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PROTECTING YOUR PATIENTS THROUGH SAFE INJECTION PRACTICES

By David Abel, DO, and Sindy M. Paul, MD, MPH



LEARNING OBJECTIVES

At the conclusion of this activity, participants will be able to do the following:

- 1) Discuss the misuse of injectable therapeutics and the adverse practice consequences related to unsafe injection methods
- 2) Identify viral and bacterial pathogens associated with unsafe injection practices
- 3) Understand practices to prevent transmission of pathogens via injections

INTRODUCTION

During 2001–2012, unsafe injection practices in the United States affected an estimated 150,000 patients who required notification advising them to get bloodborne pathogen testing after potential exposure from unsafe injection practices. From 2001 to 2011, more than 50 outbreaks of either viral or bacterial diseases were related to the improper use of syringes and vials in the provision of injections. According to the Centers for Disease Control and Prevention (CDC), approximately 90 percent of these outbreaks occurred in an outpatient setting, 21 involved hepatitis B or HIV transmission and 28 involved primarily invasive bacterial bloodstream infections. A recent CDC survey found that more than 3 percent of respondents reuse single-dose items, such as syringes and needles.^{1, 2, 3}



Patient protection from the potential harm of misuse of these items requires a multidisciplinary approach that includes all aspects of healthcare. Physicians need to order the appropriate injectable medications/vaccines in the proper doses and ensure that all safety regulations are followed. Staff need to be up to date on the proper procedures to draw up and administer injections.

To this end, the CDC launched the Safe Injection Practices Coalition (SIPC) in 2009. Through this coalition, the One & Only Campaign was developed to promote safety and to provide education. In 2014, Eli Lilly and Company joined this campaign with the goal of expansion and distribution of program materials to a wider audience. To date, the SIPC provides information to seven state health departments, including California, Colorado, Minnesota, New Jersey, New York, North Carolina and Wisconsin.²

This article addresses the safety concerns of unsafe injection practices and reviews the current recommendations regarding the safe practice of injection of therapeutics.

THE MISUSE OF INJECTABLE THERAPEUTICS AND ITS ADVERSE PRACTICE CONSEQUENCES

The misuse of injectable therapeutics can come in two forms. The first is the multiple use of single-use items such as syringes or vials. Single-use vials do not contain preservatives and are not meant to be stored once the seal is broken. Keeping these items after opening them can put patients at risk by allowing bacteria or viruses to grow in the vial.³ In 2012, an outbreak of meningitis, mediastinitis, sepsis and epidural abscess was associated with multiple uses of a single-use vial at a pain management clinic.⁴

The second form of misuse involves multiple-use vials. Although multiuse vials contain preservative, they can become contaminated when pathogens are introduced either through use of the same syringe barrel or needle for multiple patients or through improper use of sterile technique. These pathogens can then be transmitted to the next patient.⁵ In 2010, an outbreak of hepatitis B and C involving more than 2,000 patients occurred at a pain management clinic that was reusing needles on patients that subsequently contaminated a multiuse vial.⁶

The misuse of injectable therapeutics can put a patient at risk for bloodborne pathogens and bacterial infections and, additionally, may cause that patient to

receive an incorrect amount of the therapeutic. Certain diluents can change the pH of solutions that can inactivate medications.⁷ Therefore, the patient receiving that injection may not receive the full dose.

There are broader consequences for the misuse of injectable therapeutics that involve more than just the patient receiving the injection. A physician who is not following sterile guidelines can be investigated by the medical licensing board and potentially receive public discipline. Recently, a New Jersey physician had his license actively suspended, and thus, his practice was closed to protect the public; he was also fined \$30,000 for his role in an outbreak of hepatitis B. Infection-prevention breaches at his practice included the use of single-dose medication vials for multiple patients, the reuse of a saline bag for multiple patients and the use of multiuse vials beyond 28 days.

Patients who received an injection were placed at risk, either by receiving direct inoculation of a pathogen or by receiving inadequate doses of medications due to medication expiration. This practice also calls into question all other injections given by the physician. In this case, close to 2,700 patients had to be notified of their potential bloodborne pathogen exposure and of the follow-up testing that was then recommended. Twenty-nine patients were found to be infected with hepatitis B.⁸

Reusing syringes for multiple persons, even if the needle is changed, is a serious infection control breach that places patients at risk for bloodborne pathogen transmission. On September 30, 2015, the New Jersey Department of Health (NJDOH) was notified that a nurse had reused syringes for multiple persons at an employee influenza vaccination clinic earlier that day. The NJDOH in consultation with the CDC recommended notification and HIV, hepatitis B and hepatitis C testing of the 67 employees who participated in the clinic. Post-exposure prophylaxis with hepatitis B vaccine was also recommended. Additionally, the nurse used two multidose vials of 10 doses/vial for 67 persons, and the vaccine storage and handling did not include temperature monitoring. Influenza vaccine readministration was also recommended.⁹

PATHOGENS

The misuse of needles and vials has been associated with many viral and bacterial outbreaks. The following common pathogens have been seen with misuse.



Bloodborne Pathogens

Hepatitis B Virus (HBV): HBV is a virus in the *Hepadnaviridae* family with an incubation period up to 180 days. It can cause acute, chronic and fulminant liver disease. An acute infection can cause jaundice, fever and abdominal pain. Most patients clear the virus without intervention. Chronic HBV may require treatment with antiviral medications as it can lead to cirrhosis and hepatocellular carcinoma. Fulminant HBV with acute severe often life-threatening liver failure without obvious previous liver disease can also occur. HBV is the most infectious viral bloodborne pathogen with the highest risk of postexposure infection.¹⁰

Hepatitis C Virus (HCV): HCV is a member of the *Flaviviridae* family with an incubation period up to 45 days that causes acute, chronic and fulminant liver disease. Unlike HBV where most patients are able to clear the virus after exposure, HCV is more likely to cause chronic disease. Acute infections can be asymptomatic or be associated with abdominal pain, fevers and jaundice. Chronic disease requires treatment with antiviral medication to prevent progression to cirrhosis and hepatocellular carcinoma. Fulminant HCV with acute severe often life-threatening liver failure without obvious previous liver disease is rare. The risk of infection after exposure is lower than that of HBV.¹¹

Human Immunodeficiency Virus (HIV): HIV is a lentivirus that causes acquired immunodeficiency syndrome. Acute infection results in a flu-like illness that includes fevers, night sweats and fatigue. Infection requires treatment with combinations of antiretroviral medications to prevent advanced disease and immunosuppression. The risk of infection after exposure is considered to be lower than that of HCV.¹²

Bacterial Infections

Staphylococcus species: *Staphylococcus* species are Gram-positive bacteria that are usually found on the skin and in the respiratory tract. They are a common cause of skin, soft tissue and respiratory tract infections that may be difficult to treat due to antimicrobial resistance.¹³

Streptococcus species: *Streptococcus* species are Gram-positive organisms that are commonly found on the skin and in the respiratory tract. They are common causes of skin, soft tissue and respiratory tract infections, as well as bacteremia with endocarditis.¹⁴

Pseudomonas species: *Pseudomonas* species are Gram-negative bacteria that are commonly found in water

sources and on plants. These species may be difficult to treat due to antimicrobial resistance.¹⁵

PREVENTION THROUGH SAFE INJECTION PRACTICES

Prevention of unsafe injection practices through the proper use of needles, syringes, vials and ampules requires a multifaceted approach that involves physicians, staff and patients. The CDC's One & Only Campaign was designed to promote proper injection practices in healthcare settings. The following recommendations have been put forth by the campaign.

These recommendations apply to the use of needles, cannulas that replace needles and, where applicable, intravenous delivery systems. The CDC considers these recommendations to have good evidence from a randomized controlled trial supporting their use and thus should always be followed.¹⁶

- 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, cannulas and syringes are sterile, single-use items; they should not be reused for another patient or to access a medication or solution that might be used for a subsequent patient.
- 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, the needle or cannula and syringe used to access the multidose vial must be sterile.
- 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.
- Use single-dose vials for parenteral medications whenever possible.

The following CDC recommendations have moderate evidence supporting their use and thus should generally be followed.¹⁶

- Use fluid infusion and administration sets (i.e., intravenous bags, tubing and connectors) for one patient only and dispose appropriately after use. Consider a



Table 1. Injection Safety Checklist¹⁷

Injection Safety	Practice Performed?		If Answer Is No, Document Plan for Remediation
Injections 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	
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	
Multidose 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.	Yes	No	
Multidose vials are dedicated to individual patients whenever possible.	Yes	No	
Multidose vials to be used for more than one patient are kept in a centralized medication area and do not enter the immediate patient treatment area (e.g., operating room, patient room/cubicle).	Yes	No	

Note: Adapted from "Injection Safety Checklist," by Centers for Disease Control and Prevention.

syringe or needle/cannula contaminated once it has been used to enter or connect to a patient's intravenous infusion bag or administration set.

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

To help medical practices comply with the current safety standards, the One & Only Campaign also provides a checklist of safety guidelines that should be followed. Every question presented in Table 1 should be answered Yes prior to performing an injection. If the answer is No, remedi-

ation steps are available on the One & Only Campaign website at www.cdc.gov/injectionsafety/IP07_standardPrecaution.html and in the CDC's 2007 Guideline for Isolation Precautions at www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf.


DISCUSSION

Safe injection practices are part of the provision of quality medical care. Improper injection practices can cause adverse outcomes such as bacterial and viral infections, inadequate dosing (which requires additional administration of medication or vaccines), the potential for disciplinary



action against the practitioner's medical license and the potential for medical liability. Look-back investigations may be necessary to rule out bloodborne pathogen transmission and to identify patients who might require another dose of medication or vaccine.

All of these adverse outcomes come at great cost to the community and practitioner. Following the CDC's guidelines from the One & Only Campaign can help reduce the risk of unsafe injection practices and reduce the risk for patients and providers.

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- ⁴ Centers for Disease Control and Prevention. (2012, July 13). Invasive *Staphylococcus aureus* infections associated with pain injections and reuse of single-dose vials—Arizona and Delaware, 2012. *Morbidity and Mortality Weekly Report*, 61(27), 501–504. [Available at www.cdc.gov/mmwr/preview/mmwrhtml/mm6127a1.htm?s_cid=mm6127a1_w]
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- ⁶ Guh, A. Y., Thompson, N. D., Schaefer, M. K., Patel, P. R., & Perz, J. F. M. (2012, September). Patient notification for bloodborne pathogen testing due to unsafe injection practices in the U.S. health care settings, 2001–2011. *Medical Care*, 50, 785–791.
- ⁷ National Center for Immunization and Respiratory Diseases. (n.d.). *Vaccine preparation and disposal*. www.dhhs.nh.gov/dphs/immunization/documents/vpd-doc.pdf.
- ⁸ Greely, R. D., Semple, S., Thompson, N. D., High, P., Rudowski, E., Handschur, E., Xia, G. L., . . . Montana, B. (2011). Hepatitis B outbreak associated with a hematology-oncology office practice in New Jersey, 2009. *American Journal of Infection Control*, 39(8), 663–670.
- ⁹ Centers for Disease Control and Prevention. (2015, December 18). Notes from the field: Injection safety and vaccine administration errors at an employee influenza vaccination clinic—New Jersey. *Morbidity and Mortality Weekly Report*, 64(49), 1363–1364. [Available at www.cdc.gov/mmwr/preview/mmwrhtml/mm6449a3.htm?s_cid=mm6449a3_w]
- ¹⁰ Thio, C. L., & Hawkins, C. (2015). Hepatitis B virus and hepatitis delta virus. In J. E. Bennett, R. Dolin, & M. J. Blaser (Eds.), *Mandell, Douglas, and Bennett's principles and practice of infectious diseases* (8th ed.; pp. 1815–1839). Philadelphia, PA: Elsevier.
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PROTECTING YOUR PATIENTS THROUGH SAFE INJECTION PRACTICES

CME EXAMINATION (Deadline February 1, 2017)

- 1) It is acceptable to reuse a syringe barrel if it is for another patient, provided the needle is exchanged.
- True
 - False
- 2) The following infections have been associated with outbreaks due to improper injection practices.
- Meningitis
 - Septic arthritis
 - Epidural abscess
 - Hepatitis
 - All of the above have been associated with outbreaks
- 3) The following bloodborne pathogen has the highest risk of transmission after improper reuse of a needle:
- HIV
 - Hepatitis B
 - Hepatitis C
- 4) Multidose vials should be dated when they are first opened and discarded within 28 days, unless the manufacturer specifies a different date.
- True
 - False
- 5) A patient does not need to be offered another vaccination if the provider gave an incorrect dosage, as long as the provider is sure that the patient received most of the recommended dose.
- True
 - False
- 6) A multiuse vial of vaccine should be kept in patient rooms so that it can be accessed more rapidly.
- True
 - False
- 7) The following is an example of misuse of injectable medications:
- Using the same syringe barrel for multiple patients
 - Using the same needle for multiple patients as long as the syringe barrel was changed
 - Combining the remnants of single-use items in order to not waste any medicine
 - Not wiping the rubber septum of a medication vial with alcohol as long as a completely new syringe and needle is used
 - All of the above are examples of the misuse of injectable medications
- 8) You should consider a syringe or needle contaminated once it has been used to enter or connect to a patient's intravenous infusion bag or administration set.
- True
 - False
- 9) The CDC has published a set of guidelines that can help practitioners safely administer injections.
- True
 - False
- 10) Which of the following consequences can occur if a single-dose vial or syringe is reused?
- Bacterial infection
 - Viral infection
 - Bloodborne pathogen investigation
 - All of the above

PROTECTING YOUR PATIENTS THROUGH SAFE INJECTION PRACTICES

REGISTRATION AND EVALUATION FORM

(Must be completed in order for your CME Quiz to be scored - Deadline for Response: February 1, 2017)

REGISTRATION FORM

First Name	Middle Initial	Last Name	Degree
Address			
City	State	ZIP	
Phone	E-mail Address	Specialty	

ANSWER SHEET

Circle the correct answer.

- | | | | | |
|--------|--------------|----------|--------|-------------|
| 1) T F | 2) A B C D E | 3) A B C | 4) T F | 5) T F |
| 6) T F | 7) A B C D E | 8) T F | 9) T F | 10) A B C D |

Number of hours spent on this activity _____ (reading article and completing quiz)

I attest that I have read the article "Protecting Your Patients Through Safe Injection Practices" and am claiming 1 AMA PRA Category 1 Credit.™

Signature	Date
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EVALUATION

Completed by

Physician

Non-Physician

- | | |
|--|----------------------------------|
| 1. The content of the article was: | Excellent__ Good__ Fair__ Poor__ |
| 2. The authors' writing style was: | Excellent__ Good__ Fair__ Poor__ |
| 3. The graphics included in the article were: | Excellent__ Good__ Fair__ Poor__ |
| 4. The stated objectives of this program were: | Exceeded__ Met__ Not met__ |

Was this article free of commercial bias? Yes _____ No _____
If not, why not _____

Please share your name and contact information so that we may investigate further.

Participant Name _____ Telephone/E-mail: _____

5. Will the knowledge learned today affect your practice? Very Much__ Moderately__ Minimally__ None__

6. Based on your participation in the CME activity, will you change the way you practice medicine?

__Yes Describe _____

__No Why not _____

__N/A Were you the wrong audience for this activity? _____

7. Did this CME activity change what you know about:

• The misuse of injectable therapeutics and the adverse practice consequences related to unsafe injection practices. Yes No

• Viral and bacterial pathogens associated with unsafe injection practices. Yes No

• Practices to prevent transmission of pathogens via injections. Yes No

8. Based on your participation today, what barriers to the implementation of the strategies or skills taught today have you identified?

Suggested topics for future programs: _____

