

AORN Guideline for Medical Device and Product Evaluation  
Evidence Table

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
1	Atwood D, Larose P, Uttley R. Strategies for success in purchasing medical technology. <i>Biomed Instrum Technol.</i> 2015;49(2):93-98.	Expert Opinion	N/A	N/A	N/A	N/A	Strategies are suggested for healthcare organizations when evaluating technology includes identifying key stakeholders, decision making evaluation, and implementation.	VB
2	Grundy Q. "Whether something cool is good enough": the role of evidence, sales representatives and nurses' expertise in hospital purchasing decisions. <i>Soc Sci Med.</i> 2016;165:82-91.	Qualitative	4 acute care hospitals in the western US.	N/A	N/A	Themes related to framework analysis and decision making.	A framework may assist in the decision making process for the evaluation of medical devices and products.	IIIB
3	Grundy Q, Bero LA, Malone RE. Marketing and the most trusted profession: the invisible interactions between registered nurses and industry. <i>Ann Intern Med.</i> 2016;164(11):733-739.	Qualitative	72 participants/ staff nurses, administrators, industry, and supply chain professionals.	N/A	N/A	Themes related to interactions between nurses and health care industry representatives.	The researchers indicated the importance for clinicians to be informed on new product developments to be prepared when new products are presented for evaluation. The researcher also found that involvement of nurses in hospital value analysis committees can drive quality and cost-savings.	IIIB
4	Hinrichs S, Dickerson T, Clarkson J. Stakeholder challenges in purchasing medical devices for patient safety. <i>J Patient Saf.</i> 2013;9(1):36-43.	Qualitative	23 /5 hospitals in the UK.	N/A	N/A	Themes related to challenges in the purchasing process	Results of the study suggests responsibility of purchasing medical devices is shared among clinical end-users, financial, and technical stakeholders.	IIIB

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5	Li CS, Vannabouathong C, Sprague S, Bhandari M. Orthopedic implant value drivers: a qualitative survey study of hospital purchasing administrators. <i>J Long Term Eff Med Implants</i> . 2015;25(3):237-244.	Qualitative	34 hospital executives in North America	N/A	N/A	Themes related to clinical evidence and cost effectiveness	The researchers focused on healthcare executives responsible for purchasing decisions.	IIIC
6	Jayakumar KL, Lavenberg JA, Mitchell MD, et al. Evidence synthesis activities of a hospital evidence-based practice center and impact on hospital decision making. <i>J Hosp Med</i> . 2015;11(3):185-192.	Organizational Experience	N/A	N/A	N/A	N/A	An evidence-based practice center (EPC) was found to be an effective method for promoting evidence-based purchasing decisions.	VA
7	Plonien C, Williams M. Vendor presence in the OR. <i>AORN J</i> . 2014;100(1):81-86.	Expert Opinion	N/A	N/A	N/A	N/A	Recommendations address , behavior, credentialing, compliance, and confidentiality of vendors in the OR. Perioperative nursing leadership is responsible for vendor credentialing.	VB
8	Sohrakoff K, Westlake C, Key E, Barth E, Antognini J, Johnson V. Optimizing the OR: a bottom-up approach. <i>Hosp Top</i> . 2014;92(2):21-27.	Organizational Experience	N/A	N/A	N/A	N/A	Opportunities for improvement include a 4 step process. 1) identify the key opportunities for improvement. 2) develop, 3) implement, and 4) evaluate the process changes.	VB

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9	Vockley M. Choosing wisely: trends and strategies for capital planning and procurement. <i>Biomed Instrum Technol.</i> 2016;50(4):230-241.	Expert Opinion	N/A	N/A	N/A	N/A	Trends in product procurement include patient safety, healthcare technology, sterile processing, approaches for decision making, and collaboration among stakeholders.	VC
10	Lerner DG, Pall H. Setting up the pediatric endoscopy unit. <i>Gastrointest Endosc Clin N Am.</i> 2016;26(1):1-12.	Non experimental - survey	18 pediatric gastroenterology (GI) centers	N/A	N/A	N/A	The results from the survey helps to guide decision making related to capital equipment and setting up pediatric endoscopy suites.	IIIB
11	<i>NHS Procurement &amp; Commercial Standards.</i> 2016. <a href="https://nhsprocurement.org.uk/files/2016-07/Standards_of_Procurement.pdf">https://nhsprocurement.org.uk/files/2016-07/Standards_of_Procurement.pdf</a> . Accessed August 23, 2017.	Consensus	N/A	N/A	N/A	N/A	These standards were developed to support the procurement process in the NHS healthcare provider organizations.	IVC
12	Martelli N, Hansen P, van den Brink H, et al. Combining multi-criteria decision analysis and mini-health technology assessment: a funding decision-support tool for medical devices in a university hospital setting. <i>J Biomed Inform.</i> 2016;59:201-208.	Nonexperimental	25/MDs and PharmDs	N/A	N/A	N/A	Development of the innovative device assessment (IDA) tool may promote a more structured approach when evaluating medical devices and may useful as a decision support tool.	IIIB

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13	Vincent CJ, Blandford A. How do health service professionals consider human factors when purchasing interactive medical devices? A qualitative interview study. <i>Appl Ergon</i> . 2017;59(Pt A):114-122.	Qualitative	20 participants; included various professional stakeholders involved in the evaluation and usability of infusion devices; by the UK National Health Service.	N/A	N/A	Themes related to evaluation, usability, and replacement issues	Evaluating medical device and product usability of products includes involving staff, multidisciplinary involvement, standardize the purchasing process, address usability, and supports the need for the equipment under evaluation.	IIIA
14	Lynch PK. Do group purchasing organizations really save money on capital equipment? <i>Biomed Instrum Technol</i> . 2017;51(2):170-171.	Expert Opinion	N/A	N/A	N/A	N/A	Healthcare technology management professionals developed metrics that measures the cost of maintaining medical devices, cost of service ratio (COSR). Closer scrutiny of the group purchasing model (GPO).	VC
15	Walsh SS. Suture cost savings in the OR. <i>AORN J</i> . 2012;95(5):631-634.	Organizational Experience	A level 1 Trauma center in Baltimore, Maryland	N/A	N/A	N/A	A standardized process was developed with materials service personnel, service line leaders, and tracked suture inventory. They had a 38% decrease in suture costs.	VB
16	Kobernick T. How to negotiate with high-pressure vendors. <i>Biomed Instrum Technol</i> . 2013;47(1):36-37.	Expert Opinion	N/A	N/A	N/A	N/A	Strategies such as understanding service contracts, cost containment, clinical risk, response time, parts and service, open communication with vendors may assist with high-pressure vendor tactics.	VC

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17	29 CFR §1910.1030: Bloodborne pathogens. Occupational Safety and Health Administration. <a href="https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=10051&amp;p_table=STANDARDS">https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=10051&amp;p_table=STANDARDS</a> . Accessed August 23, 2017.	Regulatory	N/A	N/A	N/A	N/A	N/A	N/A
18	Guideline for sharps safety. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 2017: 423-446.	Guideline	N/A	N/A	N/A	N/A	Provides guidance for sharps safety practices to protect patient and health care professionals.	IVA
19	Wernz C, Zhang H, Phusavat K. International study of technology investment decisions at hospitals. <i>Ind Manage Data Syst</i> [serial online]. 2014;114(4):568-582.	Qualitative	23/ Hospitals in Germany, India, Thailand, South Korea, and the US.	N/A	N/A	N/A	The findings from this study suggest that use of a computer-based decision support tool may be effective for evaluation of medical devices. Investment decisions are affected by the healthcare system, mission of the organization, and socio-economic and cultural context.	IIIC
20	42 CFR 482: Conditions of participation for hospitals. 2011. US Government Publishing Office. <a href="https://www.gpo.gov/fdsys/granule/CFR-2011-title42-vol5/CFR-2011-title42-vol5-part482">https://www.gpo.gov/fdsys/granule/CFR-2011-title42-vol5/CFR-2011-title42-vol5-part482</a> . Accessed August 23, 2017.	Regulatory	N/A	N/A	N/A	N/A	N/A	N/A

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21	42 CFR 416: Ambulatory surgical services. 2011. US Government Publishing Office. <a href="https://www.gpo.gov/fdsys/granule/CFR-2011-title42-vol3/CFR-2011-title42-vol3-part416">https://www.gpo.gov/fdsys/granule/CFR-2011-title42-vol3/CFR-2011-title42-vol3-part416</a> . Accessed August 23, 2017.	Regulatory	N/A	N/A	N/A	N/A	N/A	N/A
22	<i>ISO 20400:2017. Sustainable Procurement—Guidance.</i> Geneva, Switzerland: International Organization for Standardization; 2017.	Consensus	N/A	N/A	N/A	N/A	Provides an overview of sustainable procurement. Describes the principles and scope of sustainable procurement. Provides guidance about how sustainable considerations should be integrated at a strategic level.	IVC
23	Raft J, Millet F, Meistelman C. Example of cost calculations for an operating room and a post-anaesthesia care unit. <i>Anaesth Crit Care Pain Med</i> . 2015;34(4):211-215.	Organizational Experience	The Cancer Institute of Lorraine, Nancy, France that had 4 OR's and 6 PACU sites.	N/A	N/A	N/A	The findings from this organizational experience recognized despite difficulties with cost evaluation, a model of calculation, assisted them to develop a financial vision. This process demonstrated that global reflection is necessary during financial decision-making.	VA

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24	Sullivan SD, Mauskopf JA, Augustovski F, et al. Budget impact analysis—principles of good practice: report of the ISPOR 2012 Budget Impact Analysis Good Practice II Task Force. <i>Value Health</i> . 2014;17(1):5-14.	Expert Opinion	N/A	N/A	N/A	N/A	In some cases a financial analysis may be required for reimbursement.	VA
25	Hospital value-based purchasing. Centers for Medicare & Medicaid Services. <a href="https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/index.html?redirect=/hospital-value-based-purchasing">https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/index.html?redirect=/hospital-value-based-purchasing</a> . Updated February 15, 2017. Accessed August 23, 2017.	Regulatory	N/A	N/A	N/A	N/A	N/A	N/A
26	Stacy KM. Hospital value-based purchasing: part 1, overview of the program. <i>AACN Adv Crit Care</i> . 2016;27(4):362-367.	Expert Opinion	N/A	N/A	N/A	N/A	Hospital value-based purchasing is the newest program developed by CMS. Hospitals are reimbursed at a lower cost, but hospitals must earn the rest of the reimbursement by meeting quality measures.	VA

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27	Stacy KM. Hospital value-based purchasing: part 2, implications. <i>AACN Adv Crit Care</i> . 2017;28(1):16-20.	Expert Opinion	N/A	N/A	N/A	N/A	This is a 2nd article in a 2 part series. Statistical data is obtained thru CMS. Further implications for nurses and other health care professionals to improve quality and reimbursement.	VA
28	How healthcare executives make buying decisions. <i>Healthc Financ Manage</i> . 2012;66(6):1-7.	Expert Opinion	N/A	N/A	N/A	N/A	Two key findings include -First, the most important factor is to value the ability of a product to deliver a ROI, and second, executives are seeking reliable and neutral information about products/services to assist in the final decision making process.	VC
29	Bosko T, Dubow M, Koenig T. Understanding value-based incentive models and using performance as a strategic advantage. <i>J Healthc Manag</i> . 2016;61(1):11-14.	Expert Opinion	N/A	N/A	N/A	N/A	Health care organizations should follow strategies under the CMS Value based purchasing (VBP) program, the Hospital Readmissions Reduction Programs (HRRP), and the Hospital-Acquired Conditions (HAC) programs. Suggest to have multidisciplinary teams to include all stakeholders; and health care organization's performance on quality of care.	VB



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30	Eiferman D, Bhakta A, Khan S. Implementation of a shared-savings program for surgical supplies decreases inventory cost. <i>Surgery</i> . 2015;158(4):996-1002.	Organizational Experience	Conducted at the Ohio State University Wexner Medical Center	N/A	N/A	N/A	Opportunities for savings in the use of biologic mesh, cranial plating system, and neurostimulators were identified. Aligning surgeon and hospital incentives led to cost-savings and standardization of the inventory, while quality of care was not compromised.	VB
31	Farrokhi FR, Gunther M, Williams B, Blackmore CC. Application of lean methodology for improved quality and efficiency in operating room instrument availability. <i>J Healthc Qual</i> . 2015;37(5):277-286.	Organizational Experience	Conducted at the Virginia Mason Medical Center (VMMC)	N/A	N/A	N/A	The application of Lean methodology can improve quality at a lower cost. Complex surgical procedures offer opportunities for substantial waste reduction, simplification, and quality improvement, with potential institutional cost savings.	VB
32	Rocchio BJ. Achieving cost reduction through data analytics. <i>AORN J</i> . 2016;104(4):320-325.	Organizational Experience	Conducted at Mercy in Chesterfield, Missouri	N/A	N/A	N/A	Case costing is a method of reviewing costs related to implants and supplies used in a particular procedure by surgeon. The finding suggest that surgeons and staff need to be engaged in the decision making process.	VB
33	AORN position statement on environmental responsibility. <i>AORN J</i> . 2014;99(1):18-21.	Position Statement	N/A	N/A	N/A	N/A	Perioperative RNs have a responsibility to participate and support environmental practices.	IVB

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34	<i>ANA's Principles of Environmental Health for Nursing Practice with Implementation Strategies.</i> Silver Spring, MD: American Nurses Association; 2007. <a href="http://www.nursingworld.org/MainMenuCategories/WorkplaceSafety/Healthy-Nurse/ANAsPrinciplesofEnvironmentalHealthforNursingPractice.pdf">http://www.nursingworld.org/MainMenuCategories/WorkplaceSafety/Healthy-Nurse/ANAsPrinciplesofEnvironmentalHealthforNursingPractice.pdf</a> . Accessed August 23, 2017.	Consensus	N/A	N/A	N/A	N/A	RNs have a responsibility to promote, support, and assist in environmental practices.	IVC
35	Kaplan S, Sadler B, Little K, Franz C, Orris P. Can sustainable hospitals help bend the health care cost curve? <i>Issue Brief (Commonw Fund)</i> . 2012;29:1-14.	Nonexperimental	Data obtained at 4 separate hospitals.	N/A	N/A	N/A	Found that health care organizations are among the country's most energy-intensive facilities, accounting for a significant percentage of US greenhouse gas and carbon dioxide emissions. Health care organizations create 6,600 tons of waste per day and use large amounts of toxic chemicals. Following sustainable interventions that include energy-use reduction, recycling, minimization of regulated waste, reduction of landfill waste, reprocessing, reuse of single-use medical devices, and reformulation of OR custom packs may reduce waste.	IIIC

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36	Southorn T, Norrish AR, Gardner K, Baxandall R. Reducing the carbon footprint of the operating theatre: a multicentre quality improvement report. <i>J Perioper Pract.</i> 2013;23(6):144-146.	Organizational Experience	Two hospitals in the United Kingdom.	N/A	N/A	N/A	A simple change in practice with waste in the OR can have a positive environmental impact and represent significant cost savings.	VB
37	Wormer BA, Augenstein VA, Carpenter CL, et al. The green operating room: simple changes to reduce cost and our carbon footprint. <i>Am Surg.</i> 2013;79(7):666-671.	Organizational Experience	Carolinas Medical Center in Charlotte, North Carolina.	N/A	N/A	N/A	Formation of a green OR committee can improve a health care organization's impact on the environment as well as save money.	VA