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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.

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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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