

GUIDELINE FOR MEDICAL DEVICE AND PRODUCT EVALUATION

The Guideline for Medical Device and Product Evaluation has been approved by the AORN Guidelines Advisory Board. It was presented as a proposed guideline for comments by members and others. The guideline is effective November 1, 2017. 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 or other invasive procedures may be performed.

Purpose

This document provides guidance to perioperative team members for developing and implementing a process for evaluating US Food and Drug Administration-cleared medical devices and products for use in the perioperative setting. The safety of patients and perioperative team members, optimal patient outcomes, and product quality are the primary concerns of perioperative registered nurses (RNs) as they participate in product review and evaluation.

The evidence regarding best practices for product evaluation in the perioperative setting is limited. The health care system is complex, with many variables that make it difficult to perform research on product selection that is generalizable to all settings. These variables include the size of the organization, financial constraints, group purchasing organization relationships, and contractual agreements.

The following subjects are outside the scope of this guideline: specific processes for cleaning, disinfection, and sterilization; management of products and devices after purchase (eg, equipment maintenance, inventory control); selection of electronic health records (eg, health information technology); processes for product waste disposal; and purchasing processes (eg, supply chain).

Evidence Review

A medical librarian conducted a systematic literature search of the databases Ovid MEDLINE®, EBSCO, CINAHL®, Scopus®, and the Cochrane Database of Systematic Reviews. The search was limited to literature published in English from 2012 through April 2017. At the time of the initial search, weekly alerts were created on the topics included in the search. Results from these alerts were provided to the lead author until July 2017. The lead author requested additional articles that did not fit the original search

criteria or were discovered during the appraisal process.

Search terms included *cost control, financial management, materials management, purchasing department, cost savings, value-based purchasing, surgical instruments, operating rooms, costs and cost analysis, decision-making, organizational, cost-benefit analysis, value stream mapping, financial impact analysis, product selection, quality assurance, cost effectiveness, efficiency, perioperative nursing, device approval, surgical equipment, disposable equipment, and equipment and supplies*. Key words and phrases included *group purchasing, surgical devices, surgical services, surgical department, consignment, vendor, committee, interdisciplinary communication, cooperative behavior, single-use devices, patient care items, par level, and team*.

Included were research and non-research literature in English, complete publications, and publication 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 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).

Included articles were independently evaluated and critically appraised according to the strength and quality of the evidence. 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 divided the search results into topics, and both members of the team reviewed and critically appraised each article using the AORN Research or Non-Research Evidence Appraisal Tools as appropriate. 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.

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

Note: The evidence summary table is available at <http://www.aorn.org/evidencetables/>.

