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APIC POSITION PAPER: SAFE INJECTION, INFUSION, AND MEDICATION VIAL PRACTICES IN HEALTH CARE (2016)

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BACKGROUND

The transmission of bloodborne viruses and other microbial pathogens to patients during routine healthcare procedures continues to occur because of the use of improper injection, infusion, medication vial, and point-of-care testing practices by healthcare personnel (HCP).[1-18] These unsafe practices occur in various clinical settings throughout the United States and result in unacceptable and devastating events for patients. This document updates the Association for Professionals in Infection Control and Epidemiology (APIC) 2010 position paper on safe injection, infusion, and medication vial practices in healthcare.[19]

More than 50 outbreaks of viral and bacterial infections occurred in the United States during 1998-2014 because of these unsafe medical practices.[1-4] These outbreaks resulted in the transmission of hepatitis B virus (HBV), hepatitis C virus (HCV), and bacterial pathogens to more than 700 patients.[1-4] During 2001-2012 an estimated 150,000 patients received notification recommending that they undergo bloodborne pathogen testing after they were potentially exposed to unsafe injections.[18] The unsafe practices used by healthcare 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 use and maintenance of finger stick devices and glucometer equipment used on multiple patients.

Transmission of Infection Associated with Medication Handling and Administration Practices

In 2002, the Oklahoma State Department of Health was informed of six patients with suspected acute HCV infection who had received treatment from the same pain remediation clinic. An investigation revealed that a nurse anesthetist routinely reused needles and syringes to administer medications through heparin locks that were connected directly to intravenous cannulas. A total

of 69 HCV and 31 HBV infections were identified that probably were acquired in the clinic.[5] In another outbreak, nearly 100 Nebraska hematology/oncology clinic patients contracted HCV after a HCP responsible for medication infusions routinely used the same syringe to draw blood from patients' central vascular catheters and draw catheter-flushing solution from 500-cc saline bags used for multiple patients. As a result, patients' HCV contaminated blood on the needle of the syringe was inoculated into the IV bag, which was then used as flushing solution for other patients.[11] One of the largest HCV outbreaks occurred at an endoscopy center in Nevada in 2008, and was associated with unsafe injection practices involving reusing syringes and sharing single-use medication vials of propofol between patients. This outbreak received significant media attention because over 50,000 persons were identified as being potentially exposed and therefore at risk for acquiring hepatitis C. Eight acute hepatitis C cases were determined to be linked directly to care at the clinic and an additional 106 cases were classified as possibly linked.[6] An investigation of bloodstream infections with *Klebsiella oxytoca* and *Enterobacter cloacae* at a chemotherapy center identified 27 patients having one or both of these organisms. All patients had their central venous catheter flushed with either dextrose or isotonic sodium chloride solution at the clinic. Patient isolates were indistinguishable from isolates obtained from multiple predrawn syringes, intravenous fluid and administration sets used in the clinic. At the start of each day, isotonic sodium chloride solution was pre-drawn from the bag through a 2 way dispensing valve set; the dextrose was pre-drawn directly from the bag. The investigators concluded that the bloodstream infections were associated with use of a contaminated dispensing setup and contaminated bag of IV fluid used for multiple patients.[14]

Transmission of Infection Associated with Point of Care Testing Practices

Outbreaks of hepatitis B associated with blood glucose monitoring have been identified with increasing regularity, particularly in long-term care settings (e.g., nursing homes, assisted living facilities) where residents often require assistance with blood glucose testing and/or insulin administration. In the last 10 years alone, there have been at least 15 outbreaks of HBV infection associated with HCP failing to follow basic principles of infection control when assisting with blood glucose monitoring.[20] Due to under reporting and under recognition of acute infection, the number of outbreaks due to unsafe diabetes care practices identified to date are likely an underestimate. The risk of infection exists in any setting where blood glucose monitoring equipment is shared or those assisting with blood glucose monitoring and/or insulin administration fail to follow basic principles of infection prevention and control.[20] With innovations in the area of point-of-care testing (e.g., blood glucose, coagulation studies, etc.) that involve use of fingerstick devices, opportunities for bloodborne transmission exist due to breaches in protocols and transmission from cross-contamination. Safe injection practices should be adopted with any testing device that has the potential for a bloodborne pathogen exposure.

Transmission of Infection Associated with Drug Diversion

There are an increasing number of reported outbreaks of hepatitis C and bacterial bloodstream infections associated with drug diversion of parenteral medications by HCP. Findings from these investigations have demonstrated that drug diversion by HCP poses a serious threat to patient safety and potentially places large numbers of patients at risk for acquiring infections.[13]

RECOMMENDATIONS

APIC recognizes these outbreaks as unacceptable and believes they could have been prevented by the use of proper aseptic technique in conjunction with proper infection prevention practices for preparing, handling and administering sterile injectable and parenteral medications and proper point-of-care testing practices.

Programs for providing and documenting training and competency evaluations for HCP that prepare, handle, and administer injectable and parenteral medications and conduct point-of-care testing should be implemented in all healthcare settings in which these activities occur. It is vital to patient safety that HCP have the knowledge, skills, behaviors, and ability to perform aseptic technique and follow safe injection, infusion, and medication vial practices. To ensure effective engineering of and adherence to safe practices in everyday patient care in all healthcare settings, responsibility for the oversight and monitoring for absolute adherence to these practices should be assigned to appropriate supervisors.

To promote effective assessment and implementation of engineering and work practice controls, facilities are encouraged to develop an ongoing program for multidisciplinary product review, evaluation, and implementation. This should involve key end users and personnel from occupational/employee health, infection prevention, materials management, and purchasing. Processes should be in place to standardize products, evaluate existing and new devices, trial and support implementation of new products, train personnel, and track feedback after product implementation.

A variety of organizations have published guidelines and standards for compounding and handling sterile injectable and parenteral medications, and for safe injection and infusion practices in healthcare settings.[21-23] To prevent infections related to improper injection, infusion, medication vial, and point-of-care testing practices, healthcare organizations should have a process for developing and implementing evidence based policies and procedures. These should be based on nationally recognized standards and regulatory and accreditation requirements.

The United States Pharmacopeia (USP) General Chapter <797> *Pharmaceutical Compounding—Sterile Preparations* provides practice and quality standards for compounded sterile preparations (CSPs).[21] This includes but is not limited to preparing, labeling and storing, and timeframes for discarding CSPs. USP General Chapter <797> was first published in 2004 and first revised in 2008. The chapter is under revision and was published in September 2015 for public review and comment. Per USP Chapter <797>, CSPs include manufactured sterile products and compounded biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals that must be sterile.

USP Chapter <797> standards apply *to all persons* who compound sterile preparations and *all healthcare settings* in which compounding takes place (e.g., hospitals, patient treatment clinics, physician's offices, ambulatory surgery centers, and other locations and facilities in which CSPs are compounded, stored, and transported). "For the purposes of this chapter, CSPs include any of the following (1) 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 (e.g., colloidal dispersions, emulsions, solutions, suspensions), irrigations for wound and body cavities, ophthalmic drops and ointments, and tissue implants; (2) Manufactured sterile products that are either prepared strictly according to the instructions appearing in manufacturers' approved labeling (product package insert) or prepared differently than published in such labeling."[21]

However, the FDA notes that "compounding does not include mixing, reconstituting, or similar acts that are performed in accordance with the directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling."[24] It is important to recognize that USP Chapter <797> standards have been developed to guide safe compounding practices. They "do not pertain to the *clinical* administration of CSPs to patients via application, implantation, infusion, inhalation, injection, insertion, instillation, and irrigation, which are the routes of administration."[21]

Regardless of who compounds medications, compounding practice should be in accordance with USP Chapter <797> which (except for urgent-use (formerly called immediate-use CSPs) includes the use of an International Organization for Standardization (ISO) Class 5 environment. An ISO Class 5 environment is provided by primary engineering controls (i.e. laminar flow hoods). Additionally, USP Chapter <797> includes requirements for air quality, ventilation, personal protective equipment, personnel hygiene, aseptic work practices, surface disinfection, and personnel training and competency evaluation. According to USP Chapter <797>, urgent-use CSPs (prepared outside the ISO Class 5 environment) are exempted from the requirements described for *Low-Risk Level* CSPs providing certain criteria are met. USP Chapter <797> stipulates that the urgent-use provision is only intended for those situations where there is a need for emergency or immediate patient administration of a SCP. Urgent-use CSPs are not intended for storage for anticipated needs or batch compounding. USP Chapter <797> states that "opened or needle punctured single-dose containers, such as bags, bottles, syringes, and vials of sterile products and CSPs shall be used within 1 hour if opened in worse than ISO Class 5 environments" and "any remaining contents must be discarded."[21] USP Chapter <797> further clarifies the term "shall be used within 1 hour" for urgent-use CSPs to mean "administration begins not later than 1 hour following the start of the preparation of the CSP. If administration has not begun within 1 hour following the start of preparing the CSP, the CSP shall be promptly, properly, and safely discarded." USP's rationale behind the 1 hour timeframe is to limit the potential for microbial proliferation since compounding in worse than ISO Class 5 conditions increases the risk of microbial contamination.[21] Once microbial contamination occurs, organism replication can begin within 1 to 4 hours with exponential growth occurring rapidly afterward.[25] However, one must keep in mind that this standard applies to *compounding practices* (from time of preparation to the initiation of administration) and not to the *administration timeframe.* In clinical practice settings, when CSPs are prepared outside an ISO Class 5 environment, it may sometimes be difficult to adhere to the 1 hour time frame between preparation and initiation of administration to the patient (such as between drawing medication into a syringe and injecting that medication, or between spiking an IV bag and starting the infusion). In these situations, the adoption and application of the USP Chapter <797> 1 hour time frame between preparation and administration in a clinical practice setting has proven challenging.

Many clinical settings do not have ISO Class 5 environments readily available. Clinicians draw up syringes, spike IV solutions and prime IV tubing in perioperative areas, on patient care units, and in other healthcare settings in advance of their intended use so as to improve work flow and productivity. This advance preparation has been known to occur at set time frames on the morning of or the evening prior to their intended use. APIC supports the USP Chapter <797> 1 hour time frame between preparation and initiation of administration in most clinical practice settings/scenarios but acknowledges that in certain settings, this practice can be challenging to safely implement. APIC *does not support* the advance preparation (the night before or many hours before administration) of IV bags or syringes. APIC *supports* the practice of preparing injectable and parenteral medications *as close as possible* to the time of administration and recommends a risk assessment when considering any extension of the 1 hour USP Chapter <797> recommendation. APIC 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 preparation and administration of sterile medications. Allowing only trained staff to prepare parenteral medications can decrease the risk of error and contamination. Preparation of parenteral medications must be performed in a clean, dry work space that is free of clutter and obvious contamination sources (e.g., water, sinks). Prepared parenteral solutions should be stored in a controlled environment to limit the risk of contamination, degradation and tampering. Major factors that contribute to microbial contamination of drugs are the cleanliness of the work environment and the competency and technique of personnel.[26] HCP who prepare sterile injectable and parenteral medications (e.g., withdraw medication from a vial or ampul into a syringe) outside of ISO Class 5 settings for direct patient use do so in environments that likely have microbial, chemical, and physical contamination. Such settings and preparation practices can potentially contribute to contamination of vials, IV solutions, and syringes via touch contact with hands and surfaces, inadvertent introduction of particulate matter or organisms, or poor aseptic technique.[27] For example, clinicians that prepare injections and infusions outside of an ISO Class 5 environment may perform hand hygiene but not wear sterile gloves and a mask or contain their hair during preparation. This may lead to inadvertent contamination of sterile medications.

Spiking a bag, vial, or bottle of sterile fluid with a dispensing device and leaving that device in place to withdraw medication for multiple patients increases the risk for microbial contamination. When performed outside of an ISO Class 5 environment, the device and subsequently the fluid can become contaminated.[14] For this reason, using a dispensing device to spike parenteral solutions outside of an ISO Class 5 environment and leaving it in place to dispense medication for multiple patients puts patients at risk for infection and must be prohibited.

Transporting medications in pockets or clothing is a controversial issue. Assuring medication is safe for patient use is critical. The Association of periOperative Registered Nurses (AORN) and The Joint Commission (TJC) have issued statements on this practice.[28,29] Other professional and accreditation organizations should be consulted as necessary to confirm their position on this practice. According to the 2015 AORN Guidelines for Perioperative Practice, perioperative team members should not prepare medication products in advance and then store them in clothing or

pockets since this practice increases the risk for contamination and errors.[28] At least one medication error resulting in a life-threatening event has been reported involving an anesthesia care professional removing from their pocket and administering a paralytic agent outside of the OR.[30] In 2011, The Joint Commission, issued a statement that allows "carrying of medications in accordance with institutional policy" which includes written medication storage and transport information.[29] Additionally, the policy should include: drug storage; protection during transport (e.g., plastic bag, sealed hard plastic case); administration within 1 hour of preparation; medication security; labeling; and stability.

To ensure safe injection practices in all healthcare settings, a multifaceted approach that focuses on surveillance, oversight, enforcement, and personnel competency, continuing education and accountability will be required.[31] APIC strongly supports adherence to the following safe injection, infusion, medication vial, and point-of-care testing practices.

ASEPTIC TECHNIQUE

- Aseptic technique refers to the use of various barriers and precautions to prevent the transfer of microorganisms from HCP and the environment to the patient during a procedure.[32] Sterile is the absence of all microbes.
- Perform hand hygiene (clean hands with alcohol based hand sanitizer or with soap and water) before accessing supplies, handling vials and IV solutions, preparing or administering medications, and conducting point-of-care testing (e.g., blood glucose, coagulation studies, etc.).
- Use aseptic technique in all aspects of parenteral medication preparation, administration, medication vial use, injection, and point-of-care testing.
- Use a mask to contain respiratory droplets when preparing and injecting solution into an intracapsular space (joint), the spine and during lumbar puncture.[33]
- Store, access and prepare medications and supplies in a clean area on a clean surface.
- Avoid having nonsterile contact with sterile areas of devices, containers and drugs.
- Following an emergency event, discard all opened or needle-punctured vials of sterile parenteral products, IV solutions, and single-use containers, such as bags, bottles, syringes.
- Never store needles and syringes unwrapped because sterility cannot be ensured. Keep bulk unwrapped syringes in the original package (e.g., intradermal syringes).
- Place only pre-filled flush syringes (e.g., saline, heparin) that are terminally sterilized by the manufacturer *after* packaging onto a sterile field immediately after opening.
- Never place items sterilized by manufacturers *before* final packaging onto a sterile field (e.g., some types of IV tubing and pre-filled syringes)
- Disinfect the rubber stopper of medication vials and the neck of glass ampuls [21,34,35] with sterile 70% alcohol before inserting a needle or breaking the ampul.
- Use needle free systems for all aspects of parenteral medication administration and transfer of solutions between containers.[36]
- Disinfect catheter hubs, needleless connectors, and injection ports before accessing. Use either an antiseptic containing port protector cap[37-41] or vigorously apply mechanical friction with chlorhexidine/alcohol,[42-43] sterile 70% isopropyl alcohol,[44-47] or other approved disinfectant swab.

- Change disinfecting port protectors as directed per manufacturer's recommendations.
- Follow institutional policy when using the wiping method to disinfect catheter hubs, needleless connectors, and injection ports. Published studies, guidelines and organizations vary (from 3 to 15 seconds) on the amount of time to disinfect when using the wiping method.[22,42,48-53] Some of these studies were product and /or device specific therefore results may not be able to be extrapolated to other types of devices.
- Allow adequate dry time (unless directed otherwise by manufacturer's instructions) before entry.

- Never pool left over parenteral medications (vials or IV solutions) for later administration.
- Do not use prefilled syringes to further dilute medication for administration. This is an unsafe practice due to potential for contamination, dosing errors, drug diversion and needlestick injuries. For drugs that require further dilution prior to administration, pharmacy personnel should prepare and dispense the diluted formulation in syringes or minibags whenever possible or dispense single-use vials of the drug and diluent together.[54]

TRANSPORTING MEDICATIONS

- Discourage the transporting of medication filled syringes/needles in pockets or clothing. If a facility allows this activity to occur, it must be addressed in the institution's policy on medication storage and transportation.[29]

IV SOLUTIONS

- Use an IV solution (e.g., bag, bottle) for only one patient, and then discard.
- Use needleless spiking devices to remove fluid from IV bottles/bags and vials and use for only one patient.[36]
- Never use a container of IV solution (e.g., bag, bottle) to obtain flush solutions for more than one patient.
- Never use infusion supplies, such as needles, syringes, and administration sets, for more than one patient.
- Use needle free systems for all aspects of parenteral medication administration and transfer of solutions between containers.[41,49,55-6]
- Use an ISO Class 5 primary engineering control to prepare CSPs when urgent-use is not required.[21]
- Avoid removing closed system transfer devices used for chemotherapy administration once attached. If a second medication needs to be administered, the device should remain on the port, and be flushed before connecting the second medication.[57-8]

FLUSHING

- Use single-use containers for flush solutions, whenever possible.[23,44]
- If a multidose vial must be used, use it for only one patient and then discard it. Use a new, unused sterile needle and new, unused sterile syringe for each entry into the vial.[44]

INJECTABLES IN THE OPERATING ROOM

- Whenever possible, prepare injections that require compounding (e.g., two or more medications combined) such as those designed to reduce post op bleeding and pain, and/or administered into intra-articular space during orthopedic surgical procedures) in a pharmacy ISO Class 5 environment instead of in the operating room.[59-60]
- When a single medication needs to be reconstituted outside an ISO Class 5 environment prepare according to manufacturer's instructions and just prior to administration.
- Multidose medication vials used for more than one patient should be stored and labeled appropriately and should not enter the immediate patient care area (e.g., operating room, anesthesia carts). If multi-dose vials enter the immediate patient care area, they must be dedicated for single patient use and discarded immediately after use.[61]
- Never use a decapping device to remove the top from a vial to pour the contents onto the sterile field (e.g., into a sterile basin) as vials are not designed for aseptic pouring.[28,62-3]
    - Use a commercially available sterile transfer device (e.g., vial spike, filter straw, plastic cannula) to aseptically transfer medications/solutions to the sterile field. The circulator should hold the vial so a designated scrub person can withdraw the medication or solution using a sterile syringe and needleless adapter. Remove the vial and transfer device after each use as they are not intended for multiple uses.
- When utilizing sequential dosing for one patient (e.g., anesthesia), draw the entire contents of a vial into a sterile syringe and use the same syringe for the sequential doses in only that patient never leaving the syringe unattended *OR* obtain sequential doses individually from the same vial using a new needle/cannula/syringe each time the vial is accessed for a dose. The vial should then be discarded when empty or no later than the end of the case.[64-5]
- Save and isolate all medication containers and delivery devices until the case is completed and the patient leaves the room as this is important evidence should an adverse event/error be identified.

SYRINGES AND NEEDLES

- Remove needle, cannula, syringe and/or accessory items from sterile packaging immediately before use.
- In the clinical setting, avoid using Pharmacy Bulk Packages of sterile unwrapped syringes whenever possible. These bulk packages are primarily intended for use under an ISO Class 5 environment for medication compounding. If used for a mass immunization clinic or allergy testing, open a new, sterile package and discard any remaining syringes at the conclusion of the activity. Do not save for later use.
- Do not use prefilled syringes to further dilute medication for administration. This is an unsafe practice due to potential for contamination, dosing errors, drug diversion and needlestick injuries. For drugs that require further dilution prior to administration, pharmacy personnel should prepare and dispense the diluted formulation in syringes or minibags whenever possible or dispense single-use vials of the drug and diluent together.
- Do not prepare medication in one syringe to transfer to another syringe (e.g., HCP draws up solution into a syringe then transfers the solution to a syringe that has the plunger removed or injects it into the bevel of the syringe).
- Never withdraw medication from a manufacturer prefilled syringe barrel (carpuject style syringe barrel).[54]
- Never use a syringe for more than one patient even if the needle has been changed

between patients.

- Use a new sterile syringe and a new sterile needle for each entry into a vial or IV bag.
- Utilize sharps safety devices (needles/syringes) to administer injections whenever possible.
- Discard syringes, needles, and cannulas in an approved sharps container/receptacle immediately after use and at the point of use.
- Discourage the transporting of medication filled syringes in pockets or clothing.
- Draw up medication into a syringe as close to administration time as feasible. Inject within 1 hour (or as soon as feasible) after drawing up the medication.
- Label all syringes containing medication if not immediately administered. Include patient identification information, names and amounts of all ingredients, and the name or/initials of the person who prepared the CSP,[21] date and time the CSP was prepared, and beyond use date and time.[61]

MEDICATION VIALS

- Always follow the manufacturer's instructions for storage and use.
- Check the manufacturer's expiration date on all medication vials prior to use.
- Inspect vials and discard if sterility is known or suspected to be compromised. Examine vials for particulate matter, discoloration, or turbidity; if present, do not use and discard immediately.
- Read the vial label carefully. Vial size does not indicate whether or not a vial is single-use or multidose.
- Store vials with same colored labels and/or same medication with different dosages separately.
- Disinfect the rubber septum on all vials prior to each entry, even after initially removing the cap of a new, unused vial.
- Always use a new sterile syringe and new needle/cannula when entering any vial. Never enter a vial with a syringe or needle/cannula that has been previously used.
- Use single-use or single-dose vials or ampuls whenever possible and discard after use on one patient.
- Use multidose medication vials for one patient whenever possible. The risk of viral hepatitis transmission posed by multidose vials has been clearly demonstrated and mandates a practice of using one vial per one patient whenever possible. Infection transmission risk is reduced when multidose vials are dedicated to one patient.[44]
- Store and access multidose vials away from the immediate patient care environment and always use a sterile syringe and needle/cannula each time the vial is accessed.
- Never leave a needle in the septum of a medication vial for multiple medication draws. This provides a direct route for microorganisms to enter the vial and contaminate the fluid.[44, 66]
- Never use a decapping device to remove the top from a vial (e.g., to pour medications). Draw solutions through the diaphragm with a sterile syringe and sterile transfer device or needle using aseptic technique.[28,62-3]
- Use needleless transfer devices when reconstituting drugs. Discard transfer device with the vial at the end of the transfer.[67-8]
- Use a filter needle or filtered transfer device to draw medications from an ampul into a syringe to prevent glass shard and/or potential microbial contamination.[34-5]

- Never pool or combine leftover contents of vials for later use.[44]
- Discard any vial that has been placed on a known or visibly contaminated surface or a used procedure tray.
- Following an emergency event, discard all opened or needle-punctured vials.[26]
- Label a multidose vial with a beyond-use-date when first accessing it. The beyond-use-date after initially entering a multidose vial is 28 days, unless otherwise specified by the manufacturer. The beyond-use date must never be after the manufacturer specified expiration date.[21]
- Check both the beyond-use-date and the manufacturer's expiration date prior to using an opened multidose vial.[21]
- Use multidose *vaccine* vials before the vial expiration date or as noted in the package insert. For additional information on vaccine preparation, storage and handling best practices, refer to the CDC Vaccine Storage and Handling Toolkit.[69]
- Discard any vials that were used to draw two or more medications into a single syringe.
- Discard the multidose vial with a needleless vial access device after use with a patient.

DRUG DIVERSION

- Institute drug diversion monitoring systems and security measures to assist in averting and/or identifying diversion activity.
- CDC defines an appropriate response to a drug diversion event as including "assessment of harm to patients, consultation with public health officials when tampering with injectable medications is suspected, and prompt reporting to enforcement agencies."[13]

POINT-OF-CARE TESTING (e.g., BLOOD GLUCOSE, COAGULATION STUDIES)

LANCETS

- Use single-use, auto-retracting lancing devices for each patient.[20,70-1]
- Dispose of all capillary tubes and sharp devices in a sharps container immediately after use and at the point-of-care.
- To ensure the safety of the patient and HCP, implement policies that address patients bringing their own lancing devices from home. These policies should address the following:
  - Personnel training and competency: If a facility cannot ensure that staff are properly trained on a patient's home device, HCP should not operate the device.[70]
  - Patient education: Patients that bring in their own devices must be able to insert and remove the lancets.
  - Proper disposal of the lancets.[70]
  - Labeling and storage of patient devices from home.
- Never use a fingerstick device (e.g., single-use lancets, lancet holding device or pen-like devices that provide multiple lancets in a reloadable cartridge) for more than one patient.[70-1]
  - Dedicate pen-like lancing devices to one patient and label the device with the patient's name; do not reprocess for use on other patients.[70]
  - Ensure that HCP use hemostats, not bare hands, to change out cartridges.[67]

TESTING DEVICES (e.g., BLOOD GLUCOSE METERS, INR METERS)

- Whenever possible, blood glucose meters should be assigned to an individual person and not be shared.[20,72]
- If blood glucose meters must be used on more than one patient, ensure they are labeled by the manufacturer for multiple patient use and include adequate instructions for disinfection of the meter between patients.[20,73]
- Clean and disinfect multiple patient use meters (specifically for bloodborne pathogens and other infectious agents) after each patient use, using manufacturer recommendations.[20,72] If the manufacturer does not provide instructions for cleaning and disinfection, then the testing meter should not be used for more than one patient.[20,61,71]
- Avoid handling test strip containers with soiled gloves to avoid contamination.[72] If a new test strip is needed, discard soiled gloves and perform hand hygiene before obtaining a new test strip.[74]
- Clean visible blood and dirt from meters before disinfecting.[72]
- Use an EPA approved disinfectant and follow manufacturer's contact time when disinfecting meters between patients.[72]
- Provide training and oversight for HCP that are responsible for conducting point-of-care testing. Conduct training and competency testing at the time of hire and regularly thereafter.[72]

BLOOD GLUCOSE MANAGEMENT

MULTIDOSE INSULIN VIALS

- If multidose vials of insulin are used, dedicate each to only one patient. [75]

INSULIN PENS

- Provide training and oversight on the use of insulin pens to assure competency and use of proper infection prevention practices.[71,76]
- Dedicate insulin pens for use with only one patient. Never use insulin pens for more than one person. Do not use unassigned or unlabeled insulin pens.[76-78]
- Affix patient label directly to the insulin pen.[77]
- Label the pen only, not an outer bag, which could contain the incorrect pen; HCP could falsely verify the contents by the label on the bag.[77]
- In healthcare settings, use only single-use, auto-retracting safety needles with insulin pens.[70]
- Dispose of auto-retracting safety needles (e.g., insulin pens) immediately after use at the point-of-care in a sharps container.
- Never store insulin pens with a needle attached.[72]
- Maintain an ample supply of back-up insulin in vials in case of lost or missing pen to discourage resorting to sharing a device.
- Employ workflow supports to prevent the inadvertent use of an insulin pen on more than one patient.[61]
    - Store properly labeled insulin pens in secure area with limited access.
    - If barcoding is used at the facility, individually barcode the insulin pens for a specific patient. The manufacturer's barcode should not be used as a default. [77]
    - Visible alerts and "hard stops" should be built into the barcode scanning process for insulin pens. This added safety check can confirm that the correct pen is being used for the correct patient before continuing with administration and documentation.[77]

- Consider collecting data on "near-misses" generated by alerts triggered by barcoding to identify patterns or opportunities for improvement.[77]

HEALTHCARE PERSONNEL (HCP)

Provide hepatitis B vaccination series to all previously unvaccinated, nonimmune HCP whose activities involve contact with blood or body fluids.[79-81]

- Check and document post-vaccination titers 1 to 2 months after completion of the Hepatitis B vaccination series.[81]
- Require HCP to immediately report body fluid exposure and needlestick/sharps injuries.[80]
- Ensure HCP that prepare or administer injections or other parenteral medications are competent to perform these tasks.[70]
- Ensure HCP that perform point-of-care testing are competent to perform this task.
- Periodically assess competency and compliance with safe injection, medication handling, and point-of-care testing practices by observing and evaluating all HCP performing these procedures.[70]

OVERSIGHT AND ENFORCEMENT

- Assure that policies and mechanisms are in place to 1) support and ensure that injection safety and infection prevention and control procedures are followed, and 2) mandate corrective action when infection control lapses are identified.[18]
- Enforce absolute adherence to proper infection prevention and control practices during the preparation and administration of injected medications.[2]
- Hold HCP accountable for adhering to safe injection, infusion, medication vial, and point-of-care testing practices.
- Conduct surveillance to identify infections that may be associated with injection, infusion, medication vial, and point-of-care testing practices in all healthcare settings.
- Report epidemiologically significant clusters of infection to the appropriate public health authorities as soon as possible to assist in identification of healthcare associated outbreaks and direct interventions to control and prevent further spread of disease.

References

1. Kuehn BM. Unsafe injection practices plague US outpatient facilities, harm patients. JAMA 2012;308(24):2251-2.
2. Perz JP, Thompson ND, Schaefer MK, Patel PR. US Outbreak investigations highlight the need for safe injection practices and basic infection control. Clin Liver Dis 2010;14:137–51.
3. Centers for Disease Control and Prevention. Healthcare-Associated Hepatitis B and C Outbreaks Reported to the Centers for Disease Control and Prevention (CDC) in 2008-2014. Available at: http://www.cdc.gov/hepatitis/Outbreaks/HealthcareHepOutbreakTable.htm. Accessed July 23, 2015.
4. Thompson ND, Perz JF, Moorman AC, Holmberg SD. Nonhospital health care–associated hepatitis B and C virus transmission: United States, 1998–2008. Ann Intern Med 2009;150:33-9.
5. Centers for Disease Control and Prevention. Transmission of hepatitis B and C viruses in outpatient settings—New York, Oklahoma, and Nebraska, 2000-2002. MMWR Morb Mortal Wkly Rep 2003;52:901-6.
6. Outbreak of Hepatitis C at Outpatient Surgical Centers. Public Health Investigation Report. December 2009. Southern Nevada Health District Outbreak Investigation Team, Las Vegas, Nevada. Available at: http://southernnevadahealthdistrict.org/download/outbreaks/final-hepc-investigation-report.pdf. Accessed July 23, 2015.
7. Centers for Disease Control and Prevention. Investigation of viral hepatitis infections possibly associated with health-care delivery — New York City, 2008–2011. MMWR Morb Mortal Wkly Rep 2012;61:333-8. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6119a2.htm. Accessed July 23, 2015.
8. Kim M, Tyson C, Mascola L. Outbreak of joint infections associated with magnetic resonance arthrograms performed at an outpatient radiology center. Infect Control Hosp Epidemiol 2013;34:1215-7.
9. Zheteyeva Y, Tosh P, Patel P, Martinez D, Kilborn C, Awosika-Olumo D, et al. Hepatitis B outbreak associated with a home health care agency serving multiple assisted living facilities in Texas, 2008-2010. Am J Infect Control 2014;42:77-81.
10. Redd JT, Baumbach J, Kohn W, Nainan O, Khristova M, Williams I. Patient-to-patient transmission of hepatitis B virus associated with oral surgery. J Infect Dis 2007;195:1311-4.
11. Macedo de Oliveira A, White KL, Leschinsky DP, Beecham BD, Vogt TM, Moolenaar RL, et al. An outbreak of hepatitis C virus infections among outpatients at a hematology/oncology clinic. Ann Intern Med 2005;142:898-902.
12. Samandari T, Malakmadze N, Balter S, Perz JF, Khristova M, Swetnam L, et al. A large outbreak of hepatitis B virus infections associated with frequent injections at a physician's office. Infect Control Hosp Epidemiol 2005;26:745-50.
13. Schaefer MK, Perz JF. Outbreaks of infections associated with drug diversion by healthcare personnel, United States. Mayo Clinic Proceedings 2014;89:878-87.
14. Watson JT, Jones RC, Siston AM, Fernandez JR, Martin K, Beck E, 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.
15. Wiersma P, Schillie S, Keyserling H, Watson R, De A, Banerjee SN, et al. Catheter-related polymicrobial bloodstream infections among pediatric bone marrow transplant outpatients-Atlanta, Georgia, 2007. Infect Control Hosp Epidemiol 2010; 31:522-7.

16. Seña A, Moorman A, Njord L, Williams R, Colborn J, Khudyakov Y, et al. . Acute hepatitis B outbreaks in two skilled nursing facilities and possible sources of transmission—North Carolina, 2009-2010. Infect Control Hosp Epidemiol 2013;34:709-716.
17. Wong MR, Del Rosso P, Heine L, Volpe V, Lee L, Kornbum J, et al. An outbreak of Klebsiella pneumoniae and Enterobacter aerogenes bacteremia after interventional pain management procedures, New York City, 2008. Re.g., Anesth Pain Med 2010;35:496-9.
18. CDC Grand Rounds: Preventing unsafe injection practices in the U.S. health-care system. MMWR Morb Mortal Wkly Rep 2013;62:423-5.
19. Dolan SA, Felizardo G, Barnes S, Cox TR, Patrick M, Ward KS, et al. APIC position paper: Safe injection, infusion, and medication vial practices in health care. Am J Infect Control 2010;38:167-72.
20. Centers for Disease Control and Prevention. Infection Prevention during Blood Glucose Monitoring and Insulin Administration. Available from http://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html. Accessed July 23, 2015.
21. US Pharmacopeial Convention, Inc. General Chapter <797>: Pharmaceutical Compounding – Sterile Preparations. *United States Pharmacopeia 38 – National Formulary 33*. Rockville, MD: United States Pharmacopeial Convention, Inc.; 2015:567-611.
22. O'Grady NP, Alexander M, Burns LA, Dellinger EP, Garland J, Heard SO, et al. Guideline for the prevention of intravascular catheter-related infections. Am J Infect Control 2011;39:S1-34.
23. Infusion Nurses Society. Infusion nursing standards of practice. J Infus Nurs. 2011;34(1suppl):S1-S110.
24. Food and Drug Administration. Federal Food, Drug, and Cosmetic Act. Section 503A. Pharmacy Compounding. Available at: http://www.fda.gov/Drugs/GuidanceComplianceRe.g.,ulatoryInformation/PharmacyCompounding/ucm376733.htm. Accessed February 23, 2015.
25. Newton DW. A review of bacterial and fungal growth rates: implications for urgent-use compounded sterile drugs. October 12,2009. Prepared for the Virginia Board of Medicine. Available from dnewton@su.edu.
26. Stucki C, Sautter AM, Favet J, Bonnabry P. Microbial contamination of syringes during preparation: the direct influence of environmental cleanliness and risk manipulations on end-product quality. Am J Health-Syst Pharm 2009;66:2032-6.
27. Bennett SN, McNeil MM, Bland LA, Arduino MJ, Villarino MS, Perrotta MP, et al. Postoperative infections traced to contamination of an intravenous anesthetic, propofol. N Engl J Med 1995; 333:147-154.
28. Association of periOperative Registered Nurses. Guidelines for Perioperative Practice, 2015. IX.a.2 Medication Safety. Denver AORN, Inc.
29. American Society of Anesthesiology. The Joint Commission adopts ASA recommendations on medication management issues. May 17, 2011. Available from: http://www.asahq.org/advocacy/fda-and-washington-alerts/washington-alerts/2011/05/the-joint-commission-adopts-asa-recommendations-on-medication-management-issues. Accessed July 21, 2015.
30. Hicks RW, Becker SC, Cousins DD. MEDMARX Data Report: A chartbook of medication error findings from the perioperative settings from 1998-2005. Rockville, MD: US Center for the Advancement of Patient Safety; 2006.

31. Pugliese G, Gosnell C, Bartley JM, Robinson S. Injection practices among clinicians in United States health care settings. Am J Infect Control 2010;38:789-9.
32. Association for Safe Aseptic Practice. Aseptic non touch technique (ANTT). Theoretical framework for clinical practice. Available from: http://antt.org/ANTT_Site/Home.html. Accessed March 11, 2015.
33. Centers for Disease Control and Prevention. Safe injection practices to prevention transmission of infections to patients. Available from: http://www.cdc.gov/injectionsafety/IP07_standardPrecaution.html. Accessed February 23, 2015.
34. Zacher AN, Zornow MH, Evans G. J. Drug contamination from opening glass ampules. Anesthesiology 1991;75:893-5.
35. Hemingway CJ, Malhotra S, Almeida M, Azadian B, Yentis SM. The effect of alcohol swabs and filter straws on reducing contamination of glass ampoules used for neuraxial injections. Anaesthesia 2007;62:286-8.
36. Marks Z. A needle-free reconstitution and transfer system for compounded sterile intravenous drug solutions in compliance with United States Pharmacopeia Chapter <797> standards. Int J Pharm Compd 2014;18:94-9.
37. Danielson B, Williamson S, Kaur G, Brooks C, Scholl P, Baker A. Decreasing the incidence of central line-associated blood stream infections using alcohol-impregnated port protectors in a neonatal intensive care unit. Am J Infect Control 2013;41:S97-8.
38. DeVries M. Mancos PS, Valentine M. Evaluating & choosing device to reduce bloodstream infections in both central and peripheral lines. Am J Infect Control 2013;41:S40.
39. Stango C, Stern JJ, Runyan D, Macri IM, Vacca M, Riddick S, et al. Use of alcohol impregnated caps to reduce catheter related bloodstream infections. Am J Infect Control 2013;41:S90.
40. Wright MO, Tropp J, Schora DM, Dillon-Grant M, Peterson K, Boehm S, et al. Continuous passive disinfection of catheter hubs prevents contamination and bloodstream infection. Am J Infect Control 2013;41:33-8.
41. Xu Y, Zhang J, Gao Z, Liu H, Tian L. The performance of the microbial barrier of needleless positive pressure closed connectors. Chinese Journal of Medical Instrumentation 2013;37:365-6.
42. Hong H, Morrow DF, Sandora TJ, Priebe GP. Disinfection of needleless connectors with chlorhexidine-alcohol provides long-lasting residual disinfectant activity. Am J Infect Control 2013;41:e77-9.
43. Mazher MA, Kallen A, Edwards JR, Donlan RM. An in vitro evaluation of disinfection protocols used for needleless connectors of central venous catheters. Lett Appl Microbiol 2013;57:282-7.
44. Centers for Disease Control. One and Only Campaign. Available from: http://oneandonlycampaign.org/safe_injection_practices. Accessed February 23, 2015.
45. Sweet MA, Cumpston A, Briggs F, Craig M, Hamadani M. Impact of alcohol-impre.g.,nated port protectors and needleless neutral pressure connectors on central line–associated bloodstream infections and contamination of blood cultures in an inpatient oncology unit. Am J Infect Control 2012;40:931–4.
46. Ryder M, James GA, Pulchini E, Bickle L, Parker AE. Differences in bacterial transfer and fluid path colonization through needle free connector-catheter systems in vitro. Paper

presented at Society for Healthcare Epidemiology of America meeting, Dallas, TX. April 29, 2011.
47. Dolan SA, Littlehorn C, Glode MP, Dowell E, Xavier K, Nyquist, AC, Todd, JK. Association of Bacillus cereus infection with contaminated alcohol prep pads. Infect Control Hosp Epidemiol 2012;23:666-671.
48. The Joint Commission. CLABSI Toolkit - Chapter 3. CLABSI prevention strate.g.,ies, techniques, and technologies - scrub the hub. Available from: http://www.jointcommission.org/assets/1/6/CLABSI_Toolkit_Tool_3-21_Scrub_the_Hub.pdf Accessed February 23, 2015.
49. Rupp ME, Yu S, Fey PD, Van Schooneveld T, Anderson JR. Adequate disinfection of a split-septum needleless intravascular connector with a 5-second alcohol scrub. Infect Control Hosp Epidemiol 2012; 33:661-5.
50. Simmons S, Bryson C, Porter S. "Scrub the hub": cleaning duration and reduction in bacterial load on central venous catheters." Crit Care Nurs Q 2011;34:31-5.
51. Marschall J, Mermel LA, Fakih M, Hadaway L, Kallen A, O'Grady NP, et al. SHEA/IDSA practice recommendation strate.g.,ies to prevent central line–associated bloodstream infections in acute care hospitals: 2014 Update. Infect Control Hosp Epidemiol 2014;35:753-771.
52. Kaler W, Chinn R. Successful disinfection of needleless access ports: a matter of time and friction. JAVA 2007;12:140-2.
53. Moureau NL, Flynn J. Disinfection of needleless connector hubs: Clinical evidence systematic review. Nursing Research and Practice, Article ID 796762. In Press. Available at: http://www.hindawi.com/journals/nrp/2015/796762/. Accessed July 20, 2015.
54. Institute for Safe Medication Practices Safety Alert. ISMP survey reveals user issues with Carpuject prefilled syringes, August 9, 2012. Available from: https://www.ismp.org/newsletters/acutecare/showarticle.aspx?id=28. Accessed March 18, 2015.
55. Chernecky CC, Macklin D, Jarvis WR, Joshua TV. Comparison of central line-associated bloodstream infection rates when changing to a zero fluid displacement intravenous needleless connector in acute care settings. Am J Infect Control. 2014 Feb;42(2):200-2.
56. Hadaway L. Needleless connectors for IV catheters. Am J Nurs 2012;112:32-44.
57. Wick, C, Slawson MH, Jorgenson JA, Tyler LS. Using a closed-system protective device to reduce personnel exposure to antineoplastic agents. Am J Health Syst Pharm 2003;60:2314-20.
58. National Institute for Occupational Safety and Health. Preventing occupational exposures to antineoplastic and other hazardous drugs in healthcare settings. DHHS (NIOSH) Publication No 2004-165; 2004. Available from: http://www.cdc.gov/niosh/topics/antineoplastic/default.html. Accessed July 31, 2015.
59. Rich DS, Fricker MP Jr, Cohen MR, Levine SR. Guidelines for the safe preparation of sterile compounds: Results of the ISMP sterile preparation compounding safety summit of October 2011. Hosp Pharm 2013;48:282-94.
60. Bader L, Maydl G, Gieseke K, Heesemann J. Bacterial infections following injections and infusion caused by errors of hygiene--How to avoid them. MMW Fortschr Med 2005;147:28-9,31-2.
61. Centers for Medicare & Medicaid Services. Update to Ambulatory Surgical Center (ASC) Infection Control Surveyor Worksheet (ICSW), July 17, 2015. Available from:

http://cms.gov/Re.g.,ulations-and-Guidance/Guidance/Manuals/downloads/som107_exhibit_351.pdf. Accessed July 31, 2015.
62. Association of Surgical Technologists. Guideline statement for safe medication practices in the perioperative area, Adopted BOD May 2005. Available from: http://www.ast.org/uploadedFiles/Main_Site/Content/About_Us/Guideline_Safe_Medication.pdf. Accessed July 31, 2015.
63. Verjans B. Closed vial technology: a new solution to improve sterility assurance levels and to simplify the aseptic filling process. Pharma. The Free Library. (2014). Available from: http://www.thefreelibrary.com/Closed+vial+technology%3A+a+new+solution+to+improve+sterility+assurance...-a0261453104. Accessed July 31, 2015.
64. Stackhouse RA, Beers R, Brown D, Brown M, Greene, McCann ME, et al and the American Society of Anesthesiologists committee on Occupational Health Task Force on Infection Control. Recommendations for infection control for the practice of anesthesiology (Third Edition), 2011. Available from: http://www.asahq.org/~/media/sites/asahq/files/public/resources/asa%20committees/recommendations%20for%20infection%20control%20for%20the%20practice%20of%20anesthesiology.pdf . Accessed July 31, 2015.
65. Centers for Disease Control and Prevention. Medication administration questions. Available from: http://www.cdc.gov/injectionsafety/providers/provider_faqs_med-admin.html. Accessed July 31, 2015.
66. Abe K, D'Angelo MT, Sunenshine R, Noble-Wang J, Cope J, Jensen B, et al. Outbreak of Burkholderia cepacia bloodstream infection at an outpatient hematology and oncology practice. Infect Control Hosp Epidemiol 2007;11:1311-3.
67. International Sharps Injury Prevention Society (ISIPS). Available from: http://www.isips.org/ Accessed July 31, 2015.
68. Centers for Disease Control and Prevention. FAQs regarding safe practices for medical injections. Available from: http://www.cdc.gov/injectionsafety/providers/provider_faqs_multivials.html. Accessed July 31, 2015.
69. Centers for Disease Control and Prevention. Vaccine storage and handling toolkit. May 2014. Pages 1-109. Available from: http://www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf. Accessed July 31, 2015.
70. Counard C, Perz J, Linchangco P, Christiansen D, Gampva-Raeva L, Xia G, et al. Acute hepatitis B outbreaks related to fingerstick blood glucose monitoring in two assisted living facilities. J Am Geriatr Soc 2010;58:306-11.
71. Centers for Disease Control and Prevention. Infection prevention checklist for outpatient settings: Minimum expectations for safe care. Version 1.0. Available from: http://www.cdc.gov/HAI/pdfs/guidelines/ambulatory-care-checklist-07-2011.pdf. Accessed July 31, 2015.
72. Thompson ND, Perz JF. Eliminating the blood: Ongoing outbreaks of hepatitis B virus infection and the need for innovative glucose monitoring technologies. J Diabetes Sci Technol 2009;3:283-8.
73. FDA Letter to Manufacturers of Blood Glucose Monitoring Systems Listed with the FDA. Available from: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm227935.htm. Accessed July 31, 2015.

74. Pérez-Ayala M, Oliver P, Cantalejo FR. Prevalence of bacterial contamination of glucose test strips in individual single-use packets versus multi-use vials. J Diabetes Sci Technol 2013;7:854-62.
75. Institute for Safe Medication Practices. A clinical reminder about the safe use of insulin vials. ISMP Medication Safety Alert! 2013;18:1-4. Available from: http://www.ismp.org/newsletters/default.asp. Accessed July 31, 2015.
76. U.S. Food and Drug Administration. Information for healthcare professionals: Risk of transmission of blood-borne pathogens from shared use of insulin pens. FDA Alert 3/19/2009. Available from: http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHeathcareProfessionals/ucm133352.htm. Accessed July 31, 2015.
77. Institute for Safe Medication Practices. A crack in our best armor: "Wrong patient" insulin pen injections alarmingly frequent even with barcode scanning. ISMP Medication Safety Alert! 2014;17:2. Available from: http://www.ismp.org/newsletters/default.asp. Accessed July 31, 2015.
78. Institute for Safe Medication Practices. Do not use an insulin pen for multiple patients! Hazard Alert. ISMP Medication Safety Alert! 2012;17:1-4. Available from: http://www.ismp.org/newsletters/default.asp. Accessed July 31, 2015.
79. Centers for Disease Control and Prevention. Use of Hepatitis B vaccination for adults with diabetes mellitus: Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Morb Mortal Wkly Rep 2011;60:1709-12.
80. Occupational Safety and Health Administration; Regulations. Occupational Safety and Health Standards 29 CFR 1910.1030. Bloodborne pathogens. Available from: https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051. Accessed July 31, 2015.
81. Centers for Disease Control and Prevention. Immunization of health-care personnel: Recommendations of the Advisory Committee on Immunization Practices, MMWR Morb Mortal Wkly Rep 2011;60:1–48.

January 2016