GUIDELINE FOR SELECTION AND USE OF PACKAGING SYSTEMS FOR STERILIZATION

The Guideline for Selection and Use of Packaging Systems for Sterilization has been approved by the AORN Recommended Practices Advisory Board. It was presented as proposed recommendations for comments by members and others. The guideline is effective November 15, 2013. The recommendations in the guideline are intended to be achievable and represent 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 guideline can be implemented. AORN recognizes the many diverse settings in which perioperative nurses practice; therefore, this guideline is adaptable to all areas where operative and other invasive procedures may be performed.

Purpose

This document provides guidance to perioperative personnel for evaluating, selecting, and using packaging systems and for packaging the items to be sterilized and subsequently used in the perioperative setting. Packaging systems should permit sterilization of the contents within the package, protect the integrity of the sterilized contents, prevent contamination of the contents until the package is opened for use, and permit the aseptic delivery of the contents to the sterile field. Packaging systems include woven fabrics, nonwoven materials, paper-plastic pouches, Tyvek®-plastic pouches, plastic-plastic pouches, and containment devices (eg, sterilization containers, instrument cases, cassettes, organizing trays) composed of a variety of materials. This guideline does not include recommendations for cleaning contaminated instruments, loading a sterilizer, or sterilization. The reader should refer to the AORN Guideline for Cleaning and Care of Surgical Instruments[1] and Guideline for Sterilization.[2]

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 *surgical equipment, surgical instruments, dental instruments, organizing tray, instrument set, loaner instrument, medical packaging, product packaging, device packaging, product labeling, packaging material, sterilization container, rigid container, instrument case, instrument cassette, packaging system, reusable pack, pouch, heat sealer, sequential wrapping, plastics, textiles, fabrics, Mylar, Tyvek, Kraft, olefin, paper, polypropylene, polypropene, barrier integrity, barrier system, barrier properties, sterility maintenance cover, sterilization, flash sterilization, immediate use sterilization, infection control, microbial colony count, cross infection, equipment contamination, humidity, steam, condensation, equipment reuse, single-use, event-related, time-related, time-dependent, event-dependent, outdating, monitoring, quality control, materials testing, indicators and reagents, package integrity, equipment failure, safety management, hospital central supply, sterile processing,* and *hospital purchasing.*

The lead author and the medical librarian identified and obtained relevant guidelines from government agencies, other professional organizations, and standards-setting bodies. The lead author assessed additional professional literature, including some that was cited in other articles provided to the author. The initial search was confined to the years 2005 to 2012 and limited to English-language articles. The time restriction was not applied in subsequent searches. The librarian also established continuing alerts on the topics included in this guideline and provided relevant results to the lead author. The majority of research regarding packaging was related to shelf life and was conducted more than 10 years ago when facilities were transitioning from time-related shelf life to event-related shelf life. Articles addressing other aspects of packaging were quite limited. It is evident from the literature search that there is a need for additional research on all aspects of packaging for sterilization.

Articles identified by the search were provided to a doctorally prepared evidence appraiser and to the lead author for evaluation. Articles were critically appraised using the Johns Hopkins Evidence-Based Practice Model and the Research or Non-Research Evidence-Appraisal Tools as appropriate. The articles were independently evaluated and appraised according to the strength and quality of the evidence. Each article was then assigned an appraisal score as agreed upon by the researcher and the lead author. The appraisal score is noted in brackets after each reference citation, as applicable.

The collective evidence supporting each intervention within a specific recommendation was summarized and used to rate the strength of the evidence using the AORN Evidence Rating Model. Factors considered in review of the collective evidence were the quality of the research, quantity of similar studies on a given topic, and consistency of results supporting a recommendation. The evidence rating is noted in brackets after each intervention.

Editor's note: *MEDLINE is a registered trademark of the US National Library of Medicine's Medical*