Recommended Practices for Sterilization

The following Recommended Practices for Sterilization have been approved by the AORN Recommended Practices Advisory Board. They were presented as proposed recommendations for comments by members and others. They are effective June 15, 2012. These recommended practices are intended as achievable recommendations representing what is believed to be an optimal level of practice. Policies and procedures will reflect variations in practice settings and/or clinical situations that determine the degree to which the recommended practices can be implemented. AORN recognizes the various settings in which perioperative nurses practice, and as such, these recommended practices are intended as guidelines adaptable to various practice settings. These practice settings include traditional operating rooms (ORs), ambulatory surgery centers, physicians' offices, cardiac catheterization laboratories, endoscopy suites, radiology departments, and all other areas where surgery and other invasive procedures may be performed.

Purpose

These recommended practices provide guidance for sterilizing items to be used in the perioperative setting. The creation and maintenance of an aseptic environment has direct influence on patient outcomes. A major responsibility of the perioperative registered nurse (RN) is to minimize patient risk for surgical site infections (SSIs). One of the measures for preventing SSIs is to provide reusable surgical items that are free of contamination at the time of use. This can be accomplished by subjecting them to cleaning and decontamination, followed by a disinfection or sterilization process.

The Spaulding classification system is commonly used to classify patient care items to determine the appropriate level of processing.[1] The Spaulding classification system, developed by Earl Spaulding in 1968, classifies items as noncritical, semicritical, or critical and identifies the appropriate processing method for each category. Infection preventionists and others use this system to determine the correct processing methods for preparing instruments and other items for patient use. According to the Spaulding classification system, the level of processing required is based on the nature of the item that requires processing and the manner in which the item is to be used.

These recommended practices address processing of critical medical devices. Processing of noncritical and semicritical devices is outside the scope of this document. The difference between noncritical and semicritical devices is as follows.

Noncritical devices are devices that contact only intact skin. Noncritical devices require low-level disinfection or cleaning. Examples of noncritical devices include

- tourniquets and blood pressure cuffs,
- stethoscopes, and
- Mayo stands.

Semicritical devices are devices that come in contact with nonintact skin or with mucous membranes and require a minimum of high-level disinfection. Examples of semicritical devices include

- vaginal and rectal probes,
- respiratory therapy equipment,
- bronchoscopes, and
- laryngoscope blades.[2,3]

Sterilization provides the highest level of assurance that surgical items are free of viable microbes.[1] Although these recommendations include several references to cleaning, decontamination, disinfection, and packaging, the major focus is on sterilization.

These recommended practices include recommendations for high-temperature sterilization (ie, sterilization by steam), low-temperature sterilization (ie, ethylene oxide, low-temperature hydrogen peroxide gas plasma, low-temperature hydrogen peroxide vapor, dry heat, ozone), and processing using a liquid chemical sterilant system using peracetic acid.

Cleaning, decontamination, disinfection, and packaging of sterile medical devices are outside the scope of this document. The reader should refer to the AORN "Recommended practices for cleaning and care of surgical instruments and powered equipment"[4] and "Recommended practices for high-level disinfection"[5] for additional guidance.

Evidence Review

A medical librarian conducted a systematic literature search of the databases MEDLINE®, CINAHL®, Scopus®, and Cochrane Database of Systematic Reviews for meta-analyses, randomized and nonrandomized trials and studies, systematic and nonsystematic reviews, and opinion documents and letters. Search terms included *sterilization, ethylene oxide, steam, peracetic acid, dry heat, hydrogen peroxide gas, ozone, hospital equipment and supplies, prostheses and implants, surgical equipment, infusion pumps, disposable equipment, diagnostic equipment, flash sterilization, immediate use, surgical equipment and supplies, equipment contamination, microbial contamination, indicators and reagents, fungi, bacterial contamination, ethylene oxide toxicity,* and *biofilms*, as applicable.

The search was limited to articles published in English between 2005 and 2011. Older articles were included where there were no articles within this time period. Additional articles not identified in the original literature search were obtained by reviewing the reference lists of the original articles. The librarian

