APIC Position Paper: Safe Injection, Infusion and Medication Vial Practices in Healthcare

Susan A. Dolan, RN, MS, CIC; Lead Author; Vice-chair, Public Policy Committee
Sue Barnes, RN, BSN, CIC; Member, Communications Committee
Tracy R. Cox, RN, CIC; Member, Public Policy Committee
Gwenda Felizardo, RN, BSN, CIC; Board Member, APIC Puget Sound Chapter
Marcia Patrick, RN, MSN, CIC; APIC Board Member
Katherine S. Ward, RN, BSN, MPH, CIC; Vice-chair, Practice Guidance Council

The transmission of blood borne viruses and other microbial pathogens to patients during routine healthcare procedures continues to occur due to unsafe and improper injection, infusion and medication vial practices being used by healthcare professionals within various clinical settings throughout the United States.1-13

Breaches in safe injection, infusion and medication vial handling practices continue to result in unacceptable and devastating events for patients. More than 35 outbreaks of viral hepatitis have occurred in the United States in the past 10 years due to these unsafe practices and other breaches of infection prevention procedures. These outbreaks have resulted in the transmission of either hepatitis B or C to more than 500 patients.13 The unsafe practices that were used by physicians and/or nurses in these outbreaks can be categorized by:

1. syringe reuse between patients during parenteral medication administration to multiple patients;
2. contamination of medication vials or intravenous (IV) bags by accessing them with a used syringe and/or needle;
3. failure to follow basic injection safety practices when preparing and administering parenteral medications to multiple patients;
4. inappropriate use of fingerstick devices and glucometer equipment between patients.

In 2001, an anesthesiologist at a New York endoscopy clinic infected 19 patients with hepatitis C virus (HCV) by improperly reusing syringes and contaminating a multi-dose anesthesia medication vial subsequently used for multiple patients.3 A similar HCV outbreak due to unsafe injection practices occurred in New York in 2002 and 2007, affecting 102 patients in total.13 In 2002, nearly 100 Nebraska Hematology Oncology clinic patients contracted hepatitis C after receiving port flushes from an IV bag that was used for multiple patients and entered with the same needles and syringes that were used to draw blood from these patients. 9 One of the most recent hepatitis C outbreaks occurred in Nevada in 2008 and was again due to unsafe injection practices involving the reuse of syringes and sharing single-use medication vials between patients. This outbreak occurred at an endoscopy center and received significant public media attention, in part due to the 63,000 persons identified as being at potential risk for acquisition of hepatitis. More than 12,000 patients have been tested to date with at least 115 patients infected. The investigation is ongoing.12

APIC recognizes these outbreaks as unacceptable. Each outbreak was preventable if proper infection prevention and aseptic technique was used during handling and preparation of parenteral medications, administration of injections and procurement and sampling of blood. The 3rd edition of the 2009 APIC Text of Infection Control and Epidemiology states: Aseptic technique refers to the use of procedures that break the cycle of infection and ideally eliminate cross-contamination. The practices in this document promote aseptic technique. Responsibility for the oversight and monitoring of patient safety must be clearly designated in healthcare settings to assure that staff education is available for all healthcare professionals providing such services to patients. Furthermore, periodic monitoring for absolute adherence to safe injection practices in healthcare settings is vital in order to ensure effective engineering

of and adherence to safe practices in everyday patient care. APIC strongly supports adherence to the following safe injection, infusion and medication vial practices.14-25

Aseptic Technique

- Perform hand hygiene prior to accessing supplies, handling vials and IV solutions, and preparing or administering medications.
- Use aseptic technique in all aspects of parenteral medication administration, medication 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.

Flushing

- Use single-dose containers for flush solutions whenever possible.
- If a multidose vial must be used, it should be used for only one patient and then discarded. Each entry into the multidose vial must be with a new unused sterile needle and syringe even if the vial is dedicated to a single patient.

Syringes

- Remove sterile needle/cannula and/or syringe from package just prior to use.
- Never use medication in a syringe for more than one patient even if the needle is changed between patients. Changing the needle but not the syringe is unacceptable.
- Utilize sharps safety devices whenever possible.
- Discard syringes, needles and cannulas after used directly on an individual patient or in their IV administration system.
- Dispose of used needles at the point of use in an approved sharps container.
- Do not prepare medication in one syringe to transfer to another syringe, i.e., nurse draws up solution into syringe then transfers the solution to a syringe with plunger removed or injected into the bevel of the syringe to then be injected into the patient.

Vials

- Always follow the manufacturer's instructions for storage and use.
- Use single-use or single-dose vials whenever possible.
- Always use a sterile syringe and needle/cannula when entering a vial. Never enter a vial with a syringe or needle/cannula that has been used on a patient.
- Cleanse the access diaphragm of vials using friction and 70% alcohol or other antiseptic. Allow to dry before inserting a device into the vial.
- Discard single-dose vials after use. Never use them again for another patient.
- If a multidose vial must be used, it should be used for a single patient whenever possible. The risk of transmission posed by inappropriate handling of multi-dose vials has been clearly demonstrated and mandates a practice of one vial per one patient whenever possible. Infection transmission risk is reduced when multi-dose vials are dedicated to a single patient.
- Keep multidose vials away from the immediate patient environment.
- Never store vials in clothing or pockets.
- Use filter needles to withdraw solution from an ampule.
- Never pool or combine leftover contents of vials for later use.
- Never leave a needle, cannula, or spike device inserted into a medication vial rubber stopper because it leaves the vial vulnerable to contamination.
- Dispose of opened multidose medication vials 28 days after opening, unless specified otherwise by the manufacturer, or sooner if sterility is questioned or compromised.22
- Exception to 28 day disposal of opened multidose vials: The CDC Immunization

Program states opened multidose vaccines are to be discarded per manufacturer's expiration date or sooner if sterility is questioned or compromised.25

- Date opened multidose vials to reflect date opened and/or date of expiration. An organization may choose to establish a system wide opened multidose discard schedule, i.e., one date a month established to discard all opened multidose vials no matter when the vial was opened during the month.
- Inspect vials and discard if sterility has been, or is thought to be compromised.

Examine the vial for any particulate matter, discoloration or turbidity. If present, do not use and discard immediately. All vials used during an emergency should be discarded as sterility cannot be guaranteed.

Blood Glucose Monitoring Devices

- Assign glucometers to individual patients. Clean and disinfect glucometers if they must be reused between patients.
- Restrict use of fingerstick capillary blood sampling devices to individual patients.
- Use single-use lancets that permanently retract upon puncture. Never reuse fingerstick devices and lancets.
- Dispose of fingerstick devices and lancets at the point of use in an approved sharps container.
- Pen style devices with a removable lancet must be dedicated to one patient and lancets removed either by the patient or if by the healthcare worker with mechanical means (hemostat) to avoid finger contact.
- Thoroughly clean all visible soil or organic material (e.g., blood) from glucometer prior to disinfection.

- Disinfect the exterior surfaces of the glucometer after each use, even if there is no visible blood or soil, following the manufacturer's directions. Use an EPA-registered disinfectant effective against HBV, HCV and HIV.

Healthcare Workers

- Provide the hepatitis B vaccination series to all previously-unvaccinated healthcare personnel whose activities involve contact with blood or body fluids.18
- Check and document post-vaccination titers one to two months after completion of the vaccination series.18
- Report body fluid and needlestick/sharps injuries immediately.
- Evaluate needlestick/sharps injuries for preventability.
- Use safety devices for liquid injection syringes. Sharps (syringes/needles) with attached safety devices must be activated prior to disposal.
- Ensure staff preparing or administering injections or other parenteral medications are competent to aseptically perform these tasks.
- Periodically assess compliance with safe injection practices by observing and evaluating personnel performing these procedures.

Conclusion:

Use of safe injection practices is critical to prevent microbial contamination of products administered to patients. The ongoing reports in the United States of hepatitis B and C transmission to patients and outbreaks of bacterial infections associated with unsafe injection practices25-28 is an indication that diligence is needed to assure that these preventive practices are being scrupulously followed in all healthcare settings. Healthcare workers and their managers must understand, practice and promote safe injection, infusion and medication vial practices. Administrators of medical facilities must support safe injection practices and provide resources to ensure employees have the training and equipment to safely implement these procedures. The role of the Infection Preventionist is to assess procedures for safety, develop programs, train, and implement safe injection, infusion and medication vial practices so they are the absolute standard of care throughout the variety of healthcare settings that exist today.

The health and safety of our patients require adherence to infection prevention practices by all healthcare workers. These infection prevention practices should prevent cross contamination, transmission and outbreaks of infection due to unsafe injection, infusion and medication handling, and preparation and administration practices.

1. Centers for Disease Control. Hepatitis B outbreak in a state correctional facility; MMWR 2001;50(25):529-523.
2. Massari M, Petrosillo N, Ippolito G et al. Transmission of hepatitis C virus in a gynecological surgery setting. J Clin Micro 2001;39:2860-2863.
3. Centers for Disease Control. Transmission of hepatitis B and C viruses in outpatient settings – New York, Oklahoma, and Nebraska, 2000-2002. MMWR 2003;52(38):901-906.
4. Krause G, Trepka MJ, Whisenhunt RS, et al. Nosocomial transmission of hepatitis C virus associated with the use of multidose saline vials. Infect Control Hosp Epidemiol 2003;24:122-7.
5. Tallis GF, Ryan GM, Lambert SB, et al. Evidence of patient-to-patient transmission of hepatitis C virus through contaminated intravenous anaesthetic ampoules. J Viral Hepat 2003;10:234-9.
6. Comstock RD, Mallonee S, Fox J.L, et. al. A large nosocomial outbreak of hepatitis C and hepatitis B among patients receiving pain remediation treatments. Infect Control Hosp Epidemiol 2004;25(7):576-83.

7. Williams IT, Perz JF, Bell BP. Viral hepatitis transmission in ambulatory health care settings. Clin Infect Dis 2004;38(11):1592-8.
8. Centers for Disease Control. Transmission of hepatitis B Virus among persons undergoing blood glucose monitoring in long-term-care facilities: Mississippi, North Carolina and Los Angeles County, California, 2003-2004. MMWR 2005; 54(09):220-223.
9. Macedo de Oliveira A, et. al. An outbreak of hepatitis C virus infections among outpatients at a hematology/oncology clinic. Anns of Interl Med.2005;142:898-902.
10. Samandari T, Malakmadze N, Balter S, et al. A large outbreak of hepatitis B virus infections associated with frequent injections at a physician's office. Infect Control Hosp Epidemiol2005;26:745-50.
11. Redd JT, Baumbach J, Kohn W, et al. Patient-to-patient transmission of hepatitis B virus associated with oral surgery. The Journal of Infectious Diseases 2007;195:1311-1314.
12. Centers for Disease Control. Acute hepatitis C virus infections attributed to unsafe injection practices at an endoscopy clinic – Nevada, 2007. MMWR 2008;57(19):513-517.
13. Honoreform. Healthcare-associated outbreaks of hepatitis, 1998-2008. Available at: http://67.228.183.132/~hardtime/HONOR/occurrences.html (Accessed 4/21/2009)
14. Infusion Nursing Standards of Practice. Journal of Infusion Nursing. 2006;29(1S).
15. O'Grady NP, Alexander M, Patchen E, et al. Centers for Disease Control and Prevention. Guidelines for the Prevention of Intravascular Catheter-Related Infections. MMWR2002;51(No.RR-10).
16. Centers for Disease Control. Guidelines for infection control in dental health-care settings—2003. MMWR 2003; 52(RR-17):10-1.
17. Guideline for environmental infection control in health-care facilities: recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee. MMWR,2003;52(No. RR-10):1-44.
18. US Department of Labor, Occupational Safety and Health Administration. 29 C.F.R. pt. 1910.1030. Occupational exposure to bloodborne pathogens; needlesticks and other sharp injuries; final rule. Fed. Reg. 2001; 66:5317-25. As amended from and includes 29 C.F.R. pt. 1910.1030. Occupational exposure to bloodborne pathogens; final rule. Fed. Reg. 1991; 56:64174-82. Available at: http://www.osha.gov/SLTC/dentistry/index.html.
19. DeBaun B. Transmission of infection with multi-dose vials. Infection Control Resource. 2005;3(3):1,5-7. Available from: http://www.infectioncontrolresource.org/past.html(Accessed 4/20/2009)
20. Siegel JD, Rhinehart E, Jackson M, et al. and HICPAC. Center's for Disease Control. Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents inHealthcare Settings 2007.Am J Infect Control 2007;35:S65-S164.
21. Hadaway L. Flushing vascular access catheters: Risks for infection transmission. Infection Control Resource. 4(2):1-8, 2007. http://www.infectioncontrolresource.org/Past_Issues/IC14.pdf (Accessed 4/20/2009)
22. United State Pharmacopeia (USP) 797: Guidebook to Pharmaceutical Compounding – Sterile Preparations. Second Edition, June 1, 2008.
23. Centers for Disease Control. Prevent patient-to-patient transmission of bloodborne pathogens in ambulatory care settings. Available at: http://wwwn.cdc.gov/pubs/hepa.aspx(Accessed 4/20/2009)
24. Centers for Disease Control. Prevent patient-to-patient transmission of bloodborne pathogens in long term care settings. Available at: http://wwwn.cdc.gov/pubs/hepa.aspx (Accessed4/20/2009)
25. Centers for Disease Control. Vaccine storage and handling toolkit. Available at: http://www2a.cdc.gov/vaccines/ed/shtoolkit/pages/inventory_management.htm(Accessed 4/20/09)
26. Grohskopf LA, Roth VR, Feikin DR, et al. Serratia liquefaciens bloodstream infections from contamination of epoetin alfa at a hemodialysis center. N Engl J Med. 2001 May17;344(20):1491-7.
27. Watson JT, Jones RC, Siston AM, et al. Outbreak of catheter-associated Klebsiella oxytoca and Enterobacter cloacae bloodstream infections in an oncology chemotherapy center. Arch Intern Med. 2005;165:2639-2643.
28. Thompson ND, Perz JD, Moorman AC, Holmberg SD. Nonhospital health care-associated hepatitis B and C virus transmission: United States, 1998–2008. Ann Intern Med.2009;150:33-39.

July 30, 2009