CMS hospital survey memo on what hospitals should be doing on safe injection practices?

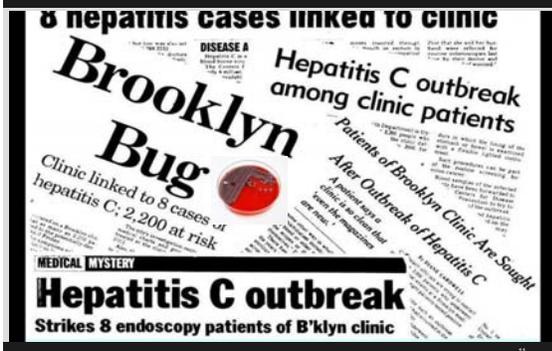
Safe Injection Practices

- Have you implemented the ISMP IVP guidelines?
- Does your hospital have a policy on safe injection practices?
- Are all staff educated on safe injection practices including your physicians?
- Are all nurses educated in orientation and periodically on safe injection practices?
- We do not want to see headlines that discuss unsafe practices that result in patient injury and death

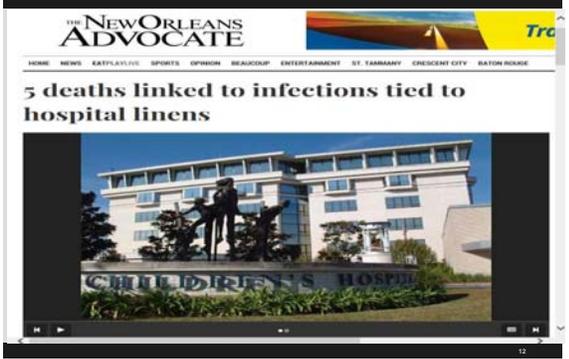
Headlines We Do Not Want to See

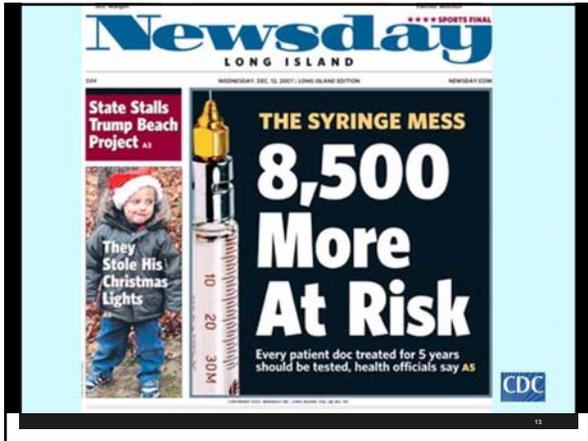


Headlines We Don't Want to See



Headlines We Don't Want to See





Headlines We Don't Want to See

Fungal Meningitis Fungal Meningitis Articles Fungal Meningitis Links About Our Lawyers Contact Our Lawyers

Fungal Meningitis Related To Contaminated Epidural Steroid Shots

The Centers for Disease Control has identified eleven deaths and more than 100 cases of **Fungal Meningitis** as related to **Contaminated Epidural Steroid Shots**. CDC is currently conducting a multi-state **outbreak investigation**. Steroid injections of Methylprednisolone Acetate are believed to have been tainted with a fungus. The particular type of meningitis this has caused is called fungal meningitis. Three lots of the product were distributed nationwide. The steroid solution has now been recalled and the factory's operations have been shut down.

News reports indicate that as many as 13,000 patients may have been affected. **News reports** link the outbreak to patients in Tennessee, Michigan, Virginia, Indiana, Florida, Maryland, Minnesota, North Carolina and Ohio.

A map showing **current outbreak statistics** is available at from the CDC. New cases are being reported on a daily basis. Even if you are outside the area of the current reports, you may have been affected.



What is Fungal Meningitis?

Fungal meningitis is rare and usually the result of spread of a fungus through blood to the spinal cord. Although anyone can get fungal meningitis, people with weak immune systems, like those with AIDS or cancer, are at higher risk.

The most common cause of fungal meningitis for people with weak immune systems is Cryptococcus. This disease is one of the most common causes of adult meningitis in Africa.

Learn more about Fungal Meningitis

Fungal Meningitis Outbreak

- CDC and FDA investigated outbreaks of meningitis (Exserohilum and Aspergillus)
- In patients who received a steroid injection from a contaminated product into the spinal area developed fungal meningitis (67%)
- Patients suffered strokes and fungus infection in a joint space (2%) such as the knee or shoulder and death
- Some patients ended up epidural abscess, vertebral osteomyelitis, discitis and arachnoiditis near the injection site

Fungal Meningitis Outbreak

- From a preservative-free steroid (methylprednisolone acetate 80mg/ml) from the NECC
 - New England Compounding Center in Framingham, Mass which has now filed a bankruptcy
- Symptoms can occur 1-4 weeks after injection
- There were a total of 14,000 patients affected including 48 deaths in 23 states
- This form of meningitis is not contagious
- Federal law on compounding is passed as a result
- CDC issues diagnostic and treatment guidance to help physicians and staff
www.cdc.gov/hai/outbreaks/clinicians/guidance_asymptomatic_persons.html

Staph Infections Reuse Single Dose Vials

The screenshot shows the CDC website with the following details:
 - CDC logo and name: Centers for Disease Control and Prevention, CDC 24/7: Saving Lives. Protecting People.
 - URL: www.cdc.gov/mmwr/preview/mmwr.html/mm6127a1.htm?s_cid=mm6127a1_w
 - Title: Invasive *Staphylococcus aureus* Infections Associated with Pain Injections and Reuse of Single-Dose Vials – Arizona and Delaware, 2012
 - Date: Weekly, July 13, 2012 / 61(27):501-504
 - Summary text: Transmission of life-threatening bacterial infections can occur when health-care personnel do not adhere to Standard Precautions and instead use medication in containers labeled as single-dose or single-use for more than one patient (1). This report summarizes the investigation of two outbreaks of invasive *Staphylococcus aureus* infection confirmed in 10 patients being treated for pain in outpatient clinics. In each outbreak, the use of single-dose or single-use vials (SDVs) for more than one patient was associated with infection transmission. In both investigations, clinicians reported difficulty obtaining the medication type or vial size that best fit their procedural needs. These outbreaks are a reminder of the serious consequences that can result when SDVs are used for more than one patient. Clinician adherence to safe injection practices, particularly when appropriately sized SDVs are unavailable, is important to prevent infection transmission. If SDVs must be used for more than one patient, full adherence to U.S. Pharmacopeia standards is critical to minimize the risks of mispuncture use.
 - Footer: Pain Management Clinic – Arizona

Staph Reuse of Single Dose Vials

- CDC issues a report on invasive staph aureus associated with patients who got pain injections
- Reused single dose vials which is a violation of CDC safe injection practices standards
- Two outbreaks in ten patients treated in an outpatient clinic in Arizona and Delaware
- Used a single dose or single-use vial (SDV) on more than one patient
- CDC said clinicians need to adhere to safe injection practices

Staph Reuse of Single Dose Vials

- Physicians did not wear face mask when doing spinal injections which is a CDC guideline
- Reused a vial of bupivacaine 30 ml which is for single dose use on multiple patients
- 7 patients suffered a staph infection and were admitted for septic arthritis or bursitis
- 2 MRSA patients have an epidural steroid injection and one a stellate ganglion block
- Two staff members who prepared the medication were colonized with staph aureus

Identify Risks for Transmitting Infections

- Hospital and ASC in Colorado where surgery tech with Hepatitis C infection steals Fentanyl and replaces it with used syringes of saline infecting 17 patients as of December 11, 2009 and 5,970 patients tested (total 36 for 3 facilities)
- Kristen Diane Parker in 2010 gets 30 years for drug theft and needle swap scheme
- Worked at Denver's Rose Medical Center and Colorado Springs' Audubon Surgery Center
- Patients often fill lawsuits when this occurs
- 1 www.krdo.com/Global/link.asp?L=399119



Kristen Parker Sentenced for Fentanyl Theft
January 16th, 2010 By: [Name]

[Back to the blog](#)



About a year ago a woman named Kristen Diane Parker, a surgery tech who worked in hospitals the Denver area, made the news, including on [LawyersAndSettlements.com](#). I wrote a couple of short pieces about her. She was addicted—maybe still is—to Fentanyl.

Also known as Duragesic, Fentanyl is a prescription pain medication—quite a strong one—and quite an addictive one by all accounts. Kristen Parker was so addicted to the stuff that she would steal syringes from hospital surgery carts where she worked—syringes that were filled with Fentanyl—and inject herself. She would then fill the used syringes with saline and replace them. Just in case this isn't crystal clear—post-operative patients were being administered saline in used syringes instead of their prescribed pain medication.

Al, but it gets worse. Parker ended up infecting some 26 people with hepatitis C, a currently incurable viral infection which leads to chronic liver inflammation, and in some cases liver cancer. Parker, who shared needles when injecting heroin, is hepatitis C positive—something she didn't know when she was filling her needles.

Thankfully, Ms. Parker got careless, and she got caught. No surprise there, given the state she must have been in: Fentanyl is 80 to 100 times stronger than morphine. Eventually,

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Legal Help Now!

Pleads Guilty

- 34 year old pleads guilty
- He pleads guilty to 16 federal drug charges
- He worked as cardiac tech and former lab tech in 18 hospitals in 7 states
- 46 patient confirmed with his strain of Hepatitis C
- 32 in New Hampshire, 7 in Maryland, 6 in Kansas, and 1 in Pennsylvania
- Stole fentanyl and replaced it with saline and used dirty needle
 - Stealing drugs since 2002 and pleads guilty Aug 2013



David Kwiatkowski Infects 46 Patients

Hepatitis C Outbreak: In Wake Of Kwiatkowski Guilty Plea, Patients Seek Accountability

By HOLLY HAMER

17 people like this. Be the first of your friends.



FOLLOW: Kwiatkowski, Kwiatkowski Guilty Plea, Kwiatkowski Hepatitis C, Hepatitis C Outbreak, New Hampshire Hepatitis C Outbreak, Healthy Living News

CONCORD, N.H. — Patients at a New Hampshire hospital who were infected with hepatitis C by a traveling medical technician with a drug problem are pleased with his guilty plea but are still pushing to hold others accountable.

David Kwiatkowski, 34, pleaded guilty last week to 16 federal drug charges under an agreement that calls for him to spend 30 to 40 years in prison. He admitted stealing insulin syringes from hospitals where he worked and replacing them with saline-filled syringes tainted with his blood.

Before he was hired at Easter Hospital in New Hampshire in 2011, Kwiatkowski worked as a cardiac technician in 18 hospitals in seven states, moving from job to

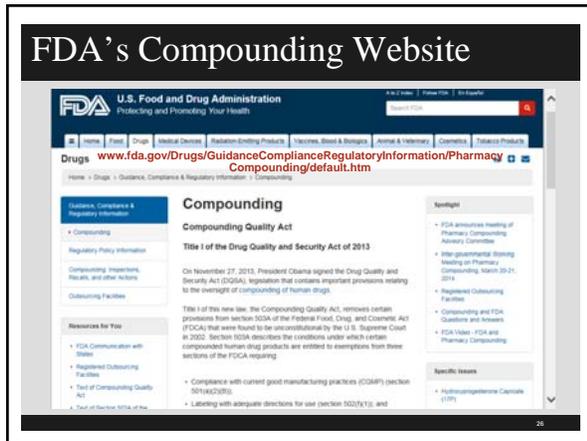
The Federal Law on Compounding



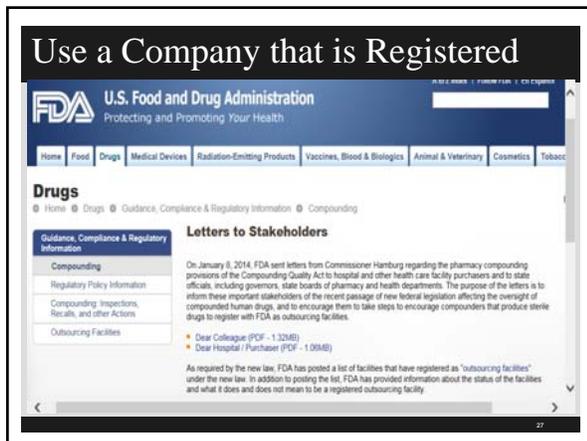
Drugs Rules Must Include

- Drug Quality and Security Act (DQSA) has sections related to compounding
- Outsourcing facilities who compound drugs register and must comply with section 503B of the FDCA and other requirements such as the FDA's current good manufacturing practice (CGMP)
 - Will be inspected by the FDA according to risk based schedule
 - Must meet certain other conditions including reporting adverse drug events to the FDA

FDA's Compounding Website



Use a Company that is Registered



Drug Rules Must Include 276 2015

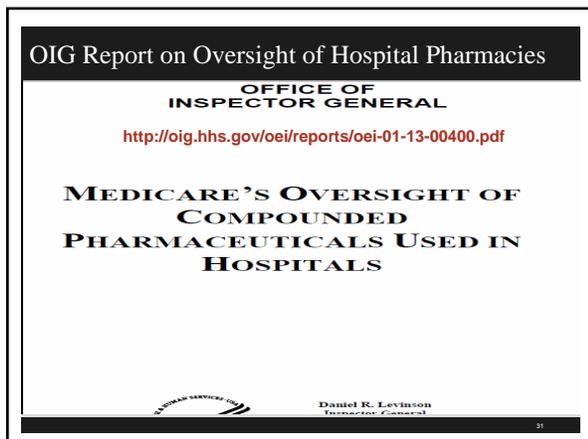
- CMS added a section to the CAH manual on this in April 2015 and November 20, 2015 to Appendix A hospital CoP manual
- If hospital obtains compounded medications from compounding pharmacy rather than a manufacturer or a registered outsourcing facility then must demonstrate that medicine received have been prepared in accordance with acceptable principles
 - Contract with the vendor would want to ensure hospital's access to their quality data verifying their compliance with USP standards
 - Should document you obtain and review this data

OIG Report January 22, 2015



Surveyor Training on Compounding

- The OIG issued a report regarding a recommendation which called on CMS to ensure hospital surveyors are trained on nationally recognized compounding practices and safe injection practices
- Recommend it change the CoPs interpretive guidelines to address hospital contracts with stand-alone compounding pharmacies
- OIG said the lack of surveyor training preventing the oversight entities from effectively evaluating the hospital's use of CSP or compounded sterile preparations



The OIG Report Jan 2015

- May find the surveyor may review the contracts of the stand alone compounding pharmacy and more scrutinize these areas
 - This includes surveyors from TJC, DNV, AOA HCAP, and CIHQ
- Surveyors will likely be more aware of standards with additional training and more likely to discover if hospital is not doing safe compounding practices
 - Discussed the 64 deaths from the fungal meningitis case from NECC
 - Made 55 recommendations on overseeing CSPs in hospitals

Table A1: Extent to Which Oversight Entity Surveys Incorporate Recommended Practices Related to the Hospital Physical Plant and Environmental Quality

Recommended Practice	Oversight Entities Responding		
	Always	Some of the Time	Never
Do surveyors request a copy of the hospital's pharmacy cleaning logs?	1	4	0
Do surveyors request a copy of the hospital's pharmacy environmental sampling logs?	0	5	0
If the hospital prepares CSPs onsite, do surveyors assess whether the area of preparation is appropriate for all CSP risk levels compounded at the hospital?	2	3	0
If the hospital prepares hazardous CSPs onsite, do surveyors assess the appropriateness of the physical area where hazardous CSPs are compounded?	3	2	0
If the hospital prepares CSPs onsite, do surveyors assess the environmental quality and control in the area of preparation?	3	2	0
If always or some of the time, do surveyors assess the adequacy of the environmental quality and control for each risk level of CSP prepared at the hospital?	2	3	0
If the hospital prepares CSPs onsite, do surveyors review the hospital's written procedures outlining the following:			
Cleaning and disinfecting of the compounding areas?	1	4	0
Personnel hand hygiene and garbing in compounding areas?	3	2	0
Employee aseptic technique in compounding areas?	2	3	0
Environmental sampling in compounding areas?	0	5	0
Facility and engineering control testing and certification in compounding areas?	0	4	1
If the hospital prepares CSPs onsite, do surveyors assess the adequacy of personal protective equipment for compounding CSPs, including applicable	2	3	0

CMS Safe Injection Practices Survey Memo and Other Survey Memos



CMS Memo on Safe Injection Practices

- CMS issues a 7 page memo on safe injection practices that every healthcare facility should follow
- Discusses the safe use of single dose medication to prevent healthcare associated infections (HAI)
- Notes new exception which is important especially in medications shortages
- General rule is that single dose vial (SDV) can only be used on one patient
- Will allow SDV to be used on multiple patients if prepared by pharmacist under laminar hood following USP 797 guidelines

Safe Injection Practices

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
200 Security Boulevard, Mail Stop 02-21-16
Baltimore, Maryland 21244-1020



Office of Clinical Standards and Quality/Survey & Certification Group

DATE: June 15, 2012 **Ref:** S&C: 12-35-ALL
TO: State Survey Agency Directors **Enrollment and**
FROM: Director **Certification/SurveyCertificationGenInfo/index.htm?redirect=SurveyCertificationGenInfo/PMSR/ii**
SUBJECT: Safe Use of Single Dose/Single Use Medications to Prevent Healthcare-associated Infections **Study**

Memorandum Summary

- Under certain conditions, it is permissible to repack 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 5501 and 502 of the Federal Food, Drug and Cosmetics Act (FDCA). These USP compounding standards include USP General Chapter 797, *Pharmaceutical Compounding - Sterile Ophthalmics* ("USP <797>"). Under USP <797>, healthcare facilities may repack SDVs into smaller doses, each intended for use with one patient. Among other things, these standards currently require that:
 - The facility doing the repackaging must use qualified, trained personnel to do so, under International Organization for Standardization (ISO) Class 5 air quality conditions within an ISO Class 7 buffer area. All entries into a SDV for purposes of repackaging under these conditions must be completed within 6 hours of the initial needle puncture.
 - All repackaged doses prepared under these conditions must be assigned and labeled with a beyond use date (BUD), based on an appropriate determination of contamination risk level in accordance with USP <797>, by the licensed healthcare professional supervising the repackaging process.

CMS Memo on Safe Injection Practices

- All entries into a SDV for purposes of repackaging must be completed with 6 hours of the initial puncture in pharmacy following USP guidelines
- Only exception of when SDV can be used on multiple patients
- Otherwise using a single dose vial on multiple patients is a violation of CDC standards
- CMS will cite the facility under the hospital CoP/CFC infection control standards since must provide sanitary environment
 - Also includes ASCs, hospice, LTC, home health, CAH, dialysis, etc.

CMS Memo on Safe Injection Practices

- Make sure pharmacist has a copy of this memo
- If medication is repackaged under an arrangement with an off site vendor or compounding facility ask for evidence they have adhered to 797 standards
- ASHP Foundation has a tool for assessing contractors who provide sterile products
- Go to www.ashpfoundation.org/MainMenuCategories/PracticeTools/SterileProductsTool.aspx
- Click on starting using sterile products outsourcing tool now

CMS Memo on Safe Injection Practices

- Bottom line is you can not use a single dose vial on multiple patients
- CMS requires hospitals to follow nationally recognized standards of care like the CDC guidelines
- SDV typically lack an antimicrobial preservative
- Once the vial is entered the contents can support the growth of microorganisms
- The vials must have a beyond use date (**BUD**) and storage conditions on the label

CMS Memo on Safe Injection Practices

- So if it is made in a single dose vial then you need to buy it in a single dose vial
 - If they only make it in a multi-dose vial then try and use it as a single dose vial
 - If not then try and use it only on one patient
- Do not take multi-dose vial into patient room or into OR
 - Unless in OR you treat it as a single dose vial and discard it
 - Mark multi-dose vial expires in 28 days unless sooner by manufacturer
- Clean off lid even if new vial for 10-15 seconds and let dry

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The screenshot shows the ASHP Foundation website. The main content area features a section titled "Outsourcing Sterile Products Preparation: Contractor Assessment Tool". It includes a sub-header "Developed with support from PharmDium Services, LLC" and a "Now available!" tag. The text describes the tool as a web-based assessment tool for evaluating proposals from external organizations for sterile product preparation services. It lists evaluation criteria: Regulatory compliance, Quality and patient safety measures, Medication administration safety features, and Service excellence. A URL is provided: www.ashpfoundation.org/MainMenuCategories/PracticeTools/SterileProductsTool.aspx. The ASHP Foundation logo is visible in the bottom right corner of the screenshot.

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Not All Vials Are Created Equal

SINGLE-DOSE OR MULTI-DOSE?

NOT ALL VIALS ARE CREATED EQUAL.

Dozens of recent outbreaks have been associated with reuse of single-dose vials and misuse of multiple-dose vials. As a result of these incidents, patients have suffered significant harms, including death. CDC and the One & Only Campaign urge healthcare providers to recognize the differences between single-dose and multiple-dose vials and to understand appropriate use of each container type. This information can literally save a life.



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DO YOU PROVIDE TREATMENT FOR PATIENTS WITH CANCER?

PROTECT YOUR PATIENTS, YOURSELF, AND YOUR BUSINESS

Since 2002, at least nine serious infectious disease outbreaks have occurred in cancer clinics. These outbreaks involved unsafe injection practices, including the reuse of syringes. As a result, hundreds of patients became infected and thousands more required notification and testing for bloodborne pathogens.

REMEMBER! WHEN PREPARING MEDICATIONS AND INJECTIONS...

NEVER reuse these items:

- Needles or syringes that have been used for any purpose
- Vials with "single-dose vial" printed on the label
- Saline bags
- Intravenous tubing

ALWAYS follow aseptic technique* when:

- Preparing any medication
- Disinfecting a vial's septum
- Accessing a central line
- Injecting any medications

*Always technique to used by health care workers to prevent the contamination of clean areas, equipment, and/or medications. This will help prevent the spread of infections. Please refer to CDC's [Basic Infection Control and Prevention Plan for Outpatient Clinics](#) for more information.

1 ONE NEEDLE, ONE SYRINGE, ONLY ONE TIME.

LEARN MORE ABOUT WAYS YOU CAN KEEP YOUR PATIENTS

The Safe Injection Practices Coalition Releases Two New Videos

EDUCATE YOUR TEAM

Dear colleagues, CDC continues to investigate outbreaks as a result of unsafe injection practices. These mistakes and knowledge gaps put healthcare providers and patients at risk. CDC's [One & Only Campaign](#) created [two short videos](#) to help make healthcare safer, one injection at a time.

- Check Your Steps! Make Every Injection Safe - For Healthcare Providers, 3:45
- Managing Patient Safety, One Injection at a Time - For Healthcare Managers, 2:33

These videos detail critical information to help all providers and facility managers double check their injection safety knowledge.

Get Connected with the [One & Only Campaign!](#) There are several ways to follow us, join the conversations, and receive updates.

[Facebook](#)
[One & Only Campaign](#)
[Twitter](#)

CMS Memo Four IC Breaches

- CMS publishes 4 page memo on infection control breaches and when they warrant referral to the public health authorities
- This includes a finding by the state agency (SA), like the Department of Health, or an accreditation organization
 - TJC, DNV Healthcare, CIHQ, or AOA HFAP
- CMS has a list and any breaches should be referred
- Referral is to the state authority such as the state epidemiologist or State HAI Prevention Coordinator for any of the four breaches

Infection Control Breaches

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850



Center for Clinical Standards and Quality/Survey & Certification Group

Ref: SAC 14-36-All

DATE: May 30, 2014
TO: State Survey Agency Directors
FROM: Director
Survey and Certification Group
SUBJECT: Infection Control Breaches Which Warrant Referral to Public Health Authorities

Memorandum Summary

- **Infection Control Breaches Warranting Referral to Public Health Authorities:** If State Survey Agencies (SAs) or Accrediting Organizations (AOs) identify any of the breaches of generally accepted infection control standards listed in this memorandum, they should refer them to appropriate State authorities for public health assessment and management.
- **Identification of Public Health Contact:** SAs should consult with their State's Healthcare Associated Infections (HAI) Prevention Coordinator or State Epidemiologist on the preferred referral process. Since AOs operate in multiple States, they do not have to confer with State public health officials to set up referral processes, but are expected to refer identified breaches to the appropriate State public health contact identified at: <http://www.cdc.gov/HAI/state-based/index.html>

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CMS Memo Infection Control Breaches

- Using the same needle for more than one individual
- Using the same (pre-filled/manufactured/insulin or any other) syringe, pen or injection device for more than one individual
- Re-using a needle or syringe which has already been used to administer medication to an individual to subsequently enter a medication container (e.g., vial, bag), and then using contents from that medication container for another individual
- Using the same lancing/fingerstick device for more than one individual, even if the lancet is changed

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CMS Memo on Insulin Pens

- CMS issues memo on insulin pens on May 18, 2012
- Insulin pens are intended to be used on one patient only
- CMS notes that some healthcare providers are not aware of this
- Insulin pens were used on more than one patient which is like sharing needles
- Every patient must have their own insulin pen
- Insulin pens must be marked with the patient's name

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New Standards Prevent Tubing Misconnections

- New and unique international standards being developed in 2015-2016 for connectors for gas and liquid delivery systems
- To make it impossible to connect unrelated systems
 - Includes new connectors for enteral, respiratory, limb cuff inflation neuraxial, and intravascular systems
- Phase in period for product development, market release and implementation guided by the FDA and national organizations and state legislatures
 - FAQ on small bore connector initiative
 - TJC does SEA to help hospitals in the transition period

Managing Risk During the Transition

Sentinel Alert Event

A complementary publication of The Joint Commission
Issue 53, August 20, 2014

Managing risk during transition to new ISO tubing connector standards

Published for Joint Commission accredited organizations and interested health care professionals, *Sentinel Alert Event* 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 Alert Event* when designing or redesigning processes and consider implementing relevant suggestions contained in the alert or resolvable alternatives.

Tubing misconnections continue to cause severe patient injury and death, since tubes with different functions can easily be connected using luer connectors, or connectors can be "rigged" (constructed) using adapters, tubing or catheters. This is why new ISO (International Organization for Standardization) tubing connector standards are being developed for manufacturers. Through an international consensus process, the standards are being developed, tested and approved to assure reliable designs and processes. The phased implementation of redesigned tubing connectors that are the result of these new ISO connector standards begins now. The Joint Commission urges health care organizations to be vigilant and begin planning for the upcoming period of transition, which will introduce changes and new risks into the health care environment. Under the new ISO connector standards, small-bore (less than 8.5 mm inner diameter) connectors will be engineered to make it nearly impossible to connect one delivery system to another delivery system that serves a completely different function^{1,2,3,4*} – for example, accidentally connecting a feeding administration set to a tracheostomy tube, or an intravenous (IV) tube to an epidural site.

The first new ISO connector standard (ANSI/AAMI/ISO 80369-1) has been adopted and others are expected to be introduced and adopted through 2014 and 2015. Health care organizations should begin preparing for changes in

Safe Injection Practices Memo

- The Emergency Medicine Patient Safety Foundation has a free patient safety memo on safe injection practices
- Available at www.empsf.org and click on resources
- 12 page memo which summarized important issues including the CDC and CMS guidelines on safe injection practices
- Discusses recommendations for hospitals
- Discusses CMS worksheet on infection control which contains a section on safe injection practices

Fingerstick Devices



- Anyone performing fingerstick procedures should ensure that a device is not used on more than one patient
- Use auto-disabling single-use disposable fingerstick devices
- Pen like devices should not be used on multiple patients due to difficulty with cleaning and disinfection (one patient use)



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CDC Poster on Fingerstick Devices

CDC CLINICAL REMINDER

Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens

Summary: The Centers for Disease Control and Prevention (CDC) has become increasingly concerned about the risks for transmitting hepatitis B virus (HBV) and other bloodborne pathogens to persons undergoing fingerstick procedures for blood sampling – for instance, persons with diabetes who require assistance monitoring their blood glucose levels. Reports of HBV infection outbreaks linked to diabetes care have been increasing^{1,2}. This notice serves as a reminder that fingerstick devices should never be used for more than one person.

Background www.cdc.gov/injectionsafety/PDF/Clinical_Reminder_Fingerstick_Devices_RiskBSP.pdf

Fingerstick devices are devices that are used to prick the skin and obtain drops of blood for testing. There are two main types of fingerstick devices: those that are designed for reuse on a single person and those that are disposable and for single-use.



- **Reusable Devices:** These devices often resemble a pen and have the means to remove and replace the lancet after each use, allowing the device to be used more than once (see Figure 1). Due to difficulties with cleaning and disinfection after use and their link to numerous outbreaks, CDC recommends that these devices never be used for more than one person. If these devices are used, it should only be by individual persons using these devices for self-monitoring of blood glucose.

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ISMP IV Push Guidelines for Adults



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ISMP IV Push Medications Guidelines

- ISMP has published a 26 page document called "ISMP Safe Practice Guidelines for Adult IV Push Medications"
- The document is organized into factors that increase the risk of IV push medications in adults,
 - Current practices with IV injectible medications
 - Developing consensus guidelines for adult IV push medication and
 - Safe practice guidelines
 - About 90% of all hospitalized patients have some form of infusion therapy

IV Push Medicine Guidelines

ISMP Safe Practice Guidelines for Adult IV Push Medications

A compilation of safe practices from the ISMP Adult IV Push Medication Safety Summit

Remember; CMS says you have to follow standards of care and specifically mentions the ISMP so surveyor can cite you if you do not follow this.

Prepared by the Institute for Safe Medication Practices (ISMP)
ISMP
 INSTITUTE FOR SAFE MEDICATION PRACTICES

IV Push Medications Guidelines

- Provide IV push medications in a ready to administer form
- Use only commercially available or pharmacy prepared prefilled syringes of IV solutions to flush and lock vascular access devices
- If available in a single dose vial then need to buy in single dose vial
- Aseptic technique should be used when preparing and administering IV medication
 - This includes hand hygiene before and after administration

IV Push Medications Guidelines

- The diaphragm on the vial should be disinfected even if newly opened
 - The top should be cleaned using friction and a sterile 70% isopropyl alcohol, ethyl alcohol, iodophor, or other approved antiseptic swab for at least ten seconds to it dr
- Medication from a glass vial should be with a filter needle unless the specific drug precludes this
- Medication should only be diluted when recommended by the manufacturer or in accordance with evidence based practice or approved hospital policies

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IV Push Medications Guidelines

- If IV push medication needs to be diluted or reconstituted these should be performed in a clean, uncluttered, and separate location
- Medication should not be withdrawn from a commercially available, cartridge type syringe into another syringe for administration
- It is also important that medication not be drawn up into the commercially prepared and prefilled 0.9% saline flushes
 - This are to flush an IV line and are not approved to use to dilute medication

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3.6 Do NOT dilute or reconstitute IV push medications by drawing up the contents into a commercially-available, prefilled flush syringe of 0.9% sodium chloride.

Discussion: Commercially available prefilled syringes of saline and heparin are regulated by the US Food and Drug Administration as devices, not as medications. These devices have been approved for the flushing of vascular access devices, but have NOT been approved for the reconstitution, dilution, and/or subsequent administration of IV push medications. Such use would be considered "off label" and not how manufacturers intended these products to be used, nor have prefilled flush syringes been tested for product safety when used in this manner.

Warnings intended to limit the use of prefilled syringes for medication preparation and administration appear on some syringe barrels, clearly stating "IV flush only." Some manufacturers have also limited or removed the gradation markings on the prefilled flush syringes in order to prevent measurement of a secondary medication in the flush syringe. When prefilled syringes are used in an off-label manner, the practitioner and employer bear the legal liability for any adverse events occurring from this practice.²¹

The mislabeling that occurs when medications are added to a prefilled syringe and a secondary label is not applied creates significant risk for errors. In many cases, the manufacturer's label is permanently affixed to the syringe barrel and contains product codes and a barcode as well as specific information about the fluid and its volume. When another medication is added to this syringe, there is no adequate method to amend the manufacturer's label, without covering the current information.²¹ Thus, the syringe frequently remains labeled as 0.9% sodium chloride, when it also contains the diluted or reconstituted medication.

Although this unsafe practice is widespread, and many who use it mistakenly believe the risk of an error is insignificant—a belief clearly reinforced during public comment regarding this guidance statement—summit participants arrived at a consensus that the practice must be eliminated.

²¹ When necessary to prepare mixtures, medication in a single vial may be IV push administration.

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IV Push Medications Guidelines

- Combination of more than one medication in a single syringe is seldom necessary and could result in unwanted changes in the medication
- Never use IV solution or mini bags as a common source to flush an IV as to dilute for more than one patient
- Label syringes of IVP medication unless prepared and immediately given with no break
- Administer IV push medication at rate recommended by manufacturer or supported by evidenced based practices and often given too fast

CMS Infection Control Worksheet

Section on Safe Injection Practices



CMS Hospital Worksheets History

- 3 final worksheets which addresses discharge planning, infection control, and QAPI (performance improvement)
 - Final ones issued November 26, 2014
 - Infection control has safe injection practices section and also antimicrobial stewardship program
 - CMS also issued separate memo on safe injection practices
 - Infection control worksheet is 49 pages

Final Infection Control Worksheet

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850


Center for Clinical Standards and Quality/Survey & Certification Group
REF: S&C: 15-12-Hospital

DATE: November 26, 2014
TO: State Survey Agency Directors www.cms.gov/SurveyCertificationGenInfo/PMSR/list.asp#TopOfPage
FROM: Director, Survey and Certification Group
SUBJECT: Public Release of Three Hospital Surveyor Worksheets

Memorandum Summary

- **Three Hospital Surveyor Worksheets Finalized:** The Centers for Medicare & Medicaid Services (CMS) has finalized surveyor worksheets for assessing compliance with three Medicare hospital Conditions of Participation (CoPs): Quality Assessment and Performance Improvement (QAPI), Infection Control, and Discharge Planning. The worksheets are used by State and Federal surveyors on all survey activity in hospitals when assessing compliance with any of these three CoPs.
- **Final Worksheets Made Public:** Via this memorandum we are making the worksheets publicly available. The hospital industry is encouraged, but not required, to use the worksheets as part of their self-assessment tools to promote quality and patient safety.

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CMS Hospital Worksheets

- Hospitals should be familiar with the IC worksheet which has a section on safe injection practices and preventing MDRO and antibiotic use
 - Will use whenever a validation survey or certification survey is done at a hospital by CMS
 - CMS says worksheets are used by State and federal surveyors on all survey activity in assessing compliance with any of the three CoPs
 - Hospitals are encouraged by CMS to use the worksheet as part of their self assessment tools which can help promote quality and patient safety

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Infection Control Program and Resources

Module 1: Infection Prevention Program

Section 1.A. Infection Prevention Program and Resources

Elements to be assessed		
1.A.1 The hospital has designated one or more individual(s) as its Infection Control Officer(s).	<input type="radio"/> Yes <input type="radio"/> No	
1.A.2 The hospital has evidence that demonstrates the Infection Control Officer(s) is qualified and maintains qualifications through education, training, experience or certification related to infection control consistent with hospital policy.	<input type="radio"/> Yes <input type="radio"/> No	
1.A.3 The Infection Control Officer(s) can provide evidence that the hospital has developed general infection control policies and procedures that are based on nationally recognized guidelines and applicable state and federal law.	<input type="radio"/> Yes <input type="radio"/> No	
If no to any of 1.A.1 through 1.A.3, the all 42 CFR 482.41(a) (1)(g) & 7(h)		
1.A.4 The Infection Control Officer can provide an updated list of diseases reportable to the local and/or state public health authorities.	<input type="radio"/> Yes <input type="radio"/> No	
1.A.5 The Infection Control Officer can provide evidence that hospital complies with the reportable diseases requirements of the local health authority.	<input type="radio"/> Yes <input type="radio"/> No	
No citation risk for questions 1.A.4 and 1.A.5		
1.A.6 The hospital has infection control policies and procedures relevant to construction, renovation, maintenance, demolition, and repair, including the requirement for an infection control plan.	<input type="radio"/> Yes <input type="radio"/> No	

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Section 1.C. Systems to Prevent Transmission of MDROs and Pr Stewardship		
Elements to be assessed	Survey Results	Survey Status
1.C.1 The hospital has policies and procedures to minimize the risk of development and transmission of multidrug-resistant organisms (MDROs) within the hospital (applicable to all persons in the hospital).	<input type="radio"/> Yes <input type="radio"/> No	
1.C.2 Systems are in place to designate patients known to be colonized or infected with a targeted MDRO and to notify receiving units and personnel prior to movement of such patients within the hospital.	<input type="radio"/> Yes <input type="radio"/> No	
1.C.3 Systems are in place to designate patients known to be colonized or infected with a targeted MDRO and to notify receiving healthcare facilities and personnel prior to transfer of such patient between facilities.	<input type="radio"/> Yes <input type="radio"/> No	
If no to any part of 1.C.1 through 1.C.3, cite at 42 CFR 482.42(a) (7)(g)-(i) (749)		
1.C.4 The hospital can provide a list of target MDROs. Note: Hospitals should provide a list of MDROs that are targeted for infection control because they are epidemiologically important (e.g., MRSA, VRE). Please refer to CDC's Guideline for Isolation Precautions for criteria that may be used to define epidemiology important organisms: http://www.cdc.gov/hicpac/pdf/isolation/isolation2007.pdf	<input type="radio"/> Yes <input type="radio"/> No	
1.C.5 The hospital can demonstrate the criteria used to determine epidemiologically important MDROs on their list.	<input type="radio"/> Yes <input type="radio"/> No	
1.C.6 The hospital can provide justification for any epidemiologically important organisms not on their list and otherwise not targeted in their hospital.	<input type="radio"/> Yes <input type="radio"/> No	

Section 2.B. Injection Practices and Sharps Safety (Medications and Infusates)		
Elements to be assessed	Survey Results	Survey Status
Injections are given and sharps safety is managed in a manner consistent with hospital infection control policies and procedures to minimize the prevalence of infectious communicable disease including the following: Note: If possible, questions in this section should be assessed through observation in two separate patient care areas or settings of the hospital.		
2.B.1 Injections are prepared using aseptic technique in an area that has been cleaned and is free of contamination (e.g., visible blood or body fluids).	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unable to observe	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unable to observe
2.B.2 Needles are used for only one patient.	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unable to observe	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unable to observe
2.B.3 Syringes are used for only one patient (this includes manufactured prefilled syringes).	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unable to observe	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unable to observe
2.B.4 Single ports are used for only one patient.	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unable to observe	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unable to observe
2.B.5 The rubber septum on all medication vials, whether unopened or previously accessed, is disinfected with alcohol.	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unable to observe	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unable to observe

Injection Practices & Sharps Safety

- This includes medications, saline, and other infusates
- Injections are given and sharps safety is managed in a manner consistent with IC P&P
- Injections are prepared using aseptic technique in an area that have been cleaned and free of visible blood, body fluids and contaminated equipment
- One needle, one syringe for every patient and includes insulin pens and prefilled syringes

Injection Practices & Sharps Safety

- Is rubber septum on the vial disinfected with alcohol before piercing?
- Medication vials must be entered with a new needle and new syringe
- Are single dose vials, IV bags, IV tubing and connectors used on only one patient?
- IV bags of saline can not be use as a flush in multiple patients
 - Single dose saline flushes should be used

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Injection Practices & Sharps Safety

- Are multidose vials dated when opened and discarded in 28 days unless shorter time by manufacturer?
 - Remember, once opened it is not the expiration date listed on the vial
- Make sure expiration date is clear as per P&P
- If multidose vial found in patient care area must be used on only one patient

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Injection Practices & Sharps Safety

- Are all sharps disposed of in resistant sharps container?
- Are sharp containers replaced when fill line is reached?
 - Are sharps disposed of in accordance with state medical waste rules
 - Hospitals should have a system in place where someone has the responsibility to check these and ensure they are replaced when they are full

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The CDC on Safe Injection Practices



CDC on Infection Control

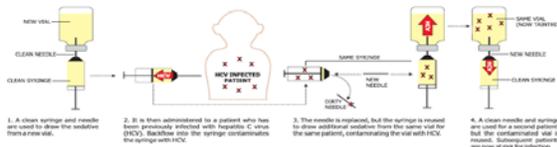
- The CDC says there are 1.7 million healthcare infection (HAI) in America every year
 - There are 75,000 deaths in American hospitals every year
 - Healthcare-Associated Infections (HAIs) are one of the top ten leading causes of death in the US1
- Leadership need to make sure there is adequate staffing and resources to prevent and manage infections
- Issue came to light in Nevada after GI doctor reuses syringes to save money in two ambulatory clinics
 - 1 www.cdc.gov/ncidod/dhqp/hai.html



How Did This Issue Get Started?

Unsafe Injection Practices and Disease Transmission

Reuse of syringes combined with the use of single dose vials for multiple patients undergoing anesthesia can transmit infectious diseases. The syringe does not have to be used on multiple patients for this to occur.



1. A clean syringe and needle are used to draw the medicine from a vial.

2. It is then administered to a patient who has been previously infected with hepatitis C virus (HCV). Backflow into the syringe contaminates the syringe with HCV.

3. The needle is removed, but the syringe is reused to draw additional medicine from the same vial for the same patient, contaminating the vial with HCV.

4. A clean needle and syringe are used for a second patient, but the contaminated vial is reused. Subsequent patients are now at risk for infection.

Source: www.southernnevadahealthdistrict.org



Infection Control

- There have been more than 35 outbreaks of viral hepatitis in the past 10 years because of unsafe injection practices
- This has resulted in the exposure of over 100,000 individuals to HBV and 500 patients to HCV
- This includes inappropriate care or maintenance of finger stick devices and glucometers
- Includes syringe reuse, contaminations of vials or IV bags and failure of safe injection practices
 - Source: APIC position paper: Safe injection, infusion, and medication vial practices in health care

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Infection Control Back to Basics

- It is important to get back to basics in infection control.
- Education and training is imperative to learn each person's role in preventing infections
- What practices and constant reminders do you use to remind staff during patient care encounters?
- New needle and syringe for every injection
 - Unless using needless syringe which is safer
- Single dose saline flush syringes

1 <http://www.jcritinc.com/infection-prevention-back-to-basics/>

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What is Injection Safety or Safe Injection Practices?

- The CDC says it is a set of measures taken to perform injections in an optimally safe manner for patients, healthcare personnel, and others
- A safe injection does not harm the recipient, does not expose the provider to any avoidable risks and does not result in waste that is dangerous for the community
- Injection safety includes practices intended to prevent transmission of infectious diseases between one patient and another, or between a patient and healthcare provider, and also to prevent harms such as needle stick injuries

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CDC 10 Safe Injection Recommendations

- Use aseptic technique to avoid contamination of sterile injection equipment.
- Do not administer medications from a syringe to multiple patients, even if the needle or cannula on the syringe is changed.
 - Needles, cannula and syringes are sterile, single-use items; they should not be reused for another patient nor to access a medication or solution that might be used for a subsequent patient.

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CDC 10 Safe Injection Recommendations

- Use fluid infusion and administration sets (i.e., intravenous bags, tubing and connectors) for one patient only and dispose appropriately after use
- Consider a syringe, needle, or cannula contaminated once it has been used to enter or connect to a patient's intravenous infusion bag or administration set

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CDC 10 Safe Injection Recommendations

- Use single-dose vials for parenteral medications whenever possible
- Do not administer medications from single-dose vials or ampules to multiple patients or combine leftover contents for later use
- If multidose vials must be used, both the needle or cannula and syringe used to access the multidose vial must be sterile

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CDC 10 Safe Injection Recommendations

- Do not keep multidose vials in the immediate patient treatment area and store in accordance with the manufacturer's recommendations;
 - Discard if sterility is compromised or questionable
- Do not use bags or bottles of intravenous solution as a common source of supply for multiple patients

CDC Safe Injection Recommendations

- Worker safety; Adhere to federal (OSHA) and state requirements for protection of healthcare personnel from exposure to blood borne pathogens
- Wear a mask when placing a catheter or injecting material into the spinal canal or subdural space
 - Example, during myelograms, lumbar puncture and spinal or epidural anesthesia.

Lumbar Puncture Procedures & Masks

- CDC investigated 8 cases of post-myelography meningitis
- Streptococcus species from oropharyngeal flora
- None of the physicians wore a mask
- Droplets of oral flora indicated
- Lead to CDC recommendations of 2007
- Later related to not wearing a mask when anesthesiologists put in epidural lines for pain relief in women in labor

CDC Guidelines Masks

- Recently, five cases where anesthesiologist inserts epidural line in OB patients without wearing a mask and patient develops bacterial meningitis
 - January 29, 2010 CDC MMWR at www.cdc.gov/mmwr/preview/mmwrhtml/mm5903a1.htm
 - CDC made recommendation in June 2007 after several reports of meningitis after myelograms
 - Bacterial meningitis in postpartum women and Ohio woman dies May 2009
 - Streptococcus salivarius meningitis (bacteria that is part of normal mouth flora)

Wear Mask When Inserting Epidural/Spinal

- Hospital in NY
 - Enhanced hand hygiene
 - Maintenance of sterile fields
 - Full gown, gloves, and mask
 - No visitors when epidural put in
- CDC has only identified 179 cases of post spinal (including lumbar punctures) world wide from 1952 to 2005

The screenshot shows the CDC website interface. At the top, it says 'CDC Home' and 'Centers for Disease Control and Prevention'. Below that is a search bar with 'All CDC Topics' and a 'SEARCH' button. A navigation menu lists letters A-Z. The main content area is titled 'Morbidity and Mortality Weekly Report (MMWR)'. The article title is 'Bacterial Meningitis After Intrapartum Spinal Anesthesia --- New York and Ohio, 2008--2009'. Below the title, it says 'Weekly' and 'January 29, 2010 / 59(03):65-69'. The text of the article begins: 'In June 2007, the Healthcare Infection Control Practices Advisory Committee (HICPAC) recommended for the first time that surgical masks be worn by spinal procedure operators to prevent infections associated with these procedures (1). HICPAC made the recommendation in response to several reports of meningitis following myelography procedures. In September 2008, three bacterial meningitis cases in postpartum women were reported to the New York State Department of Health (NYSDOH); in May 2009, two similar cases were reported to the Ohio Department of Health. All five women had received intrapartum spinal anesthesia. Four were confirmed to have Streptococcus salivarius meningitis, and one woman subsequently died. This report summarizes the investigations of these five cases, which determined that the New York cases were associated with one anesthesiologist and the Ohio cases were associated with a second anesthesiologist. In Ohio, the anesthesiologist did not wear a mask; wearing a mask might have prevented the infections. The findings underscore the need to follow established infection-control recommendations during spinal procedures, including the use of a mask and adherence to aseptic technique.'

Since facemasks have been shown to limit spread of droplets arising from the oral flora,¹ the CDC has recommended their use by healthcare providers when performing spinal injection procedures.²

In addition to wearing a facemask, healthcare providers should ensure adherence to all CDC recommended safe injection practices including using a single-dose vial of medication for only one patient.²

Recommendations:

Anyone performing a spinal injection procedure should review the following CDC recommendations to ensure that they are not placing their patients at risk for infections such as bacterial meningitis.

- Facemasks should always be used when injecting material or inserting a catheter into the epidural or subdural space.²
- Aseptic technique and other safe injection practices (e.g., using a single-dose vial of medication or contrast solution for only one patient) should always be followed for all spinal injection procedures.²

These recommendations apply not only in acute care settings such as hospitals, but in any setting where spinal injection procedures are performed, such as outpatient imaging facilities, ambulatory surgery centers, and pain management clinics.

Additional information is available at:
http://www.cdc.gov/hicpac/2007IP/2007ip_part3.html

References:

1. Centers for Disease Control and Prevention. Bacterial meningitis after intrapartum spinal anesthesia - New York and Ohio, 2008-2009. *MMWR Morb Mortal Wkly Rep*. 2010;59(3):65-9.
2. Centers for Disease Control and Prevention. 2007 Guideline for isolation precautions: preventing transmission of infectious agents in healthcare settings. Available at: <http://www.cdc.gov/hicpac/pdf/isolation/isolation2007.pdf>. Accessed January 25, 2011.
3. Phillips BJ, Fergusson S, Armstrong P, Anderson FM, Wildsmith JA. Surgical face masks are effective in reducing bacterial contamination caused by dispersal from the upper airway. *Br J Anaesth*. 1992;69(4):407-8.

CDC Guidelines

- CDC identified four outbreaks in
 - Pain clinic
 - Endoscopy clinic
 - Hematology/oncology clinic
 - Urology clinic
- Will discuss major findings later

CDC Guidelines

- Primary breaches
 - Reinsertion of used needles into multidose vials
 - Used 500cc bag of saline to irrigate IVs of multiple patients
 - Use of single needle or syringe to administer IV medications to multiple patients
 - Preparing medications in same work space where syringes are dismantled
 - Remember OSHA Bloodborne Pathogen standard (sharps containers at the bedside)

In Summary What to Do?

- Use only single dose vials and not multidose vials when available
- This includes the use of saline single dose flushes
- Single use of a disposal needle and syringe for each injection
- Prevent contamination of injection equipment and medication
- Label all medication and do one at a time unless prepared and immediately given

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What to Do? Single Dose Under USP 797

- CDC allows an exception to the single dose medication rule
 - Especially important for drugs in short supply
- Single dose medication vials may be repackaged into smaller doses if it is done by the pharmacist following the USP 797 standards for compounding
- This is because the pharmacist can do this under sterile conditions using a laminar hood following the ISO (International Organization Standards) Class 5 air quality conditions within an ISO Class 7 buffer area

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In Summary What to Do?

- TJC now allows to pre-label syringes in advance
- Wear masks when inserting epidural or spinals
- Discard used syringe intact in appropriate sharps container and don't carry to med room
- Make sure sharps container in each patient room and make sure not past the fill line
- Do not administer medications from single dose vials to multiple patients or combine left over contents for later use

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What to Do?

- If multiple-dose vials are used, restrict them to a centralized medication area or for single patient use
- Never re-enter a vial with a needle or syringe used on one patient if that vial will be used to withdraw medication for another patient
- Store vials in accordance with manufacturer's recommendations and discard if sterility is compromised
- Mark date on multi-dose vial and make expiration date is on there and usually 28 days from date opened or manufacturer recommendations

What to Do?

- Do not use bags or bottles of intravenous solution as a common source of supply for multiple patients
 - IV solutions are single patient use
- Follow the CDC 10 recommendations
- Maintaining clean, uncluttered, and functionally separate areas for product preparation to minimize the possibility of contamination
 - CMS Hospital CoP requirement, tag 501
 - TJC MM.05.01.07
 - Clean top with Bleach wipe after each use

What to Do?

- USP 797 requires administration of all medications to begin within one hour of preparation
 - An exception is made if medications are prepared in the pharmacy under ISO 5 clean room in which they are good for 48 hours
- Pre-spiking of IV fluid is limited to **one hour**
- Disinfect the rubber septum on multidose vials for 15 seconds and let dry with 70% alcohol, iodophor or an approved antiseptic agent
- Wash your hands before accessing supplies, handling vials and IV solutions and preparing meds

CDC Injections Safety for Providers

- The CDC also issues Injection Safety for Providers
- Notes several investigations leading to transmission of Hepatitis C to patients
- Thousands of patients notified to be test for HVB, HCV, and HIV
- Referral of providers to the licensing boards for disciplinary actions
- Malpractice suits filed by patients

CDC has Injection Safety FAQs for Providers

- CDC has another resources with frequently asked questions
- What is injection safety?
- Incorrect practices identified in IV medications for chemotherapy, cosmetic procedures, and alternative medicine therapies
- Available at <http://www.cdc.gov/ncidod/dhqp/injectionSafetyFAQs.html>

The screenshot shows a webpage with a navigation menu on the left, a main content area with a 'Background' section, and a right sidebar with contact information and a 'Get email updates' form. The main content area includes a table of contents for the FAQs and a paragraph of text under the 'Background' heading.

Information for Providers
FAQs regarding Safe Practices for Medical Injections

General
 Medication Preparation
 Medication Administration
 Single-dose/Single-use Vials
 Multi-dose Vials
 References

Information for Patients
 Preventing Unsafe Injection Practices
 Infection Prevention during Blood Glucose Monitoring and Insulin Administration
 Recent Publications
 Recent Meetings
 The One & Only Campaign

Related Links
 One & Only Campaign
 HICPAC

Frequently Asked Questions (FAQs) regarding Safe Practices for Medical Injections

Pages in this Set of Frequently Asked Questions

1. Background	5. Single-dose/Single-use vials
2. General	6. Multi-dose vials
3. Medication Preparation	7. References
4. Medication Administration	

Background
 Injection safety, or safe injection practices, is a set of measures taken to perform injections in an optimally safe manner for patients, healthcare personnel, and others.

The Standard Precautions section of the 2007 *Guideline for Isolation Precautions* (1)(1) provides evidence-based recommendations for safe injection practices and reflects the minimum standards that healthcare personnel should follow to prevent transmission of infections in healthcare settings.

Despite these recommendations, outbreaks and patient notifications resulting from healthcare personnel failing to adhere to Standard Precautions and basic infection control practices continue to be reported. [Unsafe injection practices](#) that have resulted in disease transmission have most commonly included:

- Using the same syringe to administer medication to more than one patient, even if the needle was changed or the injection was administered through an intervening length of intravenous (IV) tubing (1,2);
- Accessing a medication vial or bag with a syringe that has already been used to administer medication to a patient, then reusing contents from that vial or bag for another patient (3-6);
- Using medications packaged as single-dose or single-use for more than one patient (7-9).

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Contact Us:
 Centers for Disease Control and Prevention
 1600 Clifton Rd
 Atlanta, GA 30333
 800-CDC-INFO (800-232-4646)
 TTY: (888) 232-4343
Contact_CDC-INFO

www.cdc.gov/injectionsafety/providers/provider_faqs.html

CDC has Injection Safety FAQs for Providers

- Also puts patients at risk for bacterial and fungal infections beside HIV and Hepatitis
- Single dose vials do not contain a preservative to prevent bacterial growth so safe practices necessary to prevent bacterial and viral contamination
- Proper hand hygiene before handling medications
- Make sure contaminated things are not placed near medication preparation area

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CDC has Injection Safety FAQs for Providers

- Single use parenteral medication should be administered to one patient only
- Pre-filled medication syringes should never be used on more than one patient
- A needle or other device should never be left inserted into a medication vial septum for multiple uses
 - This provides a direct route for microorganisms to enter the vial and contaminate the fluid

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CDC has Injection Safety FAQs for Providers

- Multi-dose Vials
 - The safest thing to do is restrict each medication vial to a single patient, even if it's a multi-dose vial
 - Proper aseptic technique should always be followed
 - If multi-dose medication vials must be used for more than one patient, the vial should only be accessed with a new sterile syringe and needle
 - It is also preferred that these medications not be prepared in the immediate patient care area

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CDC has Injection Safety FAQs for Providers

- To help ensure that staff understand and adhere to safe injection practices, we recommend the following:
 - Designate someone to provide ongoing oversight for infection control issues
 - Develop written infection control policies
 - Provide training
 - Conduct performance improvement assessments

USP 797

- USP published a revision to the USP general Chapter of 797
- These standards apply to pharmacy compounded sterile preparation
- This includes injections, nasal inhalations, suspensions for wound irrigations, eye drops etc.
- Applies to the pharmacy setting as well as to all persons who prepare medications that are administered
- And it applies to all healthcare centers

USP 797

- This chapter includes standards for preparing, labeling, and discarding prepared medications
- Pharmacies compound sterile preparations under laminar flow hoods with stringent air quality and ventilation to maintain the sterility of the drug (ISO class 5 setting)
- If prepare outside the pharmacy then environment has particulates and microorganisms increasing the potential for contaminating the vial, IV solution or syringes
 - Need to wash hands before preparing medication outside the pharmacy

USP 797

- Want to prepare IVs and piggybacks in the pharmacy when at all possible
- Breathing over the sterile needle and vial stopper can create the potential for microbial contamination
- USP exempts preparation outside the pharmacy for immediate use
 - 1 hour limit from completing preparation and this includes spiking an IV bag
 - Cost of medication disposal can be daunting if case not started within one hour which is why should consider pharmacy preparing under ISO class 5 environment

USP 797

- This way the drugs used for surgery are prepared by properly trained, cleansed, and garbed personnel to prolong the usability of the immediate use compounded sterile drugs (CSD)
- These can be stored for 48 hours
- Another option is to located a manufacturers injectable product (prepackaged syringe) that is discarded according to manufacturer expiration date
- APIC supports preparing parenteral medication as close as possible to the time of administration

USP 797 APIC Recommendations

- Make sure only trained staff are preparing medications
- Need to prepared in a clean dry workspace that is free of clutter and obvious contamination sources like water, sinks
- Medications should be stored in a manner to limit the risk of tampering
- Should verify the competency of those preparing medications and monitor compliance with aseptic technique
- 28 day discard date on multidose vials even though CDC says manufacturers recommendations

TJC Safe Injection Practices

- TJC announces that during an on-site survey, the surveyors will observe injection practices
- Will ensure staff are following standard precautions for disease free injections
- Will make sure one needle and one syringe every time
- Required to follow standards of care such as the CDC standards
- Must follow the TJC infection control and prevention standard IC.01.05.01 EP1 and IC.02.01.01 EP2

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TJC Perspectives

CLARIFICATION: Safe Injection Practices Under IC Standards

During an on-site survey, Joint Commission surveyors observe injection practices to make sure that care providers follow standard precautions for disease-free injections—that is, injections that do not employ used needles/syringes or contaminated medications and are free from the bloodstream pathogens that such items can transmit. While the majority of care providers believe they follow disease-free injection practices, major outbreaks in the last several years have been caused by some syringe and needle-related findings.

All Joint Commission-accredited **ambulatory care, behavioral health care, critical access hospital, home care, hospital, laboratory, long-term care, and office-based surgery** organizations are required to follow relevant scientific guidelines for infection prevention per Infection Control and Prevention (IC) Standard IC.01.05.01, Element of Performance (EP) 1. Safe injection practices are also a key component of standard precautions required under IC.02.01.01, EP 2. The 2007 Guideline for Infection Prevention: Preventing Transmission of

Infectious Agents in Healthcare Settings” from the Centers for Disease Control and Prevention (CDC) directly addresses infection safety and safe injection practices and can be used as a resource for safe practice. The guideline is available online at http://www.cdc.gov/injectionsafety/IP07_standardPrevention.html.

The **Web site for the One & Only Campaign** from the CDC and the **Safe Injection Practice Coalition**—available at <http://www.oneandonlycampaign.org>—includes a video that highlights the CDC/HICPAC guideline. This public health campaign advocates the use of one needle, one syringe, only one time. The Web site provides information about optimal injection practices to educate health care workers and discuss myths that lead to unsafe injection practices.

Contact the Standards Interpretation Group with questions about IC.01.05.01, EP 1, or IC.02.01.01, EP 2, by using the online question form available at <http://www.jointcommission.org/Standards/OnlineQuestionForm>.

<http://www.jointcommission.org>

October 2015

The Joint Commission Perspectives

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APIC Recommendations

- APIC issues recommendations and key talking points for hospitals and healthcare facilities
- http://apic.informz.net/apic/archives/archive_272235.html
- The infection preventionist at our facility has designed a coordinated infection control program
- This is protect everyone coming in to our facility
- Our program implements evidenced based practices from leading authorities including the CDC

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APIC Recommendations

- Cleanse the access diaphragm of vials using friction and a sterile 70% isopropyl alcohol, ethyl alcohol, iodophor, or other approved antiseptic swab
 - Allow the diaphragm to dry before inserting any device into the vial
- Never store or transport vials in clothing or pockets.
- Discard single-dose vials after use
 - Never use them again for another patient
- Use multi-dose medication vials for a single patient whenever possible

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APIC Recommendations

- Never leave a needle, cannula, or spike device inserted into a medication vial rubber stopper because it leaves the vial vulnerable to contamination
 - Even if it has a 1-way valve
- Use a new syringe and a new needle for each entry into a vial or IV bag
- Utilize sharps safety devices whenever possible
- Dispose of used needles/syringes at the point of use in an approved sharps container
 - Except in surgery dispose of vials after the case

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APIC special article

APIC position paper: Safe injection, infusion, and medication vial practices in health care

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Outbreaks involving the transmission of bloodborne pathogens or other microbial pathogens to patients in various types of health care settings due to unsafe injection, infusion, and medication vial practices are unacceptable. Study of the outbreaks could have been prevented by the use of proper aseptic techniques in conjunction with basic infection prevention practices for handling parenteral medications, administration of injections, and prevention and handling of blood. This document provides practice guidance for health care facilities on essential safe injection, infusion, and vial practices that should be consistently implemented in such settings.

Key Words: bloodborne pathogens, injection, infusion, medication vial practices, aseptic technique, parenteral medications, administration of injections, prevention of blood.

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The transmission of bloodborne viruses and other microbial pathogens to patients during routine health care procedures continues to occur because of the use of unsafe and improper injection, infusion, and medication vial practices by health care professionals in various clinical settings throughout the United States.¹⁻¹¹ Breaches in safe injection, infusion, and medication vial practices continue to result in unacceptable and devastating events for patients. More than 35 outbreaks of viral hepatitis have occurred in the United States over the past 10 years because of these unsafe practices and other breaches of infection prevention procedures. These outbreaks have resulted in the exposure of >100,000 individuals to viral hepatitis and the transmission of either hepatitis B virus (HBV) or hepatitis C virus (HCV) to more than 500 patients.¹² The unsafe practices used by health care personnel in these outbreaks can be categorized as (1) syringe reuse between patients during parenteral medication administration to multiple patients, (2) contamination of medication vials or intravenous (IV) bags after having been accessed with a used syringe and/or needle, (3) failure to follow basic injection safety practices when preparing and administering parenteral medications to multiple patients, and (4) inappropriate care/maintenance of finger stick devices and glucometer equipment between use on multiple patients.

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Hematology Oncology Clinic

- Nurse drew blood from the IV catheter
- Then she reused the same syringe to flush the catheter with saline
- She did use a new syringe for each patient
- However, she used solution from same 500cc bag for multiple patients
- Oncologist and RN license revoked
- Never use an IV solution bag to flush the solution for more than patient

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Other Cases

- Patient in US gets malaria from saline flush
 - Emerging Infectious Diseases, Vol 11, No. 7, July 2005
- Oklahoma Pain Clinic where anesthesiologist filled syringe with sedation medication to treat up to 24 patients and injected via hep lock
 - 71 patients with HCV and 31 with HBV
 - 25 million dollar settlement
 - Source: Comstock et al. ICHE, 2004, 25:576-583

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Other Cases

- 19 patients get HCV in New York in 2001 from contamination of multi-dose anesthesia vials
 - CDC MMWR September 26, 2003, Vol 52, No 38
- NY City private physician office with 38 patients with HBV
 - Associated with injections of vitamins and steroids
 - Gave 2 or 3 in one syringe
 - Source: Samandari et al. ICHE 2005 26 (9);745-50

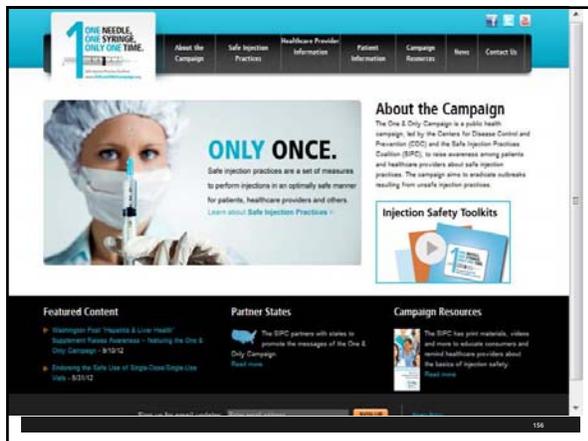
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Bacterial Outbreak Due to Unsafe Needle

- 7 patients get *serratia marcescens* from spinal injections in a pain clinic
 - Source: Cohen AI et al. Clin J Pain 2008; 24(5):374-380
- Several other studies where patients got infection from joint and soft tissue injections
 - Got staph aureus
 - In 2003 and 2009

One and Only Campaign

- Educational awareness to improve safe practices in healthcare
- One needle, one syringe, and only one time for each patient
- To empower patients and re-educate healthcare providers
- Has free posters
- Coalition partners include APIC, AANA, CDC, AAAHC, Nebraska Medical Association, Nevada State Department of Health etc.



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: Ambulatory Care Settings for Safe Care*.
 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.

Injection Safety	Practice Performed?		If answer is No, document plan for remediation
	Yes	No	
Injection site prepared using aseptic technique in a clean area free from contamination or contact with blood, body fluids or contaminated equipment.	Yes	No	
Needles and syringes are used for only one patient (this includes manufactured prefilled syringes and cartridge devices such as insulin pens).	Yes	No	
The rubber septum on a medication vial is disinfected with alcohol prior to piercing.	Yes	No	
Medication vials are entered with a new needle and a new syringe, even when obtaining additional doses for the same patient.	Yes	No	www.cdc.gov/HAI/pdfs/guidelines/ambulatory-care-checklist-07-2011.pdf
Single-dose (single-use) medication vials, ampules, and bags or bottles of intravenous solution are used for only one patient.	Yes	No	
Medication administration tubing and connectors are used for only one patient.	Yes	No	
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. <i>Note: This is different from the expiration date printed on the vial.</i>	Yes	No	
Multi-dose vials are dedicated to individual patients whenever possible.	Yes	No	
Multi-dose vials to be used for more than one			

**1 needle
1 syringe
+ 1 time
= 0 infections**

It's elementary!

Patients and health care providers must both insist on nothing less than **One Needle, One Syringe, Only One Time** for each and every injection.

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

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

Advancing ASC Quality

- ASC Quality Collaboration has ASC tool kit for infection prevention
- Includes one on hand hygiene and safe injection practices
- Includes a basic and expanded version of the toolkit
- These are available at http://www.ascquality.org/advancing_asc_quality.cfm

Sample Policy and Procedure

Injection Practices Policy and Procedure

Purpose

Safe injection practices help prevent the transmission of bloodborne infections from patient to patient.

Policy

All members of the healthcare team will comply with current Centers for Disease Control and Prevention (CDC) recommendations for safe injection practices.

Procedure

The following procedures apply to the use of needles, cannulae that replace needles, and intravenous delivery systems.

1. Needles, cannulae and syringes are sterile, single-use items. They should never be reused for another patient nor to access a medication or solution that might be used for a subsequent patient.
2. Use aseptic technique to avoid contamination of sterile injection equipment.
3. Do not administer medications from a syringe to multiple patients, even if the needle or cannula on the syringe is changed.

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4. Use fluid infusion and administration sets (i.e., intravenous bags, tubing and connectors) for one patient only and dispose appropriately after use. Once it has been used to enter or connect to a patient's intravenous infusion bag or administration set, consider a syringe or needle/cannula contaminated.

5. Use single-dose vials for parenteral medications whenever possible.

6. Do not administer medications from single-dose vials or ampules to multiple patients or combine leftover contents for later use.

7. If multidose vials must be used, both the needle or cannula and syringe used to access the multidose vial must be sterile.

8. Do not keep multidose vials in the immediate patient treatment area. Store multidose vials in accordance with the manufacturer's recommendations. Discard multidose vials if sterility is compromised or questionable.

9. Do not use bags or bottles of intravenous solution as a common source of supply for multiple patients.

Reference

To access the CDC's complete 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings, which includes recommendations on safe injection practices, see the CDC website at:

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Don't Forget the OSHA Standard

The screenshot shows the OSHA website interface. At the top, it says 'UNITED STATES DEPARTMENT OF LABOR' and 'OSHA'. Below that is a navigation menu with 'Occupational Safety & Health Administration' and 'We Can Help'. The main content area features a large banner for 'BLOODBORNE PATHOGENS and zoonotic zoonoses' with a red and black background. Below the banner are sections for 'General Guidance', 'Enforcement', 'Hazard Recognition', 'Evaluation & Controls', 'Other Resources', and 'Standards'. A 'CAUTION!' box is visible on the right side of the page.

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AANA Position Statement Safe Practices

www.aana.com/resources2/professionalpractice/Documents/PPM%20PS%202.13%20Safe%20Needle%20Syringe%20Use.pdf



American Association of Nurse Anesthetists
272 South Pingree Avenue
Park Ridge, IL 60068
www.aana.com

Safe Practices for Needle and Syringe Use
Formerly Position Statement Number 2.13

Standard IX of the American Association of Nurse Anesthetists (AANA) *Scope and Standards for Nurse Anesthesia Practice* states that Certified Registered Nurse Anesthetists (CRNAs) shall take precautions "to minimize the risk of infection to the patient, the CRNA, and other healthcare providers." Further, the AANA *Code of Ethics for the Certified Registered Nurse Anesthetist* states that every member of the AANA "has a personal responsibility to uphold and adhere" to the ethical standards contained within the Code of Ethics document. Specifically, item number 3.2 of the AANA Code of Ethics for the Certified Registered Nurse Anesthetist states that the "CRNA practices in accordance with the professional practice standards established by the profession." The AANA historically has taken a strong stance concerning infection control behaviors, and the AANA's *Infection Control Guide for Certified Registered Nurse Anesthetists* has served as a valuable resource to CRNAs on this issue for many years.

Despite attempts to educate healthcare providers regarding the public hazards of syringe and needle reuse and other unsafe injection practices, transmission of blood-borne pathogens continues to occur in the United States.¹ According to one recent report, there have been 13 different outbreaks involving transmission of the Hepatitis B or C viruses which placed over 60,000 patients at risk for contracting blood-borne infections within the past 10 years.

Preventing the transmission of infectious agents involves many considerations and best practices on the part of the anesthesia professional in order to be successful. This position statement is intended to address aspects of anesthesia care which involve the use of needles and syringes when administering intravenous medications.

The following statements reflect current safe practices for needle and syringe use by CRNAs:

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Thanks for attending! Questions??



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