Evidence Review

The Guideline for Sterilization Packaging Systems was approved by the AORN Guidelines Advisory Board and became effective as of October 1, 2019.

A medical librarian with a perioperative background conducted a systematic search of the databases Ovid MEDLINE®, Ovid Embase®, EBSCO CINAHL®, and the Cochrane Database of Systematic Reviews. The search was limited to literature published in English from January 2013 through October 2018. At the time of the initial search, weekly alerts were created on the topics included in that search. Results from these alerts were provided to the lead author until December 2018. The lead author requested additional articles that either did not fit the original search criteria or were discovered during the evidence appraisal process. The lead author and the medical librarian also identified relevant guidelines from government agencies, professional organizations, and standards-setting bodies. Search terms included barrier integrity, barrier properties, basket, biological indicators, central service department, central sterile processing, central supply (hospital), chemical indicators, clinical competence, colony count (microbial), condensation, cross infection, dental instruments, device packaging, disposable equipment, equipment and supplies, equipment contamination, equipment failure, equipment reuse, event-dependent, event-related, fabrics, flash sterilization, heat sealer, hospital central supply, hospital purchasing, humidity, immediate use steam sterilization, immediate use sterilization, indicators and reagents, infection control, instrument case, instrument cassette, instrument set, instrument tray, Kraft, loaner instruments, materials testing, medical packaging, microbial colony count, monitoring, Mylar, olefin, one tray, organizing tray, outdated, package integrity, packaging device, packaging material, packaging system, paper count sheets, peel pack, peel pouch, plastics, polypropene, polypropylene, pouch, product labeling, product packaging, purchasing department, quality control, reusable pack, rigid container, safety management, sequential wrapping, single use, steam, sterile instruments, sterile package, sterile packaging, sterile processing, sterile storage, sterile supplies, sterility maintenance cover, sterilization, sterilization and disinfection, sterilization container, sterilization wrap, surgical equipment, surgical equipment and supplies, surgical instruments, textiles, time-dependent, time-related, and Tyvek.

Included were research and non-research literature in English, complete publications, and publications with dates within the time restriction when available. Excluded were non-peer-reviewed publications and older evidence within the time restriction when more recent evidence was available. Editorials, news items, and other brief items were excluded. Low-quality evidence was excluded when higher-quality evidence was available, and literature outside the time restriction was excluded when literature within the time restriction was available (Figure 1).

Articles identified in the search were provided to the project team for evaluation. The team consisted of the lead author and one evidence appraiser. The lead author and the evidence appraiser reviewed and critically appraised each article using the AORN Research or Non-Research Evidence Appraisal Tools as appropriate. A second appraiser was consulted if there was a disagreement between the lead author and the primary evidence appraiser. The literature was independently evaluated and appraised according to the strength and quality of the evidence. Each article was then assigned an appraisal score. The appraisal score is noted in brackets after each reference as applicable.

Each recommendation rating is based on a synthesis of the collective evidence, a benefit-harm assessment, and consideration of resource use. The strength of the recommendation was determined using the AORN Evidence Rating Model and the quality and consistency of the evidence supporting a recommendation. The recommendation strength rating is noted in brackets after each recommendation.
Publication History

- Revised and reformatted; published December 2000, AORN Journal.
- Revised September 2013 for online publication in Perioperative Standards and Recommended Practices.
- Evidence ratings revised in Guidelines for Perioperative Practice, 2018 edition, to conform to the current AORN Evidence Rating Model.
- Revised 2019 for online publication in Guidelines for Perioperative Practice.

Scheduled for review in 2024.

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