



## Ambulatory Surgery Infection Control Workshop

### Safe Injection Practices FAQ

**Q. Why is the beyond-use date for open multidose vials (MDVs) 28 days?**

A. According to the United States Pharmacopeia (USP 797), MDVs are formulated for removal of portions on multiple occasions because they contain antimicrobial preservatives. The 28-day beyond-use date after initially entering, opening, or puncturing an MDV is related to antimicrobial effectiveness testing.<sup>1</sup> <http://www.usp797.org/QA-E5.htm>

**Q. Is it necessary to use a new alcohol pad for cleaning more than one vial?**

A. An alcohol pad that has been opened, handled, and used to clean contaminants from a vial septum is considered contaminated after use and is to be discarded.

**Q. Can medications be prepared or stored in a procedure room in an area clearly marked “clean”?**

A. Facilities should check with their regulatory agencies for specific instructions in the absence of a clean medication preparation area outside the procedure room. The facility should select a process from recommendations of nationally recognized guidelines. For example:

- The Centers for Medicare and Medicaid Services (CMS) Infection Control Surveyor Worksheet—Medication vials are not to be stored or accessed in the immediate area of direct patient contact (not at the bedside).<sup>2</sup> [http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107\\_exhibit\\_351.pdf](http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107_exhibit_351.pdf)
- The Association of periOperative Registered Nurses (AORN) 2013 standards—Do not store MDVs in the immediate direct patient contact area, keep MDVs separate from single-dose vials (SDVs), and do not store vials in the anesthesia cart unless using prefilled syringes.<sup>3</sup>
- Centers for Disease Control and Prevention (CDC): medication preparation—Medications should be drawn up in a designated, clean medication preparation area not adjacent to areas where potentially contaminated items are placed. Contaminated items include syringes, needles, intravenous (IV) tubing, blood collection tubes, needle holders, and soiled equipment used in any procedure.<sup>4,5</sup> [http://www.cdc.gov/injectionsafety/providers/provider\\_faqs.html](http://www.cdc.gov/injectionsafety/providers/provider_faqs.html)
- CDC: MDVs—If used for more than one patient, MDVs should not be stored or accessed in the immediate patient treatment area (e.g., patient room, bay, operating room).<sup>4,5</sup>
- CDC isolation guidelines, 2007—Do not keep MDVs in the immediate patient treatment areas.<sup>6</sup> <http://www.cdc.gov/ncidod/dhqp/pdf/isolation2007.pdf>

**Q. In facilities where there is not a separate room for medication reconstitution, such as the locked medication closet being in a different location in the facility, and the medication refrigerator is in a kitchen in another location, what is the best location to reconstitute medications? Is it acceptable to reconstitute medications in the procedure room on the counter or in the kitchen space?**

A. According to the CDC standard precautions for injection safety, draw-up medications should be drawn up in the medication room or in a designated clean area that is free of any items potentially contaminated with blood or

body fluids (for example, equipment that has been used, such as syringes, needles, IV tubing, blood collection tubes, needle holders). That designation would also include used surgical equipment. Mixing or preparing IV medications for immediate use (one hour) in an operating room setting is an exemption to the sterile USP standards for preparing compounded sterile products, and this should be done using strict aseptic technique in a clean space dedicated to medication preparation.<sup>4-7</sup>

**Q. Is it acceptable to locate a sharps disposal container on the counter in the procedure room next to other patient care equipment? Should the containers be stored in a wall holder as far from patient equipment as possible?**

A. Sharps containers should not be stored on a clean-use counter. Consider a wall-mounted container in a soiled equipment area or a floor model on wheels. The location of the sharps container should be as close to the point of use as possible for Occupational Safety and Health Administration compliance.<sup>4,5,8</sup>  
[http://www.osha.gov/SLTC/bloodborne pathogens/gen\\_guidance.html](http://www.osha.gov/SLTC/bloodborne pathogens/gen_guidance.html)

**Q. Is it acceptable to inject only half of a reconstituted vial of penicillin into the IV bag then leave the rest in the syringe and put it in the fridge for subsequent doses, since in that process it never comes into contact with a patient? Can the "extra" solution left in the syringe be used on a different patient within the time limit appropriate for the medication?**

A. Reconstituted medications are considered compounded sterile preparations (CSPs) and should be administered within one hour, according to USP standards. A syringe should never be used on a second patient. While it may not have come in contact with microscopic viral or bacterial particles from the patient's IV line, there is still the potential for airborne or *unrecognized* direct or indirect contamination during handling. Refrigeration will not stop the proliferation of organisms in or on the second syringe. The more time elapses between uses, the more time there is for viral and bacterial growth, even in a bacteriostatic solution. You may consider scheduling a meeting with your administrator, medical director, infection preventionist, risk manager, and pharmacy consultant to work out the details of how to comply with these practices in the daily workflow and in the medication ordering and purchasing process. The Institute for Safe Medication Practices advises to stress expiration dates and to label medications appropriately. Immediate-use medications cannot be stored for later use.<sup>1,6,9</sup>

**Q. Is it acceptable to insert and leave in place an anti-reflux access device on an MDV of saline flush when using a completely needleless system, as long as a new syringe is used for each access? Can an IV bag be spiked with a Luer lock device and opened and closed repeatedly until empty for multiple patients?**

A. Spiking a bag, vial, or bottle with a one-way device and leaving it in place increases the microbial contamination risk. The spike collects microorganism contamination from the environment, and the sterile solution is then poured out or withdrawn from a contaminated spout. Spiking a solution with a one-way device and leaving it in place for multiple entries puts patients at risk for infection.

However, there are spiking devices on the market that provide a tight sterile seal with the vial thus avoiding environmental or inadvertent contamination when left in place and that contain manufacturer instructions that state they can remain in place for 28 days once opened. That presupposes that the user has "scrubbed the hub" of the vial with alcohol for 15 seconds and let it dry prior to spiking. Also, with consideration to aseptic technique, the needleless septum and the Luer lock threads must also be scrubbed with alcohol and dry prior to each access. The manufacturers of these devices have single-use verbiage, meaning the devices are only to be used in one vial. When that vial is empty or the 28 days has passed, the devices are to be discarded along with the vial.<sup>6</sup>

- Q. How can reckless unsafe injection behavior that endangers patients be handled?**
- A. A formal proactive failure mode and effects analysis or a retrospective root-cause analysis can be done to highlight and develop action plans for resolution of unsafe practices. Unsafe agency practitioners can be removed from the work schedule. Progressive levels of punitive interventions may be necessary if the clinician was aware of the risk, knowingly put the patient in harm's way, and chose to consciously disregard the risk. Unsafe acts can also be reported to the facility's regulatory body or to the Pennsylvania Patient Safety Authority's anonymous reporting system in accordance with the Medical Care Availability and Reduction of Error Act. The Authority offers educational courses on just culture, which may assist facilities to alleviate this behavior.<sup>10,11</sup>
- Q. How long can a bag of IV solution be kept out of the external wrapper?**
- A. According to the US Food and Drug Administration ([www.fda.gov/psn](http://www.fda.gov/psn)) and the Institute for Safe Medication Practices ([www.ismp.org](http://www.ismp.org)), an IV bag should remain in the external wrapper until ready to use. The internal IV bags may be semipermeable and may lose fluid the longer they are exposed to the air. There is then the potential for the medications diluted in the solutions to become more concentrated. The manufacturer instructions for each bag of IV solution may provide additional information.<sup>12</sup>
- Q. Why is it not acceptable to reuse a syringe attached to a previous patient's IV tubing if the tubing manufacturer says there is no backflow and the physician says it is safe because it is not the same practice as was implicated in the 2008 hepatitis outbreak in the Nevada endoscopy center?**
- A. While there may be no visible backflow of fluids, according to the CDC safe injection guidelines, it is virtually impossible to assure that there is no microscopic backflow of viral or bacterial particles when a syringe is attached anywhere along the IV tubing. While this risky practice may differ from the syringe and vial contamination in the Nevada outbreaks, reusing syringes in this manner constitutes a very dangerous misperception of acceptable standards of safe injection practices.<sup>4,5,13</sup> <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5719a2.htm>
- Q. What is the best way to transport the sterile solution from the vial in the medication room to the sterile field in the operating room?**
- A. A labeled sterile syringe of medication can be transported to the procedure room in an aseptic manner and dispensed into the proper sterile receptacle on the sterile field using sterile technique.<sup>3</sup>
- Q. What precautions are necessary when preparing mixed syringes or vials of medications for injection or irrigation for use on one patient?**
- A. With respect to safe injections, it is important to ensure use of aseptic techniques and use of one syringe and/or one needle for each patient and to discard SDVs and CSPs after one hour. Questions regarding which medications may be mixed can be directed to the pharmacist or to the Institute for Safe Medication Practices.

## [Ambulatory Surgery Infection Control Workshop](#)

### [Disinfection and Sterilization FAQ](#)

- Q. How many years do you have to keep sterilization records?**
- A. Each facility should check with their legal department in order to determine a time frame for disposal or archiving. A facility may wish to develop a policy after appropriate consultation with their legal department.

**Q. Do we need wall barriers between clean and dirty processing areas?**

A. Environmental controls need to be in place in order to keep activities associated with clean instruments separate from activities associated with dirty instruments. Consult the American Institute of Architects (<http://www.aia.org>) for design advice and the Association for the Advancement of Medical Instrumentation (AAMI) for examples of room layout (<http://www.aami.org>).

**Q. How are challenge devices used?**

A. Process challenge device construction and use is described in ST79 of the AAMI guidelines, as well as in many sterilizer manufacturers' instructions for use. <http://www.aami.org/publications/standards/st79.html>

**Q. How can we deal with bleach wipe buildup on everything?**

A. The surface residue can be wiped off with another compatible disinfectant.

**Notes:**

1. Kastango ES. Questions and answers on USP 797 [online]. [cited 2013 Jun 7]. <http://www.usp797.org/QA-E5.htm>.
2. Centers for Medicare and Medicaid Services. Infection control surveyor worksheet [online]. 2010 Nov 24 [cited 2013 Jun 7]. [http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107\\_exhibit\\_351.pdf](http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107_exhibit_351.pdf).
3. Association of periOperative Registered Nurses (AORN). *Perioperative standards and recommended practices*. 2011 ed. Denver (CO): AORN Inc.; 2011.
4. Centers for Disease Control and Prevention. Frequently asked questions (FAQs) regarding safe practices for medical injections [online]. [cited 2013 Jun 7]. [http://www.cdc.gov/injectionsafety/providers/provider\\_faqs.html](http://www.cdc.gov/injectionsafety/providers/provider_faqs.html).
5. Centers for Disease Control and Prevention. Medication administration questions [online]. [cited 2013 Jun 7]. [http://www.cdc.gov/injectionsafety/providers/provider\\_faqs\\_med-admin.html](http://www.cdc.gov/injectionsafety/providers/provider_faqs_med-admin.html).
6. Dolan SA, Felizardo G, Barnes S, et al. APIC position paper: safe injection, infusion, and medication vial practices in health care. *Am J Infect Control* 2010 Apr;38(3):167-72.
7. Siegel JD, Rhinehart E, Jackson M, et al. 2007 Guideline for isolation precautions: preventing transmission of infectious agents in healthcare settings [online]. [cited 2013 Jun 7]. <http://www.cdc.gov/hicpac/2007IP/2007isolationPrecautions.html>.
8. Occupational Safety and Health Administration. Occupational exposure to bloodborne pathogens; needlestick and other sharps injuries; final rule [online]. Fed Regist 2001 Jan 18 [cited 2013 Jun 7]. [http://www.osha.gov/pls/oshaweb/owadisp.show\\_document?p\\_table=FEDERAL\\_REGISTER&p\\_id=16265](http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=FEDERAL_REGISTER&p_id=16265).
9. Centers for Disease Control and Prevention. Injection safety: information for providers [online]. [cited 2013 Jun 7]. <http://www.cdc.gov/injectionsafety/providers.html>.
10. Marx D. Patient safety and the "just culture" [slide presentation online]. 2007 [cited 2013 Jun 7]. [http://www.health.ny.gov/professionals/patients/patient\\_safety/conference/2007/docs/patient\\_safety\\_and\\_the\\_just\\_culture.pdf](http://www.health.ny.gov/professionals/patients/patient_safety/conference/2007/docs/patient_safety_and_the_just_culture.pdf).
11. Medical Care Availability and Reduction of Error (Mcare) Act, 2002 Pa. Laws 154, No. 13. Also available at <http://patientsafetyauthority.org/PatientSafetyAuthority/Governance/Pages/Act13.aspx>.
12. Store IV bags in their overwraps [online]. FDA Patient Saf News 2003 December [cited 2013 Jun 7]. <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/printer.cfm?id=186>.
13. Centers for Disease Control and Prevention. Acute hepatitis C virus infections attributed to unsafe injection practices at an endoscopy clinic--Nevada 2007 [online]. MMWR Morb Mortal Wkly Rep 2008 May 16 [cited 2013 Jun 7]. <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5719a2.htm>.

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