

Safe Injection Practices



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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 your 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

Have You Reviewed the New Pharmacy IGs?

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: 16-01-Hospital

DATE: October 30, 2015

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Revised Hospital Guidance for Pharmaceutical Services and Expanded Guidance
Related to Compounding of Medications

Memorandum Summary

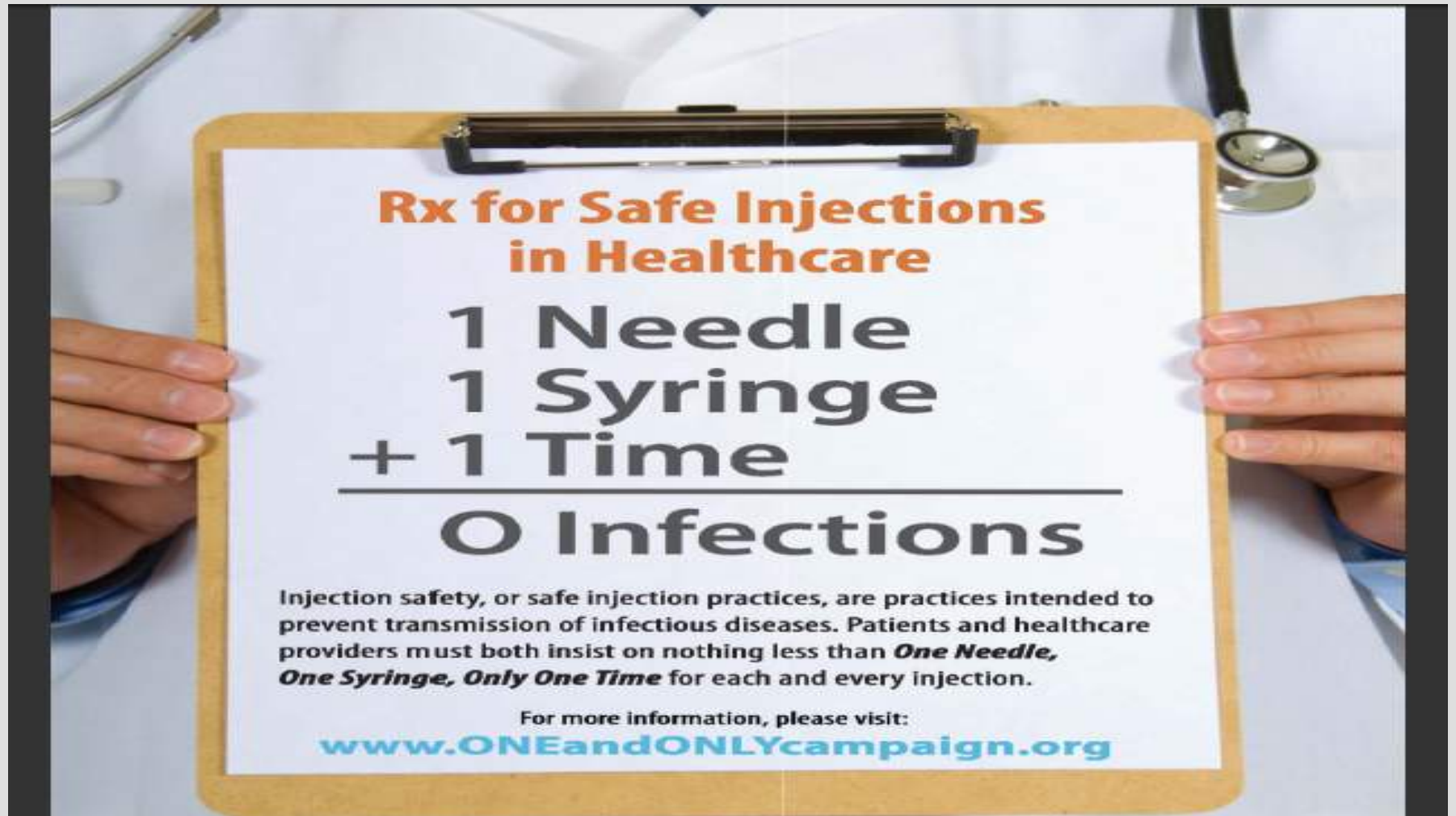
Hospital Appendix A Updated: The Centers for Medicare & Medicaid Services (CMS) has updated the State Operations Manual (SOM) Appendix A with respect to both the hospital survey process and the interpretive guidelines for the pharmaceutical services Condition of Participation (CoP). The update includes the following features:

- ***Pharmaceutical Services:*** Revisions were made to portions of the pharmaceutical services CoP to bring them into alignment with current accepted standards of practice. To improve clarity, the revised guidance addresses: accepted professional pharmacy principles, including United States Pharmacopeia (USP) standards; compounding of medications, particularly compounded sterile preparations (CSPs); determining beyond-use dates (BUDs); safe and appropriate storage and use of medications; and,

CMS Revised Pharmacy Guidelines

- Addresses compounding sterile preparations (CSP)
- Determining beyond use date (BUD)
- Safe and appropriate storage and use of medication
- Safe injection practices
- Preparing CSP outside the pharmacy
- Must follow acceptable standards of practice
- Final November 20, 2015 and CMS has revised the manual to include these ten revised tag numbers

Safe Injection Practices Posters



Headlines We Do Not Want to See



Headlines We Don't Want to See

8 hepatitis cases linked to clinic

Brooklyn Bug

Clinic linked to 8 cases of hepatitis C; 2,200 at risk

DISEASE A
Hepatitis C is a blood-borne virus. The Centers for Disease Control say 4 million people are infected.



Hepatitis C outbreak among clinic patients

Patients of Brooklyn Clinic Are Sought

After Outbreak of Hepatitis C

A patient says a clinic is so clean that even the magazines are new.

Some other way in which contamination introduced the blood of other people. There have been years of sterilization.

By DIANE CARDWELL

Health officials are trying to contact 2,000 patients who underwent endoscopies at a Brooklyn medical center last year. Eight patients tested positive for hepatitis C, such as an outbreak that occurred in the United States.

MEDICAL MYSTERY

Hepatitis C outbreak

Strikes 8 endoscopy patients of B'klyn clinic

Headlines We Don't Want to See

THE NEW ORLEANS
ADVOCATE



HOME NEWS EATPLAYLIVE SPORTS OPINION BEAUCOUP ENTERTAINMENT ST. TAMMANY CRESCENT CITY BATON ROUGE

5 deaths linked to infections tied to hospital linens



50¢

WEDNESDAY, DEC. 12, 2007 | LONG ISLAND EDITION

NEWSDAY.COM

State Stalls Trump Beach Project **A3**



THE SYRINGE MESS

8,500 More At Risk

Every patient doc treated for 5 years
should be tested, health officials say **A5**



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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

CDC Home



Centers for Disease Control and Prevention
CDC 24/7: Saving Lives. Protecting People.™

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Morbidity and Mortality Weekly Report (MMWR)

[MMWR](#)

www.cdc.gov/mmwr/preview/mmwr.html/mm6127a1.htm?s_cid=mm6127a1_w



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Invasive *Staphylococcus aureus* Infections Associated with Pain Injections and Reuse of Single-Dose Vials — Arizona and Delaware, 2012

Weekly

July 13, 2012 / 61(27);501-504

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 multipatient use.

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 technician 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 18th, 2018 By LucyC



Kristen Parker; Photo: Denver County Sheriff's Office

which leads to chronic liver inflammation, and in some cases liver cancer. Parker, who shared needles when injecting heroine, is hepatitis C positive—something she claims she didn't know when she was fixing 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,

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.

Ah, but it gets worse. Parker ended up infecting some 36 people with hepatitis C, a currently incurable viral infection

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Legal Help Now!



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Pleads Guilty





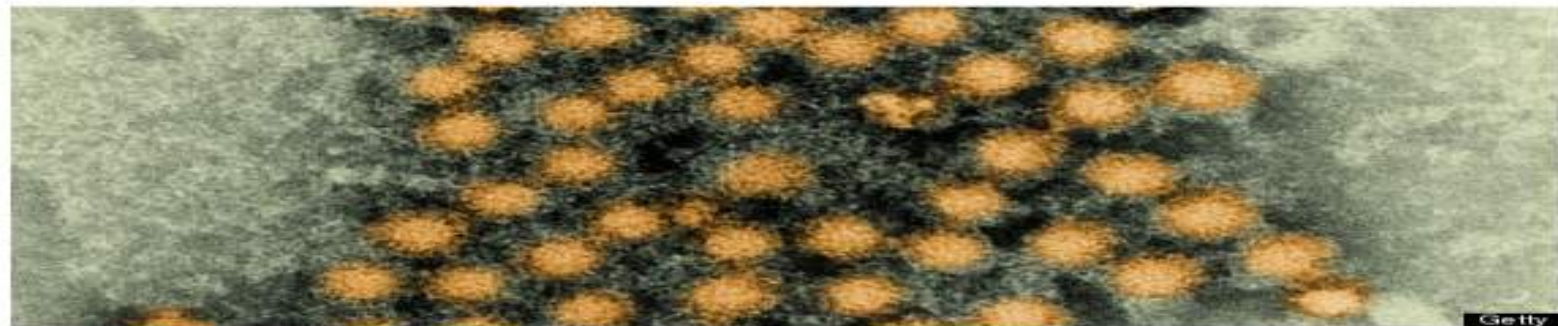
- 34 yo pleads guilty
- He pleads guilty to 16 federal drug charges
- He worked as cardiac tech and former lab tech in 18 hospitals in 7 states
- 46 patient confirmed with his strain of Hepatitis C
- 32 in New Hampshire, 7 in Maryland, 6 in Kansas, and 1 in Pennsylvania
- Stole fentanyl and replaced 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 RAMER 08/18/13 11:43 AM ET EDT **AP**

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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 painkiller syringes from hospitals where he worked and replacing them with saline-filled syringes tainted with his blood.

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

Swedish Hospital in Denver 2016

- Class action lawsuit filed against hospital stating it put thousands of patients at risk by hiring a surgical tech
 - Put patients at risk for HIV and Hepatitis B and C
- He was fired in January after being caught stealing Fentanyl off the OR cart
- When he was hired he had been fired from four other hospitals and court martialed in 2011 for the theft of fentanyl from the OR
- 2,900 patients have been offered free testing

Denver Hospital 2016



Jefferson County coroner IDs woman killed in crash with stolen pickup



Ryan Clady wants to return to Broncos



Class action suit filed in drug theft case at Swedish hospital that put thousands at risk for hepatitis, HIV

Rocky Allen's drug theft case at Swedish Medical Center triggers lawsuit

By Christopher N. Osher
The Denver Post

POSTED: 03/08/2016 05:05:12 PM MST | UPDATED: ABOUT 18 HOURS AGO

10 COMMENTS

A class-action federal lawsuit filed Tuesday alleges Swedish Medical Center negligently put thousands of patients in danger by hiring a surgical technologist who the hospital now says may have exposed them to HIV, hepatitis B or hepatitis C.

In January, the Englewood hospital fired Rocky Allen, who has since been indicted on two federal counts alleging he was caught stealing a syringe filled with fentanyl from an operating room. Allen has pleaded not guilty.

Court records show that by the time Swedish hired him, Allen had been fired from four other hospitals and also had been court-martialed in 2011, when he was serving with the Navy in Afghanistan, for the theft of fentanyl. Court testimony revealed that he is carrying an undisclosed bloodborne pathogen.

"By the time Allen appeared on the doorstep of SMC in August



A class action federal lawsuit alleges Swedish Medical Center negligently put thousands of patients in danger by hiring Rocky Allen who may have exposed them to HIV, hepatitis B or hepatitis C. (Photo provided by Denver7)

Mar 6:


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

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Drugs www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.htm

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Guidance, Compliance & Regulatory Information

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[Compounding: Inspections, Recalls, and other Actions](#)

[Outsourcing Facilities](#)

Resources for You

- FDA Communication with States
- Registered Outsourcing Facilities
- Text of Compounding Quality Act
- Text of Section 503A of the FDCA

Compounding

Compounding Quality Act

Title I of the Drug Quality and Security Act of 2013

On November 27, 2013, President Obama signed the Drug Quality and Security Act (DQSA), legislation that contains important provisions relating to the oversight of [compounding of human drugs](#).

Title I of this new law, the Compounding Quality Act, removes certain provisions from section 503A of the Federal Food, Drug, and Cosmetic Act (FDCA) that were found to be unconstitutional by the U.S. Supreme Court in 2002. Section 503A describes the conditions under which certain compounded human drug products are entitled to exemptions from three sections of the FDCA requiring:

- Compliance with current good manufacturing practices (CGMP) (section 501(a)(2)(B));
- Labeling with adequate directions for use (section 502(f)(1)); and

Spotlight

- FDA announces meeting of Pharmacy Compounding Advisory Committee
- Inter-governmental Working Meeting on Pharmacy Compounding, March 20-21, 2014
- Registered Outsourcing Facilities
- Compounding and FDA: Questions and Answers
- FDA Video - FDA and Pharmacy Compounding

Specific Issues

- Hydroxyprogesterone Caproate (17P)

Use a Company that is Registered



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Letters to Stakeholders

On January 8, 2014, FDA sent letters from Commissioner Hamburg regarding the pharmacy compounding provisions of the Compounding Quality Act to hospital and other health care facility purchasers and to state officials, including governors, state boards of pharmacy and health departments. The purpose of the letters is to inform these important stakeholders of the recent passage of new federal legislation affecting the oversight of compounded human drugs, and to encourage them to take steps to encourage compounders that produce sterile drugs to register with FDA as outsourcing facilities.

- [Dear Colleague \(PDF - 1.32MB\)](#)
- [Dear Hospital / Purchaser \(PDF - 1.06MB\)](#)

As required by the new law, FDA has posted a list of facilities that have registered as "[outsourcing facilities](#)" under the new law. In addition to posting the list, FDA has provided information about the status of the facilities and what it does and does not mean to be a registered outsourcing facility.



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

OIG Report on Oversight of Hospital Pharmacies

**OFFICE OF
INSPECTOR GENERAL**

<http://oig.hhs.gov/oei/reports/oei-01-13-00400.pdf>

MEDICARE'S OVERSIGHT OF COMPOUNDED PHARMACEUTICALS USED IN HOSPITALS



Daniel R. Levinson
Inspector General

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 personnel 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
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

Ref: S&C: 12-35-ALL

[www.cms.gov/Medicare/Provider-Enrollment-and-](http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/index.html?redirect=/SurveyCertificationGenInfo/PMSR/list.asp)

[Certification/SurveyCertificationGenInfo/index.html?redirect=/SurveyCertificationGenInfo/PMSR/list.asp](http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/index.html?redirect=/SurveyCertificationGenInfo/PMSR/list.asp)

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. 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 within 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 it 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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Advancing Practice

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Bar Code Guide

My Medicine List™

Outsourcing Sterile Products Preparation: Contractor Assessment Tool

Pharmacy Practice Model Initiative

Outsourcing Sterile Products Preparation: Contractor Assessment Tool

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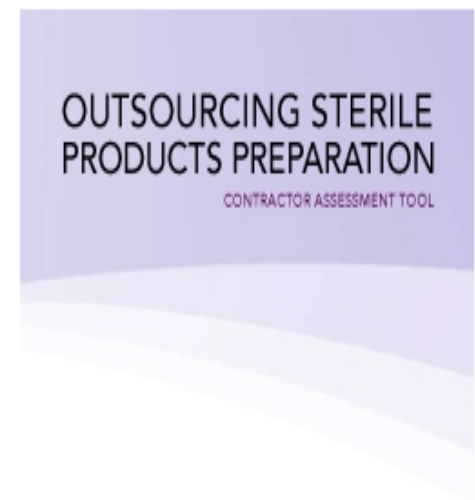
Preparation of sterile parenteral products is a critical component of health-system pharmacy practice. For departments that choose to outsource the preparation of parenteral medications, this web-based tool can be used to evaluate proposals during the selection of an external organization that would provide parenteral product preparation services.

The assessment tool helps you evaluate each of these areas:

- Regulatory compliance
- Quality and patient safety measures
- Medication administration safety features
- Service excellence

Start using the Sterile Products Outsourcing Tool now!

www.ashpfoundation.org/MainMenuCategories/PracticeTools/SterileProductsTool.aspx



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.



**1 ONE NEEDLE,
ONE SYRINGE,
ONLY ONE TIME.**



Safe Injection Practices Coalition
www.ONEandONLYcampaign.org

ONEANDONLYCAMPAIGN.ORG

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

*Aseptic technique is used by health care workers to prevent the contamination of clean areas, equipment, and sterile medications. This will help prevent the spread of infection. Please refer to [CDC's Basic Infection Control and Prevention Plan for Outpatient Oncology Settings](#) for more information.

LEARN MORE ABOUT WAYS YOU CAN KEEP YOUR PATIENTS

1 ONE NEEDLE,
ONE SYRINGE,
ONLY ONE TIME.



The Safe Injection Practices Coalition Releases Two New Videos



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 conversation, and receive updates:

[Facebook](#)

[One & Only Campaign](#)

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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: S&C: 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>

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

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

Insulin Pens Memo

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

Ref: S&C: 12-30-ALL

DATE: May 18, 2012

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Use of Insulin Pens in Health Care Facilities

Memorandum Summary

Insulin Pen devices: The Centers for Medicare & Medicaid Services (CMS) has recently received reports of use of insulin pens for more than one patient, with at least one 2011 episode resulting in the need for post-exposure patient notification. These reports indicate that some healthcare personnel do not adhere to safe practices and may be unaware of the risks these unsafe practices pose to patients. **Insulin pens are meant for use by a single patient only.** Each patient/resident must have his/her own. Sharing of insulin pens is essentially the same as sharing needles or syringes, and must be cited, consistent with the applicable provider/supplier specific survey guidance, in the same manner as re-use of needles or syringes.

Background

Insulin pens are pen-shaped injector devices that contain a reservoir for insulin or an insulin cartridge. These devices are designed to permit self-injection and are intended for single-person use. In healthcare settings, these devices are often used by healthcare personnel to administer insulin to patients. Insulin pens are designed to be used multiple times by a single patient/resident, using a new needle for each injection. Insulin pens must never be used for more than one patient/resident. Regurgitation of blood into the insulin cartridge after injection will create a risk of bloodborne pathogen transmission if the pen is used for more than one patient/resident, even when the needle is changed [1]. A previous memo (10-28-NH) dated

CMS Memo on Insulin Pens

- Regurgitation of blood into the insulin cartridge after injection can occur creating a risk if used on more than one patient
- Hospital needs to have a policy and procedure
- Staff should be educated regarding the safe use of insulin pens
 - More than 2,000 patients were notified in 2011 because an insulin pen was used on more than one patient
- CDC issues reminder on same and has free flier
- One and Only Campaign has brochure and poster

CDC Reminder on Insulin Pens

Injection Safety

www.cdc.gov/injectionsafety/clinical-reminders/insulin-pens.html

Injection Safety

CDC's Role

CDC Statement

Information for Providers

Information for Patients

Preventing Unsafe Injection Practices

Infection Prevention during Blood Glucose Monitoring and Insulin Administration

FAQs regarding Assisted Blood Glucose Monitoring and Insulin Administration

CDC Clinical Reminder: Fingerstick Devices

► **Clinical Reminder: Insulin Pens**

Recent Publications


Recent Meetings


The One & Only Campaign


[Injection Safety](#)

> [Infection Prevention during Blood Glucose Monitoring and Insulin Administration](#)


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CDC Clinical Reminder: Insulin Pens Must Never Be Used for More than One Person

Available for download [Clinical Reminder: Insulin Pens](#)  [PDF - 182 KB]

Summary

The Centers for Disease Control and Prevention (CDC) has become increasingly aware of reports of improper use of insulin pens, which places individuals at risk of infection with pathogens including hepatitis viruses and human immunodeficiency virus (HIV). This notice serves as a reminder that insulin pens must **never** be used on more than one person.



Background

Insulin pens are pen-shaped injector devices that contain a reservoir for insulin or an insulin cartridge. These devices are designed to permit self-injection and are intended for single-person use. In healthcare settings, these devices are often used by healthcare personnel to administer insulin to patients. Insulin pens are designed to be used multiple times, for a single person, using a new needle for each injection. Insulin pens must **never** be used for more than one person.

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- [Summary](#)
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Contact Us:

 Centers for Disease Control and Prevention
1600 Clifton Rd
Atlanta, GA 30333
 800-CDC-INFO
(800-232-4636)
TTY: (888) 232-6348
[Contact CDC-INFO](#)

Related Links

[One & Only Campaign](#)

CDC Has Flier for Hospitals on Insulin Pens

CDC CLINICAL REMINDER

Insulin Pens Must Never Be Used for More than One Person

Summary

The Centers for Disease Control and Prevention (CDC) has become increasingly aware of reports of improper use of insulin pens, which places individuals at risk of infection with pathogens including hepatitis viruses and human immunodeficiency virus (HIV). This notice serves as a reminder that insulin pens must **never** be used on more than one person.

Background

Insulin pens are pen-shaped injector devices that contain a reservoir for insulin or an insulin cartridge. These devices are designed to permit self-injection and are intended for single-person use. In healthcare settings, these devices are often used by healthcare personnel to administer insulin to patients. Insulin pens are designed to be used multiple times, for a single person, using a new needle for each injection. Insulin pens must **never** be used for more than one person. Regurgitation of blood into the insulin cartridge can occur after injection [1] creating a risk of bloodborne pathogen transmission if the pen is used for more than one person, even when the needle is changed.

In 2009, in response to reports of improper use of insulin pens in hospitals, the Food and Drug Administration (FDA) issued an alert for healthcare professionals reminding them that insulin pens are meant for use on a single patient only and are not to be shared between patients [2]. In spite of this alert, there have been continuing reports of patients placed at risk through inappropriate reuse and sharing of insulin pens, including an incident in 2011 that required notification of more than 2,000 potentially exposed patients [3]. These events indicate that some healthcare personnel do not adhere to safe practices and may be unaware of the risks these unsafe practices pose to patients.

Recommendations



Insulin Pen Posters and Brochures Available



About the
Campaign

Safe Injection
Practices

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Insulin Pen Safety – One Insulin Pen, One Person

BE AWARE
DON'T SHARE



**ONE INSULIN PEN,
ONLY ONE PERSON**

[www.oneandonlycampaign.org
/content/insulin-pen-safety](http://www.oneandonlycampaign.org/content/insulin-pen-safety)

The Safe Injection Practices Coalition created an insulin pen poster and brochure for healthcare providers as a reminder that insulin pens and other injectable medications are meant for one person and should never be shared. PDFs of these educational materials are linked below:

Specific Materials for Safe Use of Insulin Pens – for Clinicians and Patients

- [Poster](#)
- [Brochure](#)

Click [here](#) to order free copies of these materials from the Centers for Disease Control and Prevention (CDC) (publication numbers 22-1501 and 22-1503).

Additional Resources

- [VA Patient Safety Alert: Multi-Dose Pen Injectors](#) (Department of Veterans Affairs, January 2013)

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

Brochure

DON'T DO IT

Sharing Insulin Pens and Other Injection Equipment Jeopardizes Patients

In 2009, in response to reports of improper use of insulin pens in hospitals, the Food and Drug Administration issued an alert for healthcare professionals reminding them that insulin pens are meant for use on a single person only and are not to be shared. Unfortunately, there have been continuing reports of persons placed at risk of bloodborne and bacterial pathogen transmission through sharing of insulin pens.

A SIMPLE RULE

Injection equipment (e.g., insulin pens, needles and syringes) should **never** be used for more than one person.



About the Safe Injection Practices Coalition

The Safe Injection Practices Coalition (SIPC) is a partnership of healthcare-related organizations led by the Centers for Disease Control and Prevention that was formed to promote safe injection practices in all U.S. healthcare settings. The SIPC has developed the One & Only Campaign – a public health education and awareness campaign – aimed at both healthcare providers and patients to advance and promote safe injection practices.

For more information,
please visit:

www.ONEandONLYcampaign.org

BE AWARE DON'T SHARE



ONE INSULIN PEN, ONLY ONE PERSON



What Every
Healthcare Professional
Needs To Know

Luer Misconnections Memo

- CMS issues memo on luer misconnections
- This has been a patient safety issues for many years
- Staff can connect two things together that do not belong together because the ends match
 - For example, a patient had the blood pressure cuff connected to the IV and died of an air embolism
- Luer connections easily link many medical components, accessories and delivery devices
- ISMP, TJC, and PaPSA found high number of misconnections

Luer Misconnections Memo

DEPARTMENT OF HEALTH & HUMAN SERVICES
Center for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1880



Center for Clinical Standards and Quality /Survey & Certification Group

Ref: S&C: 13-14-ALL

DATE: March 8, 2013
TO: State Survey Agency Directors
FROM: Director
Survey and Certification Group
SUBJECT: Luer Misconnection Adverse Events

Memorandum Summary

- **Luer Misconnections continue to result in adverse events and deaths** – Luer connectors easily link many medical components, accessories, and delivery systems. Clinicians, in any type of provider or supplier setting, can mistakenly connect the wrong devices and deliver substances through the wrong route. Despite numerous alerts and warnings, a patient's blood pressure tubing was recently misconnected to an intravenous (IV) line in an ambulatory surgery center (ASC) resulting in a patient death.
- **Adverse Event Complaint Investigation:** During a complaint investigation for an adverse event involving delivery of an incorrect substance or utilization of an incorrect delivery route, surveyors must be alert to whether the event involved misconnection of a Luer device. If so, surveyors must determine whether the facility has taken actions to ensure systems are in place to prevent recurrence of this type of adverse event.
- **Facility Reporting to Food & Drug Administration (FDA):** Surveyors should encourage health care facilities to report problems with Luer misconnections to the FDA, even if no adverse event occurred.

PA Patient Safety Authority Article

Table. Tubing Misconnections Reported to the Pennsylvania Patient Safety Authority, January 2008 to September 2009

MISCONNECTION	NUMBER OF REPORTS
Secondary intravenous (IV) infusion connected to lower "Y" port of primary IV tubing set	8
Hemodialysis arterial and venous tubing lines reversed	5
G-tube and J-tube lines reversed	3
Incorrect tubing connection (no further explanation provided in reports)	3
Epidural and patient-controlled analgesia (PCA) tubing sets reversed	2
Nonhemodialysis arterial and venous tubing lines reversed	2
Cell saver tubing connected to cell saver reservoir	1
Feeding tube set connected to Braviac®	1
Feeding tube set connected to peripherally inserted central catheter (PICC) line	1
Feeding tube set connected to suction port	1
Imaging contrast tubing set connected to tracheostomy cuff	1
IV tubing set connected to dialysis catheter	1
IV tubing set connected to PICC line	1
IV tubing set connected to tracheostomy cuff	1
Knee irrigation connected to peripheral IV tubing	1
Miscommunication (arterial line noted in medical record as peripheral IV)	1
Oral medication delivered through peripheral IV line	1
Suction line connected to water seal	1
Suction and feeding tubing sets reversed	1
Total	36

ISMP Tubing Misconnections

www.ismp.org

ISMP Medication Safety Alert!® Acute Care

PREVENTING CATHETER/TUBING MISCONNECTIONS: MUCH NEEDED HELP IS ON THE WAY

From the July 15, 2010 issue

Catheter/tubing misconnections remain a serious problem in healthcare. Just a few weeks ago we learned of another fatal event. Over Memorial Day weekend, a 19-month-old child, who was receiving treatment for a chronic gastrointestinal disorder, died at a pediatric care center. A suspension of **QUESTRAN** (cholestyramine) was accidentally given via a central line intravenous catheter instead of through an enteral feeding tube.

In May 2010, another report was published about barium sulfate being administered via the superior vena cava during upper gastrointestinal study (Soghoian S, Hoffman RS, Nelson L. Unintentional IV injection of barium sulfate in a child. *AJ Health-Syst Pharm.* 2010;67:734-36). The patient, a 17-month-old child, had a central venous catheter (CVC) in place for antibiotic therapy. As the procedure began, approximately 3 mL of barium sulfate was injected into the CVC, which was mistaken as the child's gastrostomy tube. Fortunately, no respiratory distress developed and the child was discharged 3 days later.


Luer connector systems, common to many healthcare catheters, tubes, administration sets, extension sets, and syringes have been at the heart of many catheter/tubing misconnections. At the center of one of the most commonly reported problems is the fact that some manufactured enteral catheters still have ports that only accept parenteral administration sets and syringes. So, even if a liquid medication is prepared in an oral syringe, the medication must be transferred to a parenteral syringe for administration via this type of enteral catheter port, risking the accidental administration of the drug via a parenteral line.

Below are examples of the type of reports we have received associated with catheter/tubing misconnections, all of which we've described in this newsletter since publication began in 1996:

- IV infusions connected to epidural lines, and epidural solutions connected to IV lines
- Syringe containing IV medication given via an intrathecal catheter
- IV tubing connected to inflation balloon port of endotracheal tube or tracheostomy tube
- Sequential compression device tubing or pneumatic blood pressure cuff tubing attached to port of IV administration set
- Oxygen tubing connected to port of IV administration set
- Breast milk intravenously infused into neonates
- Bladder irrigation solutions given IV, or TPN solutions administered via foley catheter port
- IV administration set spiked into enteral nutrition container, resulting in enteral nutrition administered IV.

TJC Sentinel Event Alert #36

www.jointcommission.org

**The Joint Commission**

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Monday 3:14 CDT - April 21


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Topic Library Item

Sentinel Event Alert, Issue 36: Tubing misconnections—a persistent and potentially deadly occurrence
April 3, 2018

[Download This File](#)

Tubing and catheter misconnection errors are an important and under-reported problem in health care organizations. In addition, these errors are often caught and corrected before any injury to the patient occurs. Given the reality of and potential for life threatening consequences, increased awareness and analysis of these errors—including averted errors—can lead to dramatic improvement in patient safety.



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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 Event Alert

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

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

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

Managing risk during transition to new ISO tubing connector standards

Tubing misconnections continue to cause severe patient injury and death, since tubes with different functions can easily be connected using luer connectors, or connections 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^{1,2,3,4,5} – 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 connectors and do everything possible during the transitional period to avoid

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

Safe Injection Practices Memo



EMERGENCY
MEDICINE
PATIENT SAFETY
FOUNDATION

www.empsf.org

Safe Injection Practices Patient Safety Brief Emergency Medicine Patient Safety Foundation

By: Sue Dill Calloway RN MSN JD CPHRM
Ruth Carrico PhD RN FSHEA CIC

July 2012



The Centers for Disease Control and Prevention (CDC) says there are 1.7 million healthcare-associated infections in the US every year. Of these, it is estimated that about 99,000 deaths occur as a result. Infection prevention and control is an important issue in today's healthcare environment. It is important to accreditation organizations like the Joint Commission (TJC). The Joint Commission has eight pages of standards in the chapter on Infection Prevention and Control (IC).

Infection prevention and control is also important to the Centers for

Fingerstick Devices & Glucose Meters

- Glucose meters must be cleaned and disinfected between each patient use
- Do hand hygiene and wear gloves during fingerstick blood glucose monitoring and other procedures involving potential exposure to blood or body fluids
- Fingerstick devices (including the lancing device or the lancet itself) should never be used on more than one person
- Items contaminated with blood may not be immediately visible

Fingerstick Devices

Information for Patients

Preventing Unsafe Injection Practices

Infection Prevention during Blood Glucose Monitoring and Insulin Administration

FAQs regarding Assisted Blood Glucose Monitoring and Insulin Administration

► CDC Clinical Reminder: Fingerstick Devices

Clinical Reminder: Insulin Pens

Recent Publications

Recent Meetings

The One & Only Campaign

Related Links

[One & Only Campaign](#)

[HICPAC](#)

[2007 Guideline for Isolation Precautions](#)

[HHS Action Plan to Prevent HAIs](#)

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

Available for download [Clinical Reminder](#) [PDF - 187 KB]

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, 3]. This notice serves as a reminder that fingerstick devices should never be used for more than one person.

Background

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

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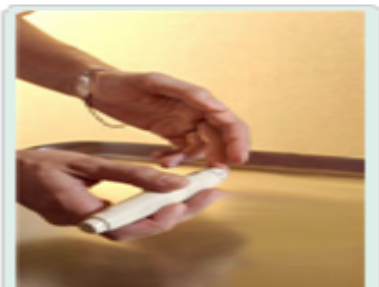


Figure 1: Reusable fingerstick device

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)

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^{1,2,3}. 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_RiskBBP.pdf](http://www.cdc.gov/injectionsafety/PDF/Clinical_Reminder_Fingerstick_Devices_RiskBBP.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.

ISMP IV Push Guidelines for Adults



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

www.ismp.org

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 site you if you do not follow this.



Prepared by the Institute for
Safe Medication Practices (ISMP)



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 dry
- Medication from a glass ampule 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

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
 - These are to flush an IV line and are not approved to use to dilute medication

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.³¹

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.³¹ 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.

3.7 When necessary to prepare more than one medication in a single syringe for IV push administration

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/SurveyCertificationGroupInfo/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.


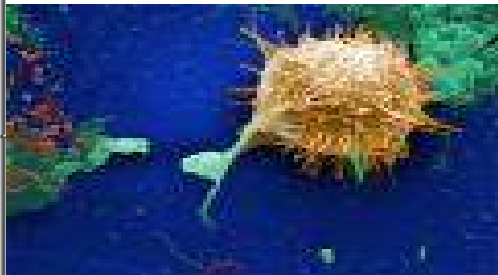
CMS Hospital Worksheets

- 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

Infection Control Program and Resources

Module 1: Infection Prevention Program

Section 1.A. Infection Prevention Program and Resources

Elements to be assessed		Sur
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 maintain(s) 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, cite at 42 CFR 482.42(a) (Tag A-748)		
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	<input type="radio"/> Yes <input type="radio"/> No	

Section 1.C. Systems to Prevent Transmission of MDROs and Pr Stewardship

Elements to be assessed		Sum
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) (Tag A-0749)		
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	

Safe Injection Practices and Sharps Safety

Section 2.B. Injection Practices and Sharps Safety (Medications and Infusates)

Elements to be assessed		Surveyor Notes		Surveyor Notes
<p>Injections are given and sharps safety is managed in a manner consistent with hospital infection control policies and procedures to maximize the prevention of infection and communicable disease including the following:</p> <p>Note: If possible, questions in this section should be assessed through observation in two separate patient care areas or settings of the hospital.</p>				
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"/> Second observation not available (If selected, questions 2.B.1 – 2.B.15 RIGHT column will be blocked) <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 Insulin pens 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 before use.	<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 (like the medication room)
- 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

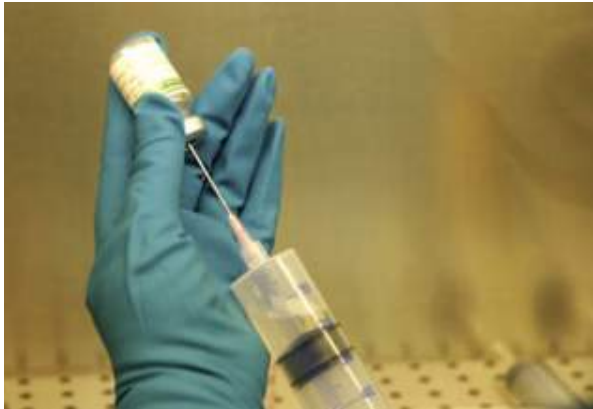
Injection Practices & Sharps Safety

- 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

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

The CDC on Safe Injection Practices



CDC on Infection Control

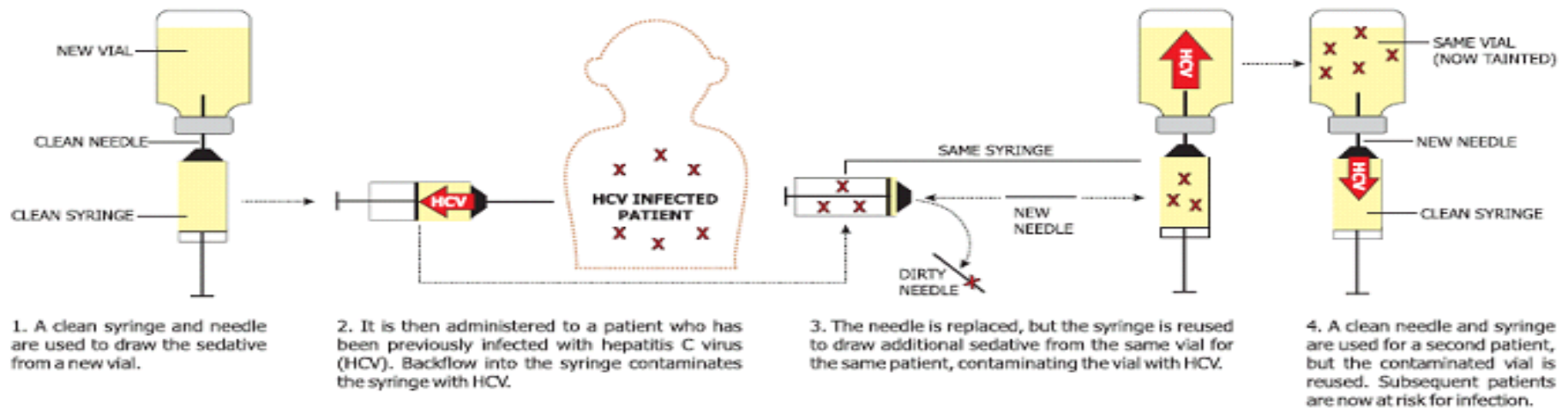


- The CDC says there are 1.7 million healthcare infection (HAI) in America every year
 - There are 75,000 deaths in American hospitals every year
 - Healthcare-Associated Infections (HAIs) are one of the top ten leading causes of death in the US¹
- Leadership need to make sure there is adequate staffing 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

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.



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

Infection Control Back to Basics

- It is important to get back to basics in infection control¹
- 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 needleless syringe which is safer
- Single dose saline flush syringes

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

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

CDC Injection Safety Website

- The CDC has an injection safety website which contains information for providers
 - Injection Safety FAQs
 - Safe Injection Practices to Prevent Transmissions of Infections to Patients
 - CDC's Position on the Improper use of single dose vials
 - Section from Guidelines for the Isolation Precautions to Prevent Transmission which has 10 safe injection practices
- www.cdc.gov/injectionsafety/

CDC Injection Safety Website

CDC Home



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CDC 24/7: Saving Lives. Protecting People.™

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Injection Safety

Injected medicines are commonly used in healthcare settings for the prevention, diagnosis, and treatment of various illnesses. Unsafe injection practices put patients and healthcare providers at risk of infectious and non-infectious adverse events and have been associated with a wide variety of procedures and settings. This harm is preventable. Safe injection practices are part of Standard Precautions and are aimed at maintaining basic levels of patient safety and provider protections. As defined by the World Health Organization, 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. [Visit the page on CDC's role in safe injection practices.](#)

Drug Diversion

A growing risk to patient safety.

[Learn More >](#)



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Public Health Education Resources



Information for Providers

Slide presentations, FAQs...



Information for Patients

Resources for Patients and family, FAQs, Syringe Reuse...



Preventing Unsafe Injection Practices

Guidelines, Recommendations...



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Injection Safety Related Publications...



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Ambulatory Surgical Centers (ASCs)...



Assisted Monitoring of Blood Glucose

CDC Clinical Reminders: Insulin Pens, Fingerstick Devices, FAQs...



Risks of Healthcare-associated Infections from Drug Diversion

Outbreaks, Resources, Reports, News...



Patient Notification Toolkit



Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care



CDC Preventing Unsafe Injection Practices

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[CDC's HAI site](#)

[2007 Guideline for
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www.cdc.gov/injectionsafety/unsafePractices.html

[Injection Safety](#)



Preventing Unsafe Injection Practices

Safe Injection Practices are a set of recommendations within Standard Precautions, which are the foundation for preventing transmission of infections during patient care in all healthcare settings including hospitals, long-term care facilities, ambulatory care, home care and hospice. The most recent guideline outlining Standard Precautions is the *Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007*.

- [Complete *Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007*](#) [PDF - 3.80 MB]
- [Excerpt: Safe Injection Practices to Prevent Transmission of Infections to Patients](#)



Preventing Unsafe Injection Practices

CDC Clinical Reminders

- [Insulin Pens Must Never Be Used for More than One Person](#)
- [Spinal Injection Procedures Performed without a Facemask Pose Risk for Bacterial Meningitis](#)
- [Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens](#)

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Improper Use of Single Dose Vials

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[2007 Guideline for Isolation Precautions](#)

[HHS Action Plan to Prevent HAIs](#)

www.cdc.gov/injectionsafety/cdc-position-singleusevial.html

Improper Use of Single-Dose/Single-Use Vials

Centers for Disease Control and Prevention
National Center for Emerging and Zoonotic Infectious Diseases
Division of Healthcare Quality Promotion
Single-dose/Single-use Vial Statement and Messages
May 2, 2012

In an effort to ensure clinicians are clear about CDC guidelines, the Agency is restating its position on the use of single-dose/single-use vials and also seeks to dispel inaccuracies being disseminated to healthcare providers.

CDC's Position — Protect Patients Against Preventable Harm from Improper Use of Single-dose/Single-use Vials

The Centers for Disease Control and Prevention's guidelines call for medications labeled as "single dose" or "single use" to be used for only one patient. This practice protects patients from life-threatening infections that occur when medications get contaminated from unsafe use. Concerns have been raised about whether these guidelines and related policies contribute to drug shortages and increased medical costs to healthcare providers. CDC recognizes the problem of drug shortages; however, such shortages are a result of manufacturing, shipping, and other issues unrelated to the above guidelines.

On this Page

- [CDC Statement](#)
- [General Messages](#)
- [Basic Safe Injection Practice Messages](#)
- [Misperceptions vs. Facts](#)
- [FAQs About Single-dose/Single-use Vials](#)
- [More Information](#)

[CDC's Position — Protect Patients Against Preventable Harm from Improper Use of Single-dose/Single-use Vials](#)

[PDF - 175 KB]

[New Medscape Article: Single-Dose Vials: Safety, Cost, and Availability](#)

Centers for Disease Control and Prevention
National Center for Emerging and Zoonotic Infectious Diseases
Division of Healthcare Quality Promotion
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CDC's Position

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General Messages

CDC 10 Safe Injection Practices

- CDC has a publication called 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings
- Has a section on Safe Injection Practices (III.A.1.b. and starts on page 68) which has the **10 safe injection practices**
- Discusses four large outbreaks of HBV and HCV among patients in ambulatory facilities
- Identified a need to define and reinforce safe injection practices

www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf

HICPAC

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Methodology Guideline

Projects in Progress

Publications

2011 Guidelines for the Prevention of Intravascular Catheter-Related Infections

2011 Norovirus Guidelines

2008 Disinfection & Sterilization Guideline

► **Guideline for Isolation Precautions 2007**

Executive Summary

Part I: Review of Scientific Data Regarding Transmission of Infectious Agents in Healthcare Settings


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 Recommend


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2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings

Download the complete PDF version [Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007](#)  PDF (3.80 MB / 225 pages)

Jane D. Siegel, MD; Emily Rhinehart, RN MPH CIC; Marguerite Jackson, PhD ; Linda Chiarello, RN MS; the Healthcare Infection Control Practices Advisory Committee

Acknowledgement: The authors and HICPAC gratefully acknowledge Dr. Larry Strausbaugh for his many contributions and valued guidance in the preparation of this guideline.

Suggested citation: Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings

www.cdc.gov/hicpac/2007IP/2007isolationPrecautions.html

10 CDC Standards Safe Injection Practices

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Safe Injection Practices to Prevent Transmission of Infections to Patients

Download the complete [2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings](#) [PDF - 3.80 MB]

III.A.1.b. Safe Injection Practices The investigation of four large outbreaks of HBV and HCV among patients in ambulatory care facilities in the United States identified a need to define and reinforce safe injection practices 453. The four outbreaks occurred in a private medical practice, a pain clinic, an endoscopy clinic, and a hematology/oncology clinic. The primary breaches in infection control practice that contributed to these outbreaks were 1) reinsertion of used needles into a multiple-dose vial or solution container (e.g., saline bag) and 2) use of a single needle/syringe to administer intravenous medication to multiple patients. In one of these outbreaks, preparation of medications in the same workspace where used needle/syringes were dismantled also may have been a contributing factor. These and other outbreaks of viral hepatitis could have been prevented by adherence to basic principles of aseptic technique for the preparation and administration of parenteral medications 453, 454. These include the use of a sterile, single-use, disposable needle and syringe for each injection given and prevention of contamination of injection equipment and medication.



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CDC 10 Recommendations

- The CDC has a page on Injection Safety that contains the excerpts from the Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings
- Summarizes their 10 recommendations
- CMS expects hospitals to follow the CDC guidelines
- Available at
<http://www.cdc.gov/ncidod/dhqp/injectionSafetyPractices.html>

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.

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

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

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



Morbidity and Mortality Weekly Report (MMWR)

[MMWR](#)Text size: [S](#) [M](#) [L](#) [XL](#)

Bacterial Meningitis After Intrapartum Spinal Anesthesia --- New York and Ohio, 2008--2009

Weekly

January 29, 2010 / 59(03);65-69

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.

Case Reports

New York. In September 2008, a healthy woman aged 24 years (patient A) was admitted in active labor to a New York City hospital. She received combined spinal-epidural anesthesia from anesthesiologist A, and delivered a healthy baby. Approximately 22 hours after receiving anesthesia, patient A experienced headache, back pain, rigors, nausea, vomiting, and disorientation.

Within 1 hour of patient A's admission, a second healthy woman aged 31 years (patient B) was admitted to the same hospital in active labor. Patient B also received combined spinal-epidural anesthesia from anesthesiologist A and delivered a healthy baby.

Wear a Mask Wear A Mask Wear A Mask

- Need to wear a mask to prevent bacterial meningitis
- During all spinal injection procedures
- During all injections into epidural or subdural space
 - Myelogram
 - Intrathecal chemotherapy
 - Administration of spinal or epidural anesthesia
 - LP done in the emergency department
- Bottom line is facemasks need to be worn by healthcare providers performing these procedures

Spinal Injection and Masks

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[HHS Action Plan to
Prevent HAIs](#)

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CDC Clinical Reminder: Spinal Injection Procedures Performed without a Facemask Pose Risk for Bacterial Meningitis

Available for download [Clinical Reminder](#) [PDF - 543 KB]

Summary

The Centers for Disease Control and Prevention (CDC) is concerned about the occurrence of bacterial meningitis among patients undergoing spinal injection procedures that require injection of material or insertion of a catheter into epidural or subdural spaces (e.g., myelogram, administration of spinal or epidural anesthesia, or intrathecal chemotherapy). Outbreaks of bacterial meningitis following these spinal injection procedures continue to be identified among patients whose procedures were performed by a healthcare provider who did not wear a facemask (e.g., may be labeled as surgical, medical procedure, or isolation mask),^[1] with the most recent occurrence in October 2010 (CDC unpublished data). This notice serves as a reminder that facemasks should always be worn by healthcare providers when performing these spinal injection procedures.^[2]

Background


CDC has investigated multiple outbreaks of bacterial meningitis among patients undergoing spinal injection procedures. Recent outbreaks have occurred among patients in acute care hospitals who received spinal anesthesia or epidural anesthesia, and also among patients at an outpatient imaging facility who underwent myelography.


In each of these outbreak investigations, nearly all spinal injection procedures that resulted in infection were performed by a common healthcare provider who did not wear a facemask. The

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www.cdc.gov/injectionsafety/SpinalInjection-Meningitis.html

CDC CLINICAL REMINDER

Spinal Injection Procedures Performed without a Facemask Pose Risk for Bacterial Meningitis

Summary:

The Centers for Disease Control and Prevention (CDC) is concerned about the occurrence of bacterial meningitis among patients undergoing spinal injection procedures that require injection of material or insertion of a catheter into epidural or subdural spaces (e.g., myelogram, administration of spinal or epidural anesthesia, or intrathecal chemotherapy). Outbreaks of bacterial meningitis following these spinal injection procedures continue to be identified among patients whose procedures were performed by a healthcare provider who did not wear a facemask (e.g., may be labeled as surgical, medical procedure, or isolation mask),¹ with the most recent occurrence in October 2010 (CDC unpublished data). This notice serves as a reminder that facemasks should always be worn by healthcare providers when performing these spinal injection procedures.²

Background:

CDC has investigated multiple outbreaks of bacterial meningitis among patients undergoing spinal injection procedures. Recent outbreaks have occurred among patients in acute care hospitals who received spinal anesthesia or epidural anesthesia, and also among patients at an outpatient imaging facility who underwent myelography.

In each of these outbreak investigations, nearly all spinal injection procedures that resulted in infection were performed by a common healthcare provider who did not wear a facemask. The strain of bacteria isolated from the cerebrospinal fluid of these patients was identical to the strain recovered from the oral flora of the healthcare provider who performed the spinal injection procedure. These findings illustrate the risk of bacterial meningitis associated with droplet transmission of the oral flora from healthcare providers to patients during spinal injection procedures.

Since facemasks have been shown to limit spread of droplets arising from the oral flora,³ 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. Philips 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

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

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

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

APIC Safe Injections IV Spike to 1 Hour

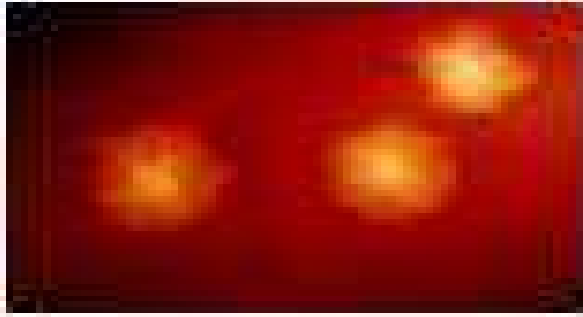
vial use, injections and glucose monitoring procedures.

- Store and prepare medications and supplies in a clean area on a clean surface.
- Never store needles and syringes unwrapped as sterility cannot be assured.
- Discard all opened vials, IV solutions and prepared or opened syringes that were involved in an emergency situation.

IV Solutions

- Never use intravenous solution containers (e.g., bags or bottles) to obtain flush solutions, etc. for more than one patient.
- Never use infusion supplies such as needles, syringes, flush solutions, administration sets or intravenous fluids on more than one patient.
- **Begin/initiate administration of spiked IV solutions (IV bag entered by the tubing spike) within one hour of preparation. If administration is not begun within 1 hour of spiking the bag, the IV and tubing shall be promptly discarded.²²**
- For unspiked IV solutions (not accessed by IV tubing spike) follow the pharmacy prepared or manufacturer prepared IV solution expiration date.
- Use a USP 797 pharmacy clean room (ISO 5) to prepare admixtures of IV solutions.
- Disinfect IV ports using friction and 70% alcohol¹⁵, an iodophor¹⁵ or an approved antiseptic agent. Allow to dry prior to accessing.

CDC IV Guidelines



- Every hospital should have the 2011 CDC Guidelines for the Prevention of Intravascular Catheter Related Infections
 - How to prep the skin for the peripheral IV
 - How to secure the needle
 - How long to change the dressing
 - How long do you change the IV tubing



www.cdc.gov/hicpac/pdf/guidelines/bsi-guidelines-2011.pdf

Guidelines for the Prevention of Intravascular Catheter-Related Infections, 2011

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A Scary Study

- The CDC says a survey of US Healthcare found that 1% to 3% reused the same syringe and/or the same needle on multiple patients
- This is what lead to the Nevada patients being exposed to HIV, HCV, and HCB
- 40,000 patients were notified who has anesthesia injections from March 2004 to January 11, 2008 and 115 patients infected with HCV
- Clinic reused syringes in colonoscopies and other gastrointestinal procedures

CDC Long List of Outbreaks

Outbreaks and Patient Notifications in Outpatient Settings

www.cdc.gov/HAI/settings/outpatient/outbreaks-patient-notifications.html

The following table includes examples of recent outbreaks and patient notification events occurring in a variety of outpatient settings including primary care clinics, pediatric offices, ambulatory surgical centers, pain remediation clinics, imaging facilities, oncology clinics, and health fairs. This is not an exhaustive list but it serves as a reminder of the serious consequences that can result when healthcare personnel fail to follow the basic principles of infection control. Such consequences include: infection transmission to patients, notification of thousands of patients of possible exposure to bloodborne pathogens, referral of providers to licensing boards for disciplinary action, and malpractice suits filed by patients.

These events are preventable, yet they continue to occur. Facilities and healthcare personnel are urged to review the [*Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care*](#) and its accompanying [*Infection Prevention Checklist*](#) to assess the policies and procedures in their facility as well as their own personal practices to assure they are in accordance with evidence-based guidelines and to prevent patient harm.

Setting	Year Investigated	Pathogen(s)	Infection(s)	Patient notification performed (# notified)	Infection Control Breaches Reported
Urology Clinic [1]	2011	N/A*	N/A*	Yes (101)	1) Single-use needle guides (for prostate biopsy) used for >1 patient
					1) Syringe reuse (i.e.,

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>

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
2. [General](#)
3. [Medication Preparation](#)
4. [Medication Administration](#)
5. [Single-dose/Single-use vials](#)
6. [Multi-dose vials](#)
7. [References](#)


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](#) [PDF - 3.80] 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, 8].

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Centers for Disease Control and Prevention
1600 Clifton Rd
Atlanta, GA 30333



800-CDC-INFO
(800-232-4636)
TTY: (888) 232-6348

[Contact CDC-INFO](#)

www.cdc.gov/injection-safety/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

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

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

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


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 bloodborne 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 myths and misunderstandings.

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 Isolation Precautions: 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_standardPrecaution.html.

The Web site for the One & Only Campaign from the CDC and the Safe Injection Practices Coalition—available at <http://oneandonlycampaign.org>—includes a video that highlights the CDC/HICPAC guidelines. 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 reeducate health care workers and debunk 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>. 

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

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

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

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. Each of the outbreaks could have been prevented by the use of proper aseptic technique in conjunction with basic infection prevention practices for handling parenteral medications, administration of injections, and procurement and sampling 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; procurement 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.¹⁻¹³ 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.¹³ 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.

In 2001, an anesthesiologist at a New York endos-

APIC Advances Efforts to Stop Unsafe Needle Practices

By James Battaglio

APIC Contributing Medical Writer

"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." CDC 2007 Guideline for Isolation Precaution

Concerned by the mounting number of cases in which clinicians in private ambulatory care centers failed to change syringes, APIC has thrown its support and expertise behind a nationwide program called HONORreform, an advocacy and education movement designed to bring a halt to these unsafe practices.

APIC will provide in-kind services to HONORreform in 2009 by tracking/mapping proposed legislation surrounding needle-safety reform and contribute its expertise to the development of educational initiatives and policy approaches, with legislative tracking as a part, but not the main part.

The decision to expand its tracking program was made when it became apparent that APIC's legislative educational efforts were needed in order to help prevent the kind of unsafe injection practices that have occurred in US ambulatory care centers across the country, causing thousands of clinic patients to face potentially life-threatening hepatitis B, C, and HIV.

In pinpointing legislative activities on its website via a map, APIC will offer a public service similar to the process now used to trace MRSA and

HAI reporting; a move that is expected to benefit HONORreform in its efforts.

HONORreform was founded by Evelyn Vinduska McKnight, AuD, 53, a breast cancer survivor who received chemotherapy at a Fremont, Nebraska ambulatory care clinic at which a nurse exposed hundreds of patients to hepatitis C when she re-used a syringe to access a 500 cc saline bag to draw off 10cc's of saline. Negative pressure drew blood particles from the syringe into the bag, including particles from patient zero, a hepatitis C patient who served as the source of the epidemic.

In addition to the Nebraska clinic, private, free standing ambulatory care centers, some connected to physician offices, have been the site of life-threatening exposure to hepatitis and HIV over the past 10 years. Unsafe needle practices have been cited at centers in Las Vegas, where 63,000 endoscopy clinic patients have been notified that they've been exposed to these diseases, along with Michigan (20,000 dermatology patients), New York (14,000 cardiology patients) and North Carolina (1,200 cardiology patients). The actual numbers of patients affected have yet to be determined, whereas additional cases of exposure in private ambulatory clinics are still being discovered. Thus far, thousands of letters have been sent to patients by health departments across various states, informing them of their exposure and suggesting they seek further testing.

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Association for
Professionals in
Infection Control &
Epidemiology, Inc.

A Patient Safety Threat-Syringe Reuse



- CDC published a fact sheet called “A Patient Safety Threat- Syringe Reuse”
- It was published for patients who had received a letter stating they could be at risk due to syringe reuse
- Discusses the dangers of the reuse of syringes
- Discusses that multidose vial be assigned to a single patient to reduce the risk of disease transmission

Hematology Oncology Clinic

- Has an outbreak of HCV among outpatients 3-00 to 7-01
- Reported to Nebraska Health Department
- 99 patients in oncology/hematology clinic acquired HCV after having chemotherapy
- All were genotype 3 a which is uncommon in the US
- Related to catheter flushing
- Source: Macedo de Oliveira et al., Annals of Internal Medicine, 2005, 142:898-902

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

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

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

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.

**1 ONE NEEDLE,
ONE SYRINGE,
ONLY ONE TIME.**



Safe Injection Practices Coalition
www.ONEandONLYcampaign.org



About the
Campaign

Safe Injection
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ONLY ONCE.

Safe injection practices are a set of measures to perform injections in an optimally safe manner for patients, healthcare providers and others.

[Learn about Safe Injection Practices >](#)

About the Campaign

The One & Only Campaign is a public health campaign, led by the Centers for Disease Control and Prevention (CDC) and the Safe Injection Practices Coalition (SIPC), to raise awareness among patients and healthcare providers about safe injection practices. The campaign aims to eradicate outbreaks resulting from unsafe injection practices.

Injection Safety Toolkits



Featured Content

- ▶ [Washington Post "Hepatitis & Liver Health" Supplement Raises Awareness – featuring the One & Only Campaign](#) - 9/10/12
- ▶ [Endorsing the Safe Use of Single-Dose/Single-Use Vials](#) - 5/31/12

Partner States



The SIPC partners with states to promote the messages of the One & Only Campaign.

[Read more](#)

Campaign Resources



The SIPC has print materials, videos and more to educate consumers and remind healthcare providers about the basics of injection safety.

[Read more](#)

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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*.

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
Injection s are 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. Note: This is different from the expiration date printed on the vial.	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 healthcare 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



www.ascquality.org/advancing_asc_quality.cfm

ASC Quality Collaboration

Quality Measures and Guide

Quality Report

Advancing ASC Quality: ASC TIPs

Advancing ASC Quality

[Hand Hygiene Toolkit](#)

[Safe Injection Practices Toolkit](#)

[Point of Care Devices Toolkit](#)

[Environmental Infection Prevention Toolkit](#)

[Single-Use Device Reprocessing Toolkit](#)

[Endoscope Reprocessing Toolkit](#)

[Sterilization and High-Level Disinfection Toolkit](#)

To support the ASC industry's focus on high quality care, the ASC Quality Collaboration is assembling **ASC Tools for Infection Prevention**, or **ASC TIPs**. Our goal is to make infection prevention resources readily accessible to ASCs by bringing them together in one location.

The following **ASC TIPs** are now available:

- [Hand Hygiene Toolkit](#)
- [Safe Injection Practices Toolkit](#)
- [Point of Care Devices Toolkit](#)
- [Environmental Infection Prevention Toolkit](#)
- [Single-Use Device Reprocessing Toolkit](#)
- [Endoscope Reprocessing Toolkit](#)
- [Sterilization and High-Level Disinfection Toolkit](#)

Each toolkit is available in two versions, **BASIC** and **EXPANDED**:

Safe Injection Practices Toolkit

The resources in this toolkit may only be used for internal improvement and education efforts. They may not be used for commercial purposes.

Safe injection practices are crucial to basic levels of patient safety and provider protection. Hepatitis C virus, hepatitis B virus, and HIV can be spread from patient to patient when safe injection practices are not used.

The ASC Quality Collaboration has assembled a variety of resources and information that may be used to supplement your current processes to enhance existing injection practices.

The BASIC Safe Injection Practices Toolkit includes three essential resources:

- [Safe Injection Practices: What CMS Surveyors Are Looking For](#)
- [One Needle, One Syringe, One Time Poster](#)
- [Injection Practices Policy and Procedure Template](#)

The EXPANDED Safe Injection Practices contains both essential resources and a broader array of materials, including:

- [Assessment Tools](#)
- [Implementation Aids](#)
- [Training Materials](#)
- [Monitoring Tools](#)
- [Workplace Reminders](#)
- [Guidelines from Leading Authorities](#)

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www.ascquality.org/SafeInjectionPracticesToolkit.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, cannulas 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.

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:

Don't Forget the OSHA Standard

UNITED STATES DEPARTMENT OF LABOR

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www.osha.gov/SLTC/bloodbornepathogens/index.html

back to SAFETY AND HEALTH TOPICS

BLOODBORNE PATHOGENS

and Needlestick Prevention

Highlights

- FDA, NIOSH and OSHA Joint Safety Communication on Blunt-Tip Surgical Suture Needles. (2012, May 30).
- Most frequently asked questions concerning the bloodborne pathogens standard.
- Quick Reference Guide to the Bloodborne Pathogens Standard.

General Guidance **Enforcement** **Hazard Recognition** **Evaluation & Controls** **Other Resources** **Standards**

What are bloodborne pathogens?

Bloodborne pathogens are infectious microorganisms in human blood that can cause disease in humans. These pathogens include, but are not limited to, hepatitis B (HBV), hepatitis C (HCV) and human immunodeficiency virus (HIV). Needlesticks and other sharps-related injuries may expose workers to bloodborne pathogens. Workers in many occupations, including first aid team members, housekeeping personnel in some industries, nurses and other healthcare personnel may be at risk

CAUTION!

If you are stuck by a needle or other sharp or get blood or other potentially infectious materials in your eyes, nose, mouth, or on broken skin, immediately flood the exposed area with water and clean any

<https://www.osha.gov/SLTC/bloodbornepathogens/index.html>

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
222 South Prospect 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.”¹ 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”² 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.”² The AANA historically has taken a strong stance concerning infection control behaviors, and the AANA’s *Infection Control Guide for Certified Registered Nurse Anesthetists*³ 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 bloodborne pathogens continues to occur in the United States.^{4,7} According to one recent report, there have been 33 different outbreaks involving transmission of the Hepatitis B or C viruses which placed over 60,000 patients at risk for contracting bloodborne infections within the past 10 years.⁵

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:

1. Never administer medications from the same syringe to multiple patients, even if the needle

The End! Questions??



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