Infection Prevention and Control Guidelines for Anesthesia Care

Chapter X: Safe Medication Preparation and Injection Practices

Introduction

Improper injection practices put patients and healthcare providers at risk of infection from bloodborne pathogens, which can lead to the spread of healthcare-associated infections (HAIs).[1-5] Following safe injection practices and appropriate medication preparation techniques can prevent the spread of disease. These measures can also protect providers from disciplinary action and legal recourse.[2,6,7]

Purpose

The purpose of this chapter is to describe evidence-based safe medication management and compounding of anesthetic drugs, safe injection practices for needle and syringe use, and infection control safety considerations for gels, lubricants, and ointments. This chapter includes content described in U.S. Pharmacopeial Convention (USP) Chapter <797> on compounding of sterile preparations.

Audience

This resource is intended for Certified Registered Nurse Anesthetists (CRNAs), also known as nurse anesthesiologists or nurse anesthetists, resident registered nurse anesthetists, other anesthesia providers, members of the interdisciplinary team, administrators involved in policy developed and implementation, quality assurance professionals, and other interested stakeholders.

USP Chapter <797> Sterile Compounding

The USP is a scientific nonprofit organization responsible for defining standards for the identity, strength, quality, and purity of drugs and compounds used in clinical practice.[8] USP standards are developed with input from various stakeholders, undergo rigorous scientific evaluation, and are presented for public input before being finalized.[8]

USP Chapter <797>, *Pharmaceutical Compounding - Sterile Preparations*, describes conditions and practices for preparing compounding sterile preparations (CSPs) in healthcare settings.[9] These standards apply to all healthcare providers preparing and administering CSPs within an institution when that institution has adopted USP <797>. USP <797> was most recently revised effective November 1, 2023.[10]

USP <797> is not law but is an accepted standard and may be incorporated into federal, state, and local statutes, regulations, and facility accreditation standards.[11] Anesthesia professionals should comply with applicable statutes, regulations, facility accreditation requirements, and facility policies in the preparation of CSPs.

The following summarizes USP <797> as it applies to anesthesia professionals:[9]

- USP <797> distinguishes three categories of CSPs: Category 1, Category 2, and Category 3, primarily based on the state of environmental control under which they are compounded, the probability of microbial growth during the storage time, and the time in which they must be used.
    - Category 1 is a CSP that is assigned a beyond-use date (BUD) of 12 hours or less at a controlled room temperature or 24 hours or less refrigerated.
    - Category 2 is a CSP that may be assigned a BUD of greater than 12 hours at a controlled room temperature or greater than 24 hours refrigerated.

- Category 3 is a CSP that has a BUD up to 90 days at a controlled room temperature or 120 days refrigerated.

- When all the following conditions are met, compounding of "immediate use" CSPs for direct and immediate administration is not subject to the requirements of Category 1, Category 2, or Category 3 CSPs:[9]
  - Aseptic techniques, processes, and procedures are followed, and written standard operating procedures (SOPs) are in place to minimize contact with nonsterile surfaces, introduction of biological fluids or particulate matter, and mix-ups with other CSPs or manufactured products.
  - Personnel are trained and demonstrate competency in aseptic processes as they relate to the facility's SOPs and assigned tasks.
  - The preparation is performed according to evidence-based information for physical and chemical compatibility of the drugs.
  - Preparation involves not more than 3 different sterile products.
  - Any unused starting component from a single-dose container must be discarded upon completion of preparation. Single-dose containers may not be used for more than one patient.
  - Administration must begin within 4 hours following the start of preparation. If administration does not begin with 4 hours following the start of preparation, it must be appropriately and promptly safely discarded.
  - Unless directly administered by the person who prepared it or administration is witnessed by the preparer, the CSP must have proper labeling with the names and amounts of all the active ingredients, the name or initials of the preparer, and the 4-hour time period within which the administration must begin.

- All labeling must be in compliance with laws and regulations of the applicable regulatory jurisdiction.[9]

Preparation Per Approved Labeling

Compounding of sterile preparations refers to the preparation of sterile solutions or drugs for injection, using strict aseptic technique. Compounding does not include mixing, reconstituting, or other acts that are performed in accordance with directions contained in approved labeling or supplemental materials provided by the manufacturer. Preparing a conventionally manufactured sterile product in accordance with the manufacturer's approved labeling is out of scope of USP <797> only if:[9]

- The product is prepared as a single dose for an individual patient; and
- The approved labeling includes the information of the diluent, the strength of the resultant, the container closure system, and the storage time.

Proprietary Bag and Vial Systems

Docking and activation of proprietary bag and vial systems in accordance with the manufacturer's labeling for "immediate" administration to an individual is not considered compounding and may be performed outside of an International Organization for Standardization (ISO) Class 5 environment.[9]

Conventionally Manufactured Single-Dose and Multi-Dose Containers

A manufactured single-dose container is a container closure system that holds sterile products for injection or infusion that is not required to abide by antimicrobial effectiveness testing requirements.[9]

If a product is manufactured in a multiple-dose container, it is intended to contain more than one dose of a product. Once it has been initially opened, the multiple-dose container must be used within 28 days, unless specified by the manufacturer's label.[9]

Compounded Multiple-Dose CSPs

Multiple-dose CSPs contain more than one dose of a sterile preparation, which is intended to be opened and closed multiple times, since the vile normally contains a preservative. Multiple-dose CSPs require the criteria for antimicrobial effectiveness testing.[9] They must be stored under the conditions on which their BUD is based. After being opened, the multiple-dose CSP must not be used longer than the assigned BUD or 28 days, whichever is shorter. The time limit for opening or closing is not supposed to restrict the BUD of the final CSP.[9]

All personnel involved in compounding should understand how they may contribute to the risk of CSP contamination during preparation. To decrease the risk of contamination, many hospital pharmacies commonly prepare medications used in anesthesia care delivery (e.g., phenylephrine) or buy ready-to-use, prefilled medications (e.g., fentanyl).

See the glossary at the end of this document for definitions of USP Chapter <797> terms used in this section.

Needle and Syringe Use

AANA *Safe Injection Guidelines for Needle and Syringe Use* address aspects of anesthesia care which involve the use of needles and syringes when administering injectable medications.[4] In addition to AANA guidance, CRNAs are advised to refer to CDC recommendations for safe

injection practice for additional guidance.[12] The following statements reflect current safe practices for needle and syringe use.

- **Never administer medications from the same syringe to multiple patients, even if the needle is changed**.[1,13-15]

- **Never reuse a needle,**[2,13,16-19] **or needleless access device even on the same patient**. Once a needle or access device has been used, it is considered contaminated and must be discarded in an appropriately identified sharps container.[20] Access devices are single- use devices.[1,2]

- **Never refill a syringe once it has been used, even for the same patient**. Syringes are single-use devices.[2,17,18,21] Once the plunger of a syringe has been completely depressed in order to expel the syringe contents (i.e., intravenous medication), the internal barrel of the syringe is considered contaminated and must be discarded in an appropriate fashion. A syringe must only be used **once** to draw up medication, and must not be used again even to draw up the same medication from the same vial for the same patient.[21-24] In recognizing the needs of anesthesia care workflow, one syringe may contain medication to be administered over a period of time in incremental doses. The syringe tip should be protected with a sterile cap at all times when not being actively used to administer an incremental dose of medication.[1] For medication administration, the sterile cap should be removed and the injection port should be cleansed with 70% alcohol prior to injection of medication.[1,25] Following medication injection, the sterile cap should be reattached, being careful not to contaminate the syringe tip.[1]

CRNAs should weigh the risks of possible syringe contamination (e.g., from anesthesia workspace contamination[26-31] that may occur when repeatedly connecting and disconnecting a medication-filled syringe from an intravenous infusion set or other administration systems.

- **Never use an infusion or intravenous administration tubing set for more than one patient**.[1] Infusion and intravenous sets are single-patient use items and must be used according to applicable policies and guidelines. These devices are to be used on one patient only and must never be used between patients.

- **Never reuse a syringe or needle to withdraw medication from a multidose vial (MDV)**.[2,32-34] A new sterile syringe and needle or access device are required each time an MDV is accessed.[2,17,33-35]

- **Avoid use of MDV for more than one patient. Practitioners should avoid using MDVs if at all possible**.[17,33,34,36] If MDV must be used, the practitioner should consider using that MDV on only one patient.[14,18,37,38] Although MDVs contain a preservative, they still may become contaminated with infectious agents due to unsafe practices that are not evident.

- **Do not access an MDV in the immediate patient treatment area** unless the MDV is dedicated to a single patient and discarded immediately thereafter.[1,34,39]

- **Never reenter a single-dose medication vial, ampoule or intravenous infusion bag**.[14,32,39,40] It is not appropriate to prepare multiple intravenous flush syringes for single

or multiple patients from the same single-dose intravenous solution bag or bottle (e.g., normal saline).[2,18,41] It is not appropriate to prepare multiple fentanyl, midazolam, or propofol syringes for the same or multiple patients from the same single-dose medication vial, ampoule, or solution. Do not store a single-dose medication vial for future use. Do not reenter a single-dose medication vial, **even for the same patient**.

- **When accessing medication vials**, complete hand hygiene, don clean gloves, use a new sterile needle, and cleanse the access diaphragm with 70% alcohol prior to needle insertion.[25,42]

Gels, Lubricants, and Ointments

Gels, ointments, and lubricants require proper handling and use as they can potentially serve as vehicles for the transmission of pathogens if not managed appropriately. Handle and use these products in a way that mitigates the risk of cross-contamination and subsequent infections.[1]

- Dedicate ointments, gels, and lubricants to a single patient when possible.
- Use sterile skin prep agents when indicated.

Chapter Glossary

Administration: The direct application of a sterile product or preparation to a single patient by injecting, infusing, or otherwise providing a sterile product or preparation in its final form.

Beyond-use date (BUD): The date, or hour and the date, after which a CSP must not be used, stored, or transported. The date is determined from the date and time the preparation is compounded.

Compounded sterile preparation (CSP): A preparation intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance.

Compounding: The process of combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance to create a sterile preparation.

Compounding record: Documents the compounding of each CSP.

Repackaging: The act of removing a sterile product or preparation from its original primary container and placing it into another primary container, usually of smaller size without further manipulation.

References

1. Siegel JD, Rhinehart E, Jackson M, Chiarello L, Health Care Infection Control Practices Advisory C. 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Health Care Settings. *Am J Infect Control*. Dec 2007;35(10 Suppl 2):S65-164. doi:10.1016/j.ajic.2007.10.007
2. Protect Patients Against Preventable Harm from Improper Use of Single–Dose/Single–Use Vials. Centers for Disease Control and Prevention. Accessed March 14, 2023. https://www.cdc.gov/injectionsafety/cdcposition-singleusevial.html
3. Safe injection practices to prevent transmission of infections to patients. Centers for Disease Control and Prevention. Accessed March 14, 2023. www.cdc.gov/injectionsafety/ip07_standardprecaution.html

4. American Association of Nurse Anesthesiology. Safe Injection Guidelines for Needle and Syringe Use. Aug 2022
5. Centers for Disease Control and Prevention. One & Only Campaign. Accessed May 9, 2024, https://www.cdc.gov/injectionsafety/one-and-only.html
6. Information for providers. Centers for Disease Control and Prevention. Accessed March 14, 2023. www.cdc.gov/injectionsafety/providers.html
7. Centers for Disease Control and Prevention. The Impact of Unsafe Medical Injections in the U.S. . Accessed May 9, 2024, https://www.cdc.gov/injectionsafety/PDF/Unsafe-Medical-Injections-Handout-P.pdf
8. The United States Pharmacopeial Convention. Accessed Jul 9, 2024, www.usp.org
9. The United States Pharmacopeial Convention. General Chapter <797>. Accessed Jul 9, 2024, https://www.usp.org/compounding/general-chapter-797
10. American Society of Health-System Pharmacists. USP <797> Key Changes. Updated 2003. Accessed Jul 9, 2024, https://www.ashp.org/-/media/assets/pharmacy-practice/resource-centers/compounding/docs/USP-797-Key-Changes.pdf
11. The United States Pharmacopeial Convention. Legal Recognition of USP Standards. Accessed Jul 9, 2024, https://www.usp.org/about/legal-recognition
12. Injection safety. Centers for Disease Control and Prevention. Accessed March 14, 2023. www.cdc.gov/injectionsafety/
13. van Vlymen JM, Magnus J, Jaeger M, et al. Hepatitis C Contamination of Medication Vials Accessed with Sterile Needles and Syringes. *Anesthesiology*. Aug 2019;131(2):305-314. doi:10.1097/ALN.0000000000002772
14. Fischer GE, Schaefer MK, Labus BJ, et al. Hepatitis C virus infections from unsafe injection practices at an endoscopy clinic in Las Vegas, Nevada, 2007-2008. *Clin Infect Dis*. Aug 1 2010;51(3):267-73. doi:10.1086/653937
15. Rathore MH, Jackson MA, Committee On Infectious Diseases. Infection Prevention and Control in Pediatric Ambulatory Settings. *Pediatrics*. Nov 2017;140(5)doi:10.1542/peds.2017-2857

16. King CA, Ogg M. Safe injection practices for administration of propofol. *AORN J*. Mar 2012;95(3):365-72. doi:10.1016/j.aorn.2011.06.009
17. Moore ZS, Schaefer MK, Hoffmann KK, et al. Transmission of hepatitis C virus during myocardial perfusion imaging in an outpatient clinic. *Am J Cardiol*. Jul 1 2011;108(1):126-32. doi:10.1016/j.amjcard.2011.03.010
18. Dolan SA, Arias KM, Felizardo G, et al. APIC position paper: Safe injection, infusion, and medication vial practices in health care. *Am J Infect Control*. Jul 1 2016;44(7):750-7. doi:10.1016/j.ajic.2016.02.033
19. Muscarella LF. Infection control and its application to the administration of intravenous medications during gastrointestinal endoscopy. *Am J Infect Control*. Aug 2004;32(5):282-6. doi:10.1016/j.ajic.2003.10.014
20. Denault D, Gardner H. OSHA Bloodborne Pathogen Standards. *StatPearls*. 2022.
21. Perz JF, Thompson ND, Schaefer MK, Patel PR. US outbreak investigations highlight the need for safe injection practices and basic infection control. *Clin Liver Dis*. Feb 2010;14(1):137-51; x. doi:10.1016/j.cld.2009.11.004
22. Perceval A. Consequence of syringe-plunger contamination. *Med J Aust*. May 17 1980;1(10):487-9. doi:10.5694/j.1326-5377.1980.tb135048.x
23. Huey WY, Newton DW, Augustine SC, Vejraska BD, Mitrano FP. Microbial contamination potential of sterile disposable plastic syringes. *Am J Hosp Pharm*. Jan 1985;42(1):102-5.
24. Olivier LC, Kendoff D, Wolfhard U, Nast-Kolb D, Nazif Yazici M, Esche H. Modified syringe design prevents plunger-related contamination--results of contamination and flow-rate tests. *J Hosp Infect*. Feb 2003;53(2):140-3. doi:10.1053/jhin.2002.1347
25. WHO Best Practices for Injections and Related Procedures Toolkit. Geneva: World Health Organization; 2010 Mar 2, Best Practices for Injection. Available from: https://www.ncbi.nlm.nih.gov/books/NBK138495/.
26. Baillie JK, Sultan P, Graveling E, Forrest C, Lafong C. Contamination of anaesthetic machines with pathogenic organisms. *Anaesthesia*. Dec 2007;62(12):1257-61. doi:10.1111/j.1365-2044.2007.05261.x

27. Jeske HC, Tiefenthaler W, Hohlrieder M, Hinterberger G, Benzer A. Bacterial contamination of anaesthetists' hands by personal mobile phone and fixed phone use in the operating theatre. *Anaesthesia*. Sep 2007;62(9):904-6. doi:10.1111/j.1365-2044.2007.05172.x
28. Loftus RW, Koff MD, Burchman CC, et al. Transmission of pathogenic bacterial organisms in the anesthesia work area. *Anesthesiology*. Sep 2008;109(3):399-407. doi:10.1097/ALN.0b013e318182c855
29. Loftus RW, Muffly MK, Brown JR, et al. Hand contamination of anesthesia providers is an important risk factor for intraoperative bacterial transmission. *Anesth Analg*. Jan 2011;112(1):98-105. doi:10.1213/ANE.0b013e3181e7ce18
30. Kawakami Y, Tagami T. Pumping infusions with a syringe may cause contamination of the fluid in the syringe. *Sci Rep*. Jul 29 2021;11(1):15421. doi:10.1038/s41598-021-94740-1
31. Munoz-Price LS, Bowdle A, Johnston BL, et al. Infection prevention in the operating room anesthesia work area. *Infect Control Hosp Epidemiol*. Jan 2019;40(1):1-17. doi:10.1017/ice.2018.303
32. Branch-Elliman W, Weiss D, Balter S, Bornschlegel K, Phillips M. Hepatitis C transmission due to contamination of multidose medication vials: summary of an outbreak and a call to action. *Am J Infect Control*. Jan 2013;41(1):92-4. doi:10.1016/j.ajic.2012.01.022
33. Folkema A, Wang HL, Wright K, et al. An outbreak of hepatitis C virus attributed to the use of multi-dose vials at a colonoscopy clinic, Waterloo Region, Ontario. *Can Commun Dis Rep*. May 7 2021;47(4):224-231. doi:10.14745/ccdr.v47i04a07
34. Miller DC, Smith C. The Safe Use of Multidose and Single-Dose Vials. *Pain Med*. May 1 2019;20(5):1047-1048. doi:10.1093/pm/pny314
35. Arrington ME, Gabbert KC, Mazgaj PW, Wolf MT. Multidose vial contamination in anesthesia. *AANA J*. Dec 1990;58(6):462-6.
36. Rehan HS, Chopra D, Sah RK, Chawla T, Agarwal A, Sharma GK. Injection practices of healthcare professionals in a Tertiary Care Hospital. *J Infect Public Health*. Apr 2012;5(2):177-81. doi:10.1016/j.jiph.2012.01.001
37. Perez F, Deshpande A, Kundrapu S, Hujer AM, Bonomo RA, Donskey CJ. Pseudo-outbreak of Klebsiella oxytoca spontaneous bacterial peritonitis attributed to contamination of multidose vials of

culture medium supplement. *Infect Control Hosp Epidemiol*. Feb 2014;35(2):139-43. doi:10.1086/674857

38. Bhatia M, Mishra B, Loomba PS, Dogra V. A pilot study for evaluation of knowledge and common practises of nursing staff regarding use of multidose injection vials and their microbial contamination rate in a super-specialty hospital. *J Educ Health Promot*. 2018;7:120. doi:10.4103/jehp.jehp_73_18
39. Silberzweig JE, Khorsandi AS, Dixon RG, Gross K, Nikolic B. Society of Interventional Radiology position statement on injection safety: improper use of single-dose/single-use vials. *J Vasc Interv Radiol*. Jan 2013;24(1):111-2. doi:10.1016/j.jvir.2012.09.031
40. Centers for Disease Control and Prevention. Infection control requirements for dialysis facilities and clarification regarding guidance on parenteral medication vials. *MMWR Morb Mortal Wkly Rep*. Aug 15 2008;57(32):875-6.
41. Greeley RD, Semple S, Thompson ND, et al. Hepatitis B outbreak associated with a hematology-oncology office practice in New Jersey, 2009. *Am J Infect Control*. Oct 2011;39(8):663-670. doi:10.1016/j.ajic.2010.11.011
42. The Joint Commission. Preventing infection from the misuse of vials. *Sentinel Event Alert*. Jun 16 2014;(52):1-6.

The *Infection Control Guide for Certified Registered Nurse Anesthetists* was adopted by the AANA Board of Directors in 1992 and revised in 1993, 1997, November 2012. In February 2015, the AANA Board of Directors archived the guide and adopted the *Infection Prevention and Control Guidelines for Anesthesia Care*.