

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 endoscopy clinic infected 19 patients with HCV by improperly reusing syringes and contaminating a multi-dose anesthesia medication vial subsequently used for multiple patients.³ A similar HCV outbreak because of unsafe injection practices occurred in New York in 2002 and 2007, affecting a total of 102 patients.¹³ In 2002, nearly 100 Nebraska hematology oncology clinic patients contracted HCV after a health care worker (HCW) responsible for medication infusions routinely used the same syringe and needle from a HCV-positive patient's blood draw to obtain saline flush solution from an IV bag. As a result, the patient's blood on the needle of the syringe was inoculated into the IV bag, which was then used as flushing solution for several other patients.⁹ One of the most recent HCV

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Conflicts of interest: None to report.

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0196-6553/\$36.00

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doi:10.1016/j.ajic.2010.01.001

outbreaks occurred at an endoscopy center in Nevada in 2008, again because of unsafe injection practices involving reusing syringes and sharing single-use medication vials between patients. This outbreak received significant media attention because, in part, of the fact that 63,000 persons were identified as being at potential risk for acquiring hepatitis. More than 12,000 patients have been tested to date, and at least 115 patients have been found to be infected with HCV. The investigation is ongoing.¹²

The Association for Professionals in Infection Control and Epidemiology (APIC) recognizes these outbreaks as 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. Responsibility for the oversight and monitoring of patient safety must be clearly designated in health care settings to ensure that staff education is available for all health care professionals providing such services to patients. Furthermore, periodic monitoring for absolute adherence to safe injection practices in health care settings is vital to ensure effective engineering of and adherence to safe practices in everyday patient care.

In 2008, the United States Pharmacopeia (USP) published a revised USP General Chapter <797> Pharmaceutical Compounding—Sterile Preparations.¹⁴ These standards apply to compounded sterile preparations (CSPs), which include compounded biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals, including but not limited to the following dosage forms that must be sterile when they are administered to patients: aqueous bronchial and nasal inhalations, baths and soaks for live organs and tissues, injections (eg, colloidal dispersions, emulsions, solutions, suspensions, irrigations for wounds and body cavities, ophthalmic drops and ointments, and tissue implants). This includes manufactured bags or bottles of intravenous or irrigation fluid that may or may not contain additives and any solution drawn into a syringe for injection.

USP <797> applies to the pharmacy setting as well as to *all persons who prepare* medications that are administered and *all settings in which they are prepared* (eg, hospitals, other health care institutions, patient treatment clinics, physician's offices, and others). This chapter includes the standards for preparing, labeling, and time frames for discarding prepared medications. Pharmacies compound sterile preparations in an International Organization for Standardization (ISO) class 5 environment with primary engineering control devices, including laminar flow hoods, located in a "cleanroom" with stringent air quality, ventilation, personal protective equipment, and personnel and surface sanitation requirements to maintain the sterility of

the preparation and safety of the compounding personnel. HCWs who prepare medications outside of ISO class 5 settings do so in environments with environmental particulates and microorganisms. Such settings and immediate-use preparation practices can potentially cause contamination of vials, IV solutions, and syringes from both airborne and direct contact sources. For example, clinicians who prepare injections and infusions may perform hand hygiene but not wear sterile gloves and a mask or contain their hair during preparation. When they remove the cap from the needle and insert it into the vial while breathing over the sterile needle and vial stopper, they create the potential for microbial contamination. Spiking a bag, vial, or bottle with a 1-way device and leaving it in place also 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. For this reason, spiking any solution with a 1-way device and leaving it in place for multiple entries puts patients at risk for infection and is strongly discouraged.

According to USP <797>, immediate-use CSPs (prepared outside the ISO 5 environment) are exempted from the rigorous environmental purity standards and personnel cleansing and garbing practices that are required for all other categories of CSPs in USP <797>.¹⁴ Immediate-use CSPs allow for certain sterile products to be prepared (compounded) without the need for special facilities (eg, clean room or ISO class 5 hood) and practices (eg, full cleansing or gowning). Dissolving, diluting, measuring, and mixing non-nutrient sterile injections using sterile devices (eg, ampuls, bags, needles, syringes, and vials) in clinical practice facilities (eg, patient care areas in hospitals, clinics, and physician offices) typify the conditions of what USP <797> calls "Immediate-use CSPs." USP <797> requires a 1-hour limit from completing preparation (eg, spiking an IV bag) until beginning administration of the immediate-use CSPs to patients. Their rationale is that the 1-hour limit is expected to preclude microbial population increase when accidental contamination of such drugs occurs with small quantities of microorganisms. Once microbial contamination occurs, the organism replication can begin within 1 to 4 hours with exponential growth occurring rapidly afterward.

For settings that prepare and use immediate-use CSPs (eg, operating rooms, ambulatory surgery centers, specialty clinics, and others), the cost of medication disposal, if administration has not begun 1-hour after preparation, can be daunting. USP recommends that these settings explore the possibility of having the pharmacy prepare the needed injectables and infusions in the ISO class 5 environment by properly trained, cleansed, and garbed personnel to prolong

the usability of the CSPs. Most such CSPs according to USP <797> would then be classified “low risk level,” for which the room temperature beyond-use date is 48 hours. This means that most CSPs prepared in a pharmacy ISO class 5 environment would be considered low risk level and could be stored for 48 hours, at which time the CSP would be discarded if not used. Another option is to locate a manufactured injectable product (eg, prepackaged syringe) that is discarded according to the manufacturer’s expiration date.

However, it is important to recognize that many perioperative and clinical settings do not have ISO class 5 environments readily available. Clinicians spike IV solutions and prime IV tubing in operating rooms/departments and on patient care units in advance of their intended use so as to improve work flow and productivity. This advance preparation can occur at set time frames on the morning of or the evening prior to their intended use. USP <797> defines the time frame between preparation and initiating administration as 1 hour. This recommendation for immediate-use CSPs is a controversial unresolved issue and in actual practice difficult to comply with in certain settings. The APIC *does not support* the advance preparation (the night before or hours before administration) of immediate-use IV bags or syringes. The APIC *supports* the practice of preparing parenteral medications as close as possible to the time of administration and stresses the importance of educating designated staff, using tactile learning methods, verifying the competency of those performing the procedure, and periodic monitoring to assure compliance with aseptic technique and prevention of contamination. Proper technique is paramount to preventing accidental contamination during the process. Allowing only trained staff to prepare parenteral medications can decrease the risk of error/contamination. Preparation of parenteral medications must be performed in a clean, dry work space that is free of clutter and obvious contamination sources (eg, water, sinks). Prepared parenteral solutions should be stored in a controlled environment to limit the risk of tampering.

Another controversial and unresolved issue is the beyond-use date for opened multi-dose vials. The beyond-use date is the date after which an accessed product must be discarded. USP <797> requires medication multi-dose vials for injections be given a beyond-use date that is 28 days after initial stopper penetration (USP chapter <51>)¹⁴ unless the product labeling (package insert) states otherwise. USP <797> requires that the vial be dated to reflect the date opened and/or beyond-use date. On the other hand, the Centers for Disease Control and Prevention (CDC) indicates that multi-dose vials can be used until the manufacturer’s expiration date unless there are any concerns regarding the sterility of the product.¹⁵

The US Food and Drug Administration defines an expiration date as “the date placed on the container/labels of a drug product designating the time during which a batch of the product is expected to remain within the approved shelf life specifications if stored under defined conditions and after which it may not be used.”¹⁶ Given the fact that this practice is variable and remains an unresolved issue at this time, the APIC recommends that facilities develop their policies and procedures based on either one of these recommendations. Rather than concentrate solely on beyond-use date or manufacturer expiration date, users of multi-dose vials must focus on the following: adhering to strict aseptic technique when accessing the vial; using a *new* sterile needle and a *new* sterile syringe for every access; removing all access devices from the vial; storing the vial in a clean, protected location according to the manufacturer’s directions (eg, at room temperature or refrigerated); and ensuring that any vial whose sterility may be comprised is immediately discarded. Survey and accrediting agencies expect facilities to have written policies, based on the guidelines selected for use, that are consistently followed by staff.

The APIC strongly supports adherence to the following safe injection, infusion, and medication vial practices.¹⁵⁻²⁸

ASEPTIC TECHNIQUE: IN LESS THAN AN ISO 5 ENVIRONMENT

- Perform hand hygiene (handwashing with soap and water or by application of a 60% or greater alcohol-based (In the United States, the alcohol component is predominantly ethyl alcohol (ethanol) or isopropyl alcohol.) hand sanitizer rub that is allowed to dry) before 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 because sterility cannot be ensured.
- Discard all opened vials, IV solutions, and prepared or opened syringes that were involved in an emergency situation.
- Avoid contacting sterile drugs and sterile areas of devices and containers with non-sterile objects and/or secretions and particles shed from personnel.²⁷

IV SOLUTIONS

- Never use IV solution containers (eg, bags, bottles) to obtain flush solutions or for any other purpose for more than 1 patient.

- Never use infusion supplies, such as needles, syringes, flush solutions, administration sets, or IV fluids, on more than 1 patient.
- Prepare IV solutions and medications as close to administration as feasible. The time frame that can be allowed between the preparation and initiation of the administration of non-nutrient IV solutions that have been spiked or have had admixtures added in less than an ISO class 5 environment remains an *unresolved issue*. With limited data on actual contamination in real practice and linking contamination with patient infection, recommending a definitive time frame is not feasible at this time.
- Disinfect IV ports and vial stoppers by wiping and using friction with a sterile 70% isopropyl alcohol,^{14,17} ethyl/ethanol alcohol, iodophor,¹⁶ or other approved antiseptic swab. Allow the port to dry before accessing.
- Use a USP <797> primary engineering control with an ISO class 5 atmosphere to prepare admixtures of IV solutions when immediate use is not required. An admixture is defined as the addition of one or more concentrated drug injections from ampules and vials to larger volume bags and bottles of intravenous infusion fluids such as dextrose and sodium chloride injections.
- Do not use spiking devices, even if they have a 1-way valve, to remove fluid from IV bottles/bags for multiple uses or patients.

FLUSHING

- Use single-dose containers for flush solutions, whenever possible.
- If a multi-dose vial must be used, use it for only 1 patient and then discard it. Each entry into the multi-dose vial (dedicated to that patient) must be made with a new, unused sterile needle and new, unused sterile syringe.

SYRINGES

- Remove the sterile needle/cannulas and/or syringe from the package immediately before use.
- Never use a syringe for more than 1 patient even if the needle has been changed between patients. Changing the needle but not the syringe is unacceptable.
- Use a new syringe and a new needle for each entry into a vial or IV bag.
- Utilize sharps safety devices whenever possible.
- Discard syringes, needles, and cannulas after use directly on an individual patient or in an IV administration system.
- Dispose of used needles/syringes at the point of use in an approved sharps container.
- Do not prepare medication in one syringe to transfer to another syringe, ie, 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.

- Never store or transport syringes in clothing or pockets.
- Prepare syringes as close to administration as feasible.

VIALS

- Always follow the manufacturer's instructions for storage and use.
- Use single-use or single-dose vials whenever possible.
- Always use a new sterile syringe and new needle/cannula when entering a vial. Never enter a vial with a syringe or needle/cannula that has been previously used (eg, to inject a patient or access a medication vial).
- Cleanse the access diaphragm of vials using friction and a sterile 70% isopropyl alcohol,^{14,17} ethyl alcohol, iodophor,¹⁷ or other approved antiseptic swab. Allow the diaphragm to dry before inserting any device into the vial.
- Discard single-dose vials after use. Never use them again for another patient.
- Discard any vial that has been placed on a contaminated surface or a used procedure tray or that has been used during an emergency procedure.
- Use multi-dose medication vials for a single patient whenever possible and access all vials using a new sterile syringe and new needle/cannula adhering to aseptic technique. The risk of viral hepatitis transmission posed by multi-dose vials has been clearly demonstrated and mandates a practice of using 1 vial per 1 patient whenever possible. Infection transmission risk is reduced when multi-dose vials are dedicated to a single patient.
- Keep multi-dose vials away from the immediate patient environment.
- Never store or transport vials in clothing or pockets.
- Never pool or combine leftover contents of vials for later use.
- Never leave a needle, cannula, or spike device (even if it has a 1-way valve) inserted into a medication vial rubber stopper because it leaves the vial vulnerable to contamination.
- The beyond-use date and disposal of opened multi-dose medication vials for injection and/or IV administration remains an *unresolved issue* with differing opinions on the approach.
 - USP <797> requires a beyond-use date of 28 days after initial stopper penetration (USP chapter <51>)¹⁴ unless the manufacturer's expiration date will be reached before 28 days or the product labeling (package insert) states otherwise. When

following USP, date the vial to reflect the date opened and/or beyond use date. Discard the vial when the beyond-use date has been reached.

- CDC indicates that the beyond-use date can be based on the manufacturer's expiration date.¹⁵ When following CDC guidelines, date the vial to reflect the date opened.
- Regardless of the beyond-use date or manufacturer's expiration date, a vial should be discarded sooner if the sterility of the product is in question.
- The CDC Immunization Program recommends discarding of vaccines according to the manufacturer's expiration date.²⁷
- Facilities should develop a policy and procedure for their institution after reviewing and weighing these recommendations, implement an education and competency evaluation program for staff, and consider audits for adherence to the facility's policy/procedure.
- Inspect vials and discard if sterility is known or suspected 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 because sterility cannot be guaranteed.

BLOOD GLUCOSE MONITORING DEVICES

- Assign a glucometer to each individual patient if possible. Clean and disinfect glucometers if they must be shared between multiple patients.
- Restrict the use of finger stick capillary blood sampling devices to individual patients.
- Maintain supplies and equipment, such as finger stick devices and glucometers, within individual inpatient rooms, if possible.
- Use single-use lancets that permanently retract after puncture.
- Never reuse finger stick devices and lancets. Dispose of them at the point of use in an approved sharps container. Lancets in a pen should be removed by mechanical means (hemostat) to avoid finger contact.
- Thoroughly clean all visible soil or organic material (eg, blood) from the glucometer before disinfection.
- Disinfect the exterior surfaces of the glucometer after each use following the manufacturer's directions. Use an Environmental Protection Agency-registered disinfectant effective against HBV, HCV, and HIV or a 1:10 bleach solution (1 part bleach to 9 parts water).

HCW

- Provide the HBV vaccination series to all previously unvaccinated health care personnel whose activities involve contact with blood or body fluids.¹⁹

- Check and document postvaccination titers 1 to 2 months after completion of the vaccination series.¹⁹
- Immediately report body fluid exposures and needle-stick/sharps injuries.
- Ensure that staff preparing or administering injections or other parenteral medications are competent to perform these tasks aseptically.
- Periodically assess compliance with safe injection practices by observing and evaluating all personnel performing these procedures.

CONCLUSION

The use of safe injection practices is critical to prevent microbial contamination of products administered to patients. The ongoing reports of HBV and HCV transmission to patients and ongoing outbreaks of bacterial infections²⁹⁻³¹ indicate that much more is needed to ensure that these preventive practices are being scrupulously followed in all health care settings. HCWs and their managers must understand and practice these procedures safely. Administrators of medical facilities must be aware of safe injection practices and ensure that employees have the knowledge, training, and equipment to safely implement these procedures. It is critical that injectable medications, IV delivery systems, and blood glucose monitoring are used safely in all health care settings. As infection preventionists, we have an obligation to reiterate and ensure that safe injection, infusion, and medication vial practices are the absolute standard of care throughout various health care settings and across the continuum of care. We must take a lead role in promoting adherence by HCWs to these safe practices to protect the health and safety of our patients.

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