Chapter 27

Cleaning and Disinfecting

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Introduction

In 2002, the estimated number of hospital-acquired infections (HAIs) in U.S. hospitals was approximately 1.7 million. The estimated deaths associated with these infections were nearly 99,000.[1] The costs of these HAIs was estimated in 2007 to be between $28.4 and $33.8 billion dollars.[2] Microbial contamination on environmental surfaces can serve as reservoirs of potential pathogens; however, these surfaces generally do not transmit infections directly to staff or patients.[3] Rather, the transfer of microorganisms from environmental surfaces to patients is largely via staff hand contact with surfaces, then hand contact with patients. Although hand hygiene is more important to minimize the impact of this transfer, an appropriate cleaning and disinfecting program for environmental surfaces is fundamental in reducing surfaces' potential contribution to the incidence of HAIs.

Cleaning

Environmental surfaces can be safely decontaminated using less rigorous methods than those used on medical instruments and devices. The following factors influence the cleaning and disinfection procedures for environmental surfaces[3,4]:

- Nature of the surface to be disinfected
- Number of microorganisms present
- Innate resistance of those microorganisms to the inactivating effects of the disinfectant
- Amount of organic soil present on surfaces
- Type and concentration of disinfectant used
- Duration and temperature of disinfectant contact
- Accuracy with which indications and directions for use are followed, if using a proprietary product

Note: The author acknowledges E. Clyde Buchanan who wrote this chapter in the previous edition.

Cleaning is the necessary first step of any disinfection process and is a form of decontamination that prepares the environmental surface for disinfection by removing organic matter, salts, and visible soil—all of which interfere with microbial disinfection. The physical action of scrubbing with detergents and surfactants and rinsing with water removes large numbers of microorganisms from surfaces. If the surface is not clean before disinfection is started, the success of disinfection is compromised.[3,4] Many companies sell cleaning supplies designed for use in pharmacy buffer areas and ante-areas (e.g., www.pppmag.com).[5,6] Ensuring that buffer area and ante-area furnishings are easy to clean is important. Such furnishings include garb dispensers, benches, tables, chairs, carts, shelving and racks, trash receptacles, cabinets, and countertops (Chapter 8).

USP Chapter <797>

USP Chapter <797> Pharmaceutical Compounding—Sterile Preparations standards for cleaning and disinfecting apply to primary and secondary engineering controls, including segregated compounding areas used for low-risk sterile preparations with 12-hour or less beyond-use dates. USP Chapter <797> sets the following requirements for cleaning and disinfecting these controls and areas[7]:

1. *Responsibility of Compounding Personnel*
    - Trained personnel write detailed procedures that include cleansers, disinfectants, and nonshedding wipe and mop materials.
    - Compounding personnel and other personnel responsible for cleaning must be visually observed during the process of performing cleaning and disinfecting procedures during initial personnel training on cleaning procedures, during changes in cleaning staff, and at the completion of any media fill test procedure. Visual documentation must be recorded using, for example, the sample form for assessing cleaning and disinfection procedures (**Figure 27-1**).
2. *Environmental Quality and Control*
    - Carts used to bring supplies from the storeroom cannot be rolled beyond the demarcation line in the ante-area, and carts used in the buffer area cannot be rolled outward beyond the demarcation line unless cleaned and disinfected before being returned.
    - No shipping or other external cartons may be taken into the buffer area or segregated compounding area. (All supplies in cartons are decontaminated by removing them from shipping cartons and wiping or spraying them with a nonresidue-generating agent while they are being transferred to a clean and properly disinfected cart or other conveyance for introduction into the buffer area.)
    - Generally, supplies required for scheduled compounding during a work shift are wiped down with an appropriate disinfecting agent and brought into the buffer area, preferably on one or more movable carts.
    - Cleaning and disinfecting surfaces in the laminar airflow workbenches (LAFWs), biological safety cabinets (BSCs), compounding aseptic isolators (CAIs), and compounding aseptic containment isolators (CACIs) must be done frequently including at the beginning of each work shift, before each batch preparation is started, every 30 minutes during continuous compounding periods of individual CSPs, when there are spills, and when surface contamination is known or suspected from procedural breaches.
    - Trained compounding personnel are responsible for developing, implementing, and practicing the procedures for cleaning and disinfecting the direct compounding area (DCA) written in the standard operating procedures (SOPs).
    - Cleaning and disinfecting must occur before compounding is performed. Items must be removed from all areas to be cleaned and surfaces must be cleaned by removing loose material and residue from spills (e.g., water-soluble solid residues are removed with sterile water [for injection or irrigation] and low-shedding wipes). This must be followed by wiping with a residue-free disinfecting agent, such as sterile 70% isopropyl alcohol (IPA), which is allowed to dry before compounding begins.
    - Work surfaces in ISO Class 7 and 8 areas (i.e., buffer areas and ante-areas, respectively) and segregated compounding areas are cleaned at least daily.