



Spread the Word: **Aseptic Technique** Prevents Infection

As pharmacists and technicians, we are an integral part of the delivery of health care to patients in a variety of practice settings. One of the most important changes that we can actively contribute to is the “Targeting Zero” initiative, created by the Association for Professionals in Infection Control and Epidemiology (APIC) to prevent the most common and fatal healthcare-associated infections (HAIs).¹

HAIs in US hospitals account for an estimated two million infections and 90,000 deaths annually with an estimated cost of \$20 billion.² This is equivalent to a Boeing 747 crashing every day of the year. The CDC estimates the most common HAIs are urinary tract infections (32%), surgical site infections (22%), pneumonias (15%), and bloodstream infections (BSIs) (14%).¹ Each year, an estimated 250,000 cases of central line-associated (i.e., central venous catheter-associated) BSIs occur in hospitals in the United States, with an estimated attributable mortality of 12% to 25% for each infection. The marginal cost to the health care system is approximately \$25,000 per episode.²

Pharmacists and technicians can impact HAI reduction efforts in three ways:

1. Use proper aseptic technique when preparing compounded sterile preparations (CSPs).
2. Work with other health care professionals (i.e., nurses, nurse anesthetists, and physicians) to establish proper aseptic technique for CSP preparation in other patient care areas.
3. Actively participate on the Infection Control Committee, including reporting, monitoring, and improving compliance with hospital-accepted quality indicators.

Pharmacists and technicians should serve as an educational resource and provide instruction in **proper aseptic technique** to those health care professionals also preparing CSPs.

Aseptic technique can be defined as a set of specific work practices and procedures performed under carefully controlled conditions with the goal of minimizing the introduction of contamination. USP Chapter <797> emphasizes the important role that compounding personnel play—especially through aseptic technique or how they use their hands—in preventing inadvertent contamination of CSPs during preparation. The introduction to Chapter <797> states, “It is generally acknowledged that direct or physical contact of critical sites (e.g., vial septa,



A smoke simulation demonstrates the first air zone.

syringe and needle hubs, and injection ports) of CSPs with contaminants, especially microbial sources, poses the greatest probability of risk to patients.”³ Unfortunately, not all compounding personnel realize that improper aseptic technique can lead to microbial contamination and medication errors.

Evidence-based Science

Several studies have repeatedly identified human-borne contamination as the greatest threat to the sterility of CSPs, making this the most critical factor to be controlled during aseptic processing.^{4,7} Trissel, et al, demonstrated that critical work practices—such as donning sterile gloves and routinely disinfecting gloved hands with isopropyl alcohol—reduced the rate of contamination of media fills from 5.2% to 0.3%.⁴

A study published by van Grafhorst, et al, was designed to determine the risk of bacterial contamination of the infusate (CSP) in a simulation model of syringes prepared for continuous intravenous drug administration by nurses using accepted standard precautions in the intensive care unit, compared with syringes prepared by pharmaceutical technicians working under standard aseptic conditions according to national guidelines. The nurses prepared the media fills in a room on the unit without special air conditioning, where other staff members could walk in and out freely. In addition, the syringes were prepared without special attention to disinfection of hands, drug packaging, or work surface. The pharmacy technicians preparing the media fill used national aseptic technique guidelines while working in an ISO Class 5 laminar airflow

workbench, garbed in a sterile suit, using sterile gloves, hair caps, and surgical masks. The technicians were not disturbed during preparation, as no other activities were occurring in the preparation room.

The study found a median contamination rate of 22% (range: 7% to 44%) for syringes prepared from 10 mL ampules by intensive care unit nurses, compared with only 1% for syringes prepared from ampules by technicians ($p < .001$). The contamination rate of syringes prepared from vials was much lower: 2% in the intensive care unit and 0% in the pharmacy. Gram-positive cocci were identified in more than 75% of all contaminated syringes. At least 12% of all prepared syringes proved to be contaminated with staphylococci species. The authors conclude that the widely accepted procedures used to prepare the syringes for intravenous drug administration in the intensive care unit lack vigorous aseptic precautions, leading to a high contamination rate of the infusate with Gram-positive cocci.⁸ Van Doorne, et al, demonstrated that compliance with proper aseptic technique and employee garb during a media fill can have a significant positive impact on the rate of contamination of CSPs, at a rate of 0.2%, even when performed in an uncontrolled environment.⁹

In 2003, ICUs in Michigan reported on their implementation of a care-team checklist of basic hygiene and sterilization practices (the Institute for Healthcare Improvement's "bundle") during the insertion of central venous catheters (CVCs). The average infection rate fell from 7.7 per 1,000 central-line catheter days (CLC) to 1.4 per 1,000 CLC after 18 months. More than half of the 103 hospitals in the study were able to report that they had zero infections after implementing the program. After 18 months, more than 1,500

lives had been saved.¹⁰

The following elements were required and verified via a checklist prior to the CVC insertion procedure:

- Perform a "time out"
- Wash hands with chlorhexidine or soap
- Sterilize the insertion site with chlorhexidine
- Drape the entire patient in a sterile fashion
- Staff performing or assisting in the procedure must:
 - Wear hat, mask, sterile gown, and gloves
 - Maintain a sterile field (proper aseptic technique)

These results have been duplicated in several hospitals, and their stories can be reviewed on the Institute for Healthcare Improvement's website, <http://www.ihl.org/ihl/programs/campaign/centrallineinfection.htm>.

Elements of Performance of Proper Aseptic Technique

There have been complaints that many of the requirements, or "shalls," in USP Chapter <797> are not evidence based. In those situations where no evidence existed, the USP Sterile Compounding Committee sought additional expertise from other experts or used best practices. However, for the Personnel Garb and Cleansing Section of USP Chapter <797>, the committee relied on the evidence-based science of hand washing and garbing procedures from the Institute for Healthcare Improvements bundle and the other studies referenced in this article.

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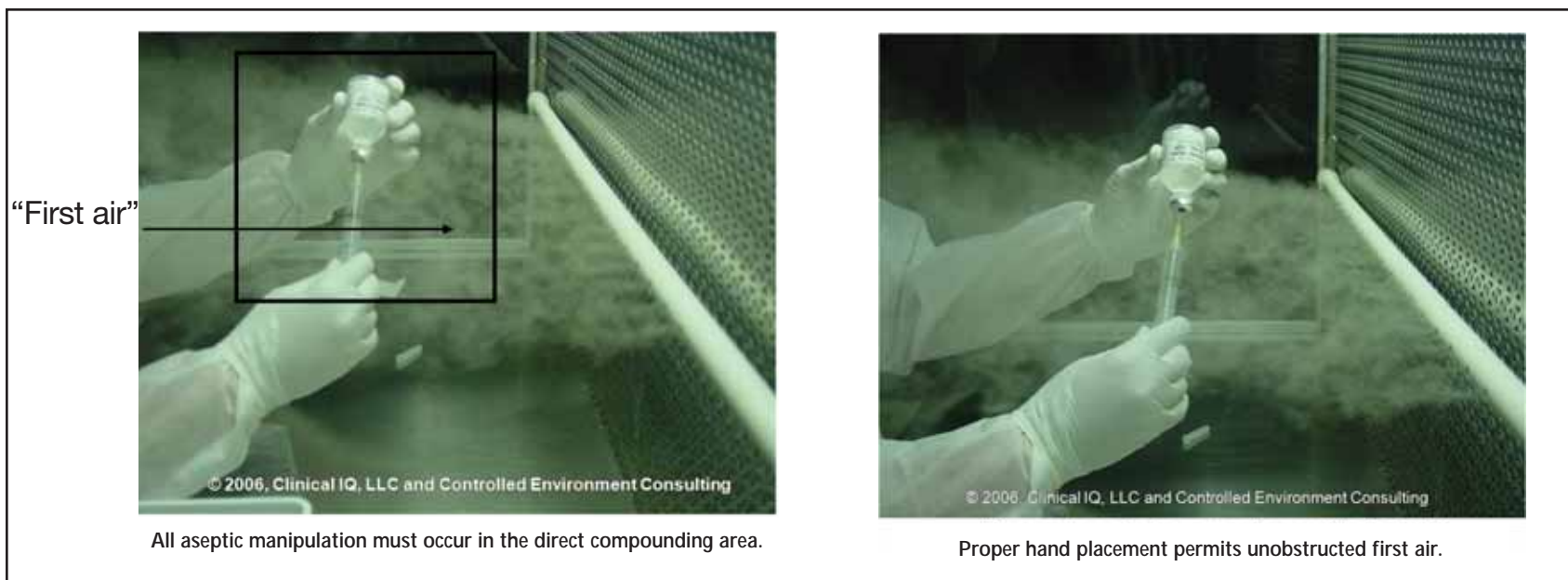
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Direct Compounding Area (DCA)



CSPs is probably low (though no evidence is available to confirm or refute this), consistently applying these same elements of performance should result in rates of contamination that approach zero. All pharmacy personnel who compound or enter the buffer area to check CSPs must perform proper hand washing and garb with a hair net, mask, gown, and sterile gloves. This includes the use of persistent antimicrobial scrub, which contains 1% chlorhexidine and 62% alcohol, prior to donning sterile gloves. In addition to these work practices, the employee must work within the direct compounding area. USP

Chapter <797> defines the direct compounding area as a critical area within the ISO Class 5 primary engineering control where critical sites (e.g., vial septa, syringe and needle hubs, and injection ports) are exposed to unidirectional HEPA-filtered air, also known as first air.

A checklist for pharmacists and technicians detailing the elements of performance of proper aseptic technique should include:

- Perform a “time out” and review all orders and ingredient packages to ensure that the identity and amounts of ingredients are correct.
- Garb from “dirtiest to cleanest”:
 - Don shoe covers, hair net, beard cover (as needed), and mask.
 - Wash hands with chlorhexidine or soap for at least 30 seconds.
 - Don gown and apply persistent antimicrobial scrub.
 - After hands have dried, put on sterile gloves.
- Understand the elements of “first air”:
 - First air is the air exiting the HEPA filter in a unidirectional air stream and is virtually free of particulate contaminants.
 - All critical manipulations must be carried out in the unobstructed first air zone in the direct path of the HEPA filter discharge.
 - Proper product and process placement with respect to the supply and discharge of first air will provide a contamination-free compounding area.
- Disinfect the work surface of the primary engineering control before and after each CSP batch. A batch can be as small as a single CSP.
- Disinfect all components with sterile 70% isopropyl alcohol prior to placement in the ISO Class 5 primary engineering control.
- Disinfect all critical sites with sterile 70% isopropyl alcohol and ensure that all critical sites are wet for at least 10 seconds and allowed to dry prior to penetrating them.
- Routinely disinfect gloved hands with sterile 70% isopropyl alcohol and inspect gloves for holes or tears. Replace as necessary.
- Visually inspect CSPs to ensure the absence of particulate matter in solutions, the absence of leakage from vials and bags, and the accuracy and thoroughness of labeling.

Confirming that all of these steps occur during the preparation of each and every CSP can ensure that the patient will receive a sterile CSP.

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Compounding Beyond Pharmacy

There are several areas in the hospital—including radiology, operating and recovery, the emergency department, and patient care units—where CSP preparation occurs and where aseptic technique is required. Pharmacists and technicians should serve as an educational resource and provide instruction in proper aseptic technique to those health care professionals also preparing CSPs.

Since these professionals will not be working within an ISO Class 5 primary engineering control, their elements of performance for proper aseptic technique should include the following:

- Personnel must perform hand hygiene procedures and properly garb (if possible) prior to using a sterile needle and syringe to prepare or administer any medication or fluid.
- All work surfaces should be disinfected prior to performing any aseptic manipulation.
- Never reuse a needle and syringe that has been used for another patient.
- Cleanse the vial septa, injection port, or the neck of an ampule with sterile 70% alcohol before accessing the container with a needle and syringe.
- When possible, use single-dose vials and discard immediately after use.
- Use a new sterile needle and syringe each time a multi-dose vial is accessed and avoid touch contamination of the needle and syringe prior to penetrating the vial septa.

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- After use, vials should be dated and then discarded 28 days after opening, unless otherwise specified by the manufacturer.¹⁰
- Refrigerate vials after they are opened if recommended by the manufacturer.
- Discard any vial, ampule, or bag if sterility is compromised or questioned.
- Never combine leftover contents of single-use vials for later use.
- Do not use any container that has visible turbidity, leaks, cracks, or particulate matter, or if the manufacturer’s expiration date has passed.
- Never leave a needle in place in the vial diaphragm.

Conclusion

These basic elements of performance for aseptic technique can positively impact the effort to minimize or eliminate HAIs. Identify the hospital departments that handle, store, compound, or transport CSPs as they will benefit from the expert knowledge and resources of pharmacists and technicians in the principles of aseptic technique and contamination control. Be a problem solver by assisting them with providing patient care that minimizes or eliminates HAIs. This is one of several professional opportunities that pharmacists and technicians have to improve the quality of patient care. By understanding and then teaching adherence to the elements of performance for proper aseptic technique, you can ensure CSP sterility throughout your organization. ■



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