REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
1	Childers CP, Maggard-Gibbons M. Understanding costs of care in the operating room. *JAMA Surg.* 2018;153(4):e176233	Nonexperimental	annual financial disclosure documents from all comparable short-term general and specialty care hospitals in California from fiscal year (FY) 2005 to FY2014 (N = 3044; FY2014,n = 302)	n/a	n/a	mean cost of 1 minute of OR time stratified by setting (inpatient v amb), teaching status, and hospital ownership. Proportion attributable to indirect and direct expenses are identified.	The mean cost of OR time is $36 to $37 per minute, using financial data from California's short-term general and specialty hospitals in FY2014. These statewide data provide a generalizable benchmark for the value of OR time.	IIIB
2	Kaye DR, Luckenbaugh AN, Oerline M et al. Understanding the costs associated with surgical care delivery in the Medicare population. *Ann Surg.* 2020;271(1):23–28.	Nonexperimental	20% national sample of Medicare beneficiaries 2008-2014	n/a	n/a	Total Medicare payments for surgical care	Surgical care accounts for half of all Medicare spending.	IIIA
3	Products and medical procedures. US Food and Drug Administration. https://www.fda.gov/medical-devices/products-and-medical-procedures. Updated September 14, 2021. Accessed June 8, 2022	Regulatory	n/a	n/a	n/a	n/a	The FDA regulates medical devices sold in the US to assure their safety and effectiveness.	n/a
4	Premarket notification 510(k). US Food and Drug Administration. https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k. Updated March 13, 2020. Accessed June 8, 2022.	Regulatory	n/a	n/a	n/a	n/a	A 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent, to a legally marketed device (section 513(i)(1)(A) FD&C Act).	n/a
5	Schuh JCL, Funk KA. Compilation of international standards and regulatory guidance documents for evaluation of biomaterials, medical devices, and 3-d printed and regenerative medicine products. *Toxicol Pathol* . 2019;47(3):344–357.	Expert Opinion	n/a	n/a	n/a	n/a	Compilation of a international standards and guidelines intended to inform toxicologic pathologists, toxicologists, bioengineers, and allied professionals with an overview of and source for regulatory documents that apply to development of products.	VA
6	Chen YJ, Chiou CM, Huang YW, Tu PW, Lee YC, Chien CH. A comparative study of medical device regulations: US, Europe, Canada, and Taiwan. *Ther Innov Regul Sci* . 2018;52(1):62–69.	Expert Opinion	n/a	n/a	n/a	n/a	Provides information about regulatory frameworks of medical devices in the US, Europe, Canada, and Taiwan with focus on changes in these countries and status of global harmonization.	VA
7	Hunter NL, Sherman RE. Combination products: modernizing the regulatory paradigm. *Nat Rev Drug Discov.* 2017;16(8):513–514.	Expert Opinion	n/a	n/a	n/a	n/a	Discussion of the FDA efforts in development of a modern, transparent, flexible, and consistent science-based regulatory approach for combination products with examples.	VA

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
8	Gopal AD, Rathi VK, Teng CC, Del Priore L, Ross JS. Incremental revisions across the life span of ophthalmic devices after initial Food and Drug Administration premarket approval, 1979-2015. *Ophthalmology.* 2017;124(8):1237–1246.	Nonexperimental	Ophthalmic devices initially approved via the FDA's PMA pathway between January 1979 through December 2015	n/a	n/a	Median iterated life span (timespan across which modifications occurred after initial PMA) and median number of supplements approved per device, by device type, and overall, stratified by regulatory pathway and modification type	Most ophthalmic devices approved via the FDA's PMA pathway have undergone extensive revisions, including serial design and labeling changes, since their initial approvals, often without supporting clinical data. Ophthalmologists should take into consideration that cumulative revisions may render the clinical evidence that supported an original FDA approval less relevant to newer device models.	IIIA
9	Intercenter agreement between the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research. US Food and Drug Administration. https://www.fda.gov/combination-products/jurisdictional-information/intercenter-agreement-between-center-drug-evaluation-and-research-and-center-biologics-evaluation. Updated February 16, 2018. Accessed June 8, 2022.	Regulatory	n/a	n/a	n/a	n/a	outlines the working relationships that exist between CBER and CDRH for certain categories of medical devices or specified medical devices	n/a
10	Intercenter agreements. US Food and Drug Administration. https://www.fda.gov/combination-products/jurisdictional-information/intercenter-agreements. Updated February 15, 2018. Accessed June 8, 2022.	Regulatory	n/a	n/a	n/a	n/a	The Center for Biologics Evaluation and Research (CBER), the Center for Drug Evaluation and Research(CDER), and the Center for Devices and Radiological Health (CDRH), are subject to three IntercenterAgreements (ICAs) that outline jurisdictional agreements for combination product governance.	n/a
11	Selzman KA, Patel H, Cavanaugh K. Electrophysiology devices and the regulatory approval process within the US FDA and abroad. *J Interv Card Electrophysiol.* 2019;56(2):173–182.	Expert Opinion	n/a	n/a	n/a	n/a	Discussion of the history and background of the US device clearance process using EP devices as example. Provides an overview of regulatory pathways in the US in contrast to other countries (EU and Japan).	VA
12	Muskens IS, Gupta S, Hulsbergen A, Moojen WA, Broekman MLD. Introduction of novel medical devices in surgery: ethical challenges of current oversight and regulation. *J Am Coll Surg.* 2017;225(4):558–565.	Expert Opinion	n/a	n/a	n/a	n/a	Regulation of medical devices in surgery carries ethical challenges and there is a need to strike a balance between patient safety and innovation.	VA
13	Janetos TM, Xu RS, Walter JR, Xu S. Reducing FDA regulations for medical devices: cutting red tape or putting patients' lives at risk? *Expert Rev Med Devices* . 2018;15(12):859–861.	Expert Opinion	n/a	n/a	n/a	n/a	There is limited evidence that lowering regulatory standards is better for patients. There must be a balance between evidence, time to market, cost, and the continued presence of device-related safety concerns suggest the need for more rigor, not less.	VA

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
14	Atwood D, Larose P, Uttley R. Strategies for success in purchasing medical technology. *Biomed Instrum Technol* . 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
15	Grundy Q. "Whether something cool is good enough": the role of evidence, sales representatives and nurses' expertise in hospital purchasing decisions. *Soc Sci Med* . 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
16	Grundy Q, Bero LA, Malone RE. Marketing and the most trusted profession: the invisible interactions between registered nurses and industry. *Ann Intern Med.* 2016;164(11):733–739.	Qualitative	purposive sample of 72 participants in four acute care hospitals in a western US city including staff nurses, administrators, and industry/supply chain professionals	n/a	n/a	semi-structured interviews about interactions and financial relationships between nurses and industry representatives	Nurse–industry interactions may be common and influential, but they remain invisible in the current policy climate. Although some aspects of these interactions may be beneficial, others may pose financial risks to hospitals or safety risks to patients. Disclosure strategies alone do not provide health professionals with adequate support to manage day-to-day interactions. Management of industry interactions must include guidance for nurses.	IIIB
17	Hinrichs S, Dickerson T, Clarkson J. Stakeholder challenges in purchasing medical devices for patient safety. *J Patient Saf.* 2013;9(1):36–43.	Qualitative	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
18	Li CS, Vannabouathong C, Sprague S, Bhandari M. Orthopedic implant value drivers: a qualitative survey study of hospital purchasing administrators. *J Long Term Eff Med Implants* . 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
19	Jayakumar KL, Lavenberg JA, Mitchell MD et al. Evidence synthesis activities of a hospital evidence-based practice center and impact on hospital decision making. *J Hosp Med.* 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
20	Plonien C, Williams M. Vendor presence in the OR. *AORN J.* 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
21	Sohrakoff K, Westlake C, Key E, Barth E, Antognini J, Johnson V. Optimizing the OR: a bottom-up approach. *Hosp Top.* 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

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
22	Vockley M. Choosing wisely: trends and strategies for capital planning and procurement. *Biomed Instrum Technol.* 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
23	Lerner DG, Pall H. Setting up the pediatric endoscopy unit. *Gastrointest Endosc Clin N Am.* 2016;26(1):1–12.	Nonexperimental	18 pediatric gastroenterology centers	n/a	n/a	survey	The results from the survey helps to guide decision making related to capital equipment and setting up pediatric endoscopy suites.	IIIB
24	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. *J Biomed Inform.* 2016;59:201–208.	Nonexperimental	25 MDs and PharmDs	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
25	Vincent CJ, Blandford A. How do health service professionals consider human factors when purchasing interactive medical devices? A qualitative interview study. *Appl Ergon* . 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
26	Henry A. Product evaluation. In: Boston KM, ed. *APIC Text Online.* Association for Professionals in Infection Control and Epidemiology, Inc. https://text.apic.org/. Accessed June 8, 2022.	Position Statement	n/a	n/a	n/a	n/a	The infection preventionist should participate in the product evaluation committee and ensure that products with infection prevention relevance are selected using evidence-based national guidelines or expert consensus.	IVA
27	Lynch PK. Do group purchasing organizations really save money on capital equipment? *Biomed Instrum Technol.* 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
28	Kobernick T. How to negotiate with high-pressure vendors. Biomed Instrum Technol. 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
29	Gresch A. *Healthcare Technology Management Manual.* Arlington, VA: Association for the Advancement of Medical Instrumentation (AAMI); 2019.	Expert Opinion	n/a	n/a	n/a	n/a	Guidance for health technology management leaders to support the safe and effective use of medical technology.	VA

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
30	Toor J, Du JT, Koyle M, et al. Inventory optimization in the perioperative care department using Kotter's Change Model. *TJC J on Qual Patient Safety.* 2022;48:5-11 [VA].	Organizational Experience	Single organization (tertiary academic hospital) across the four highest-volume surgical services	n/a	n/a	n/a	Describes successful implementation of Kotter's Change Model to facilitate change in the perioperative setting in inventory optimization.	VA
31	29 CFR 1910.1030: Bloodborne pathogens. Electronic Code of Federal Regulations. https://www.ecfr.gov/current/title-29/subtitle-B/chapter-XVII/part-1910/subpart-Z/section-1910.1030. Accessed June 8, 2022.	Regulatory	n/a	n/a	n/a	n/a	Federal bloodborne pathogens occupational exposure regulations.	n/a
32	Guideline for sharps safety. In: *Guidelines for Perioperative Practice.* Denver, CO: AORN, Inc; 2022:947–970.	Guideline	n/a	n/a	n/a	n/a	Provides guidance for sharps safety practices to protect patient and health care professionals.	IVA
33	29 CFR 1910.134: Respiratory protection. Electronic Code of Federal Regulations. https://www.ecfr.gov/current/title-29/subtitle-B/chapter-XVII/part-1910/subpart-I/section-1910.134tection. Accessed June 8, 2022.	Regulatory	n/a	n/a	n/a	n/a	Federal respiratory protection for occupational exposure regulations	n/a
34	Wernz C, Zhang H, Phusavat K. International study of technology investment decisions at hospitals. *Industrial Management & Data Systems.* 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 socioeconomic and cultural context	IIIC
35	42 CFR 482: Conditions for participation for hospitals. Electronic Code of Federal Regulations. https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-482. Accessed June 8, 2022.	Regulatory	n/a	n/a	n/a	n/a	Code of participation (Medicare) for hospitals	n/a
36	42 CFR 416: Ambulatory surgical services. Electronic Code of Federal Regulations. https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-416. Accessed June 8, 2022.	Regulatory	n/a	n/a	n/a	n/a	Conditions of participation for ambulatory surgical services	n/a
37	ISO 20400:2017. *Sustainable Procurement – Guidance* . 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.	IVA
38	Raft J, Millet F, Meistelman C. Example of cost calculations for an operating room and a post-anaesthesia care unit. *Anaesth Crit Care Pain Med.* 2015;34(4):211–215.	Organizational Experience	The Cancer Institute of Lorraine, Nancy, France with 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.	IIIA

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
39	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. *Value Health.* 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
40	Stacy KM. Hospital value-based purchasing: part 1, overview of the program. *AACN Adv Crit Care.* 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
41	Stacy KM. Hospital value-based purchasing: part 2, implications. *AACN Adv Crit Care.* 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
42	Wang E, Jootun R, Foster A. Management of acute appendicitis in an acute surgical unit: a cost analysis. *ANZ J Surg* . 2018;88(12):1284–1288	Nonexperimental	Patients who had uncomplicated acute appendicitis and appendectomy in a single hospital (n=271)	n/a	n/a	total care cost by category	Three cost drivers were hospital overhead costs, hospital bed day costs (LOS) and cost of running ORs including supply costs.	IIIA
43	Offodile AC 2nd, Sen AP, Holtsmith S et al. Harnessing behavioral economics principles to promote better surgeon accountability for operating room cost: a prospective study. *J Am Coll Surg.* 2020;230(4):585–593.	Nonexperimental	2,853 procedures and 26 surgeons in one health care organization	n/a	n/a	Cost after deployment of a cost feedback tool using behavioral economics principles	Use of a cost feedback tool resulted in significant decrease in OR spending for surgical products without negatively affecting surgical complication rate.	IIIB
44	Patel S, Lindenberg M, Rovers MM et al. Understanding the costs of surgery: a bottom-up cost analysis of both a hybrid operating room and conventional operating room. *Int J Health Policy Manag.* 2022;11(3):299–307	Organizational Experience	Five Dutch hospitals with hybrid OR's	n/a	n/a	n/a	Cost comparison for utilization of conventional versus hybrid OR's. Hybrid ORs were substantially more expensive to operate with inventory costs being one of the two main drivers.	VA
45	Okike K, Pollak R, O'Toole RV, Pollak AN. "Red-Yellow-Green": Effect of an initiative to guide surgeon choice of orthopaedic implants. *J Bone Joint Surg Am.* 2017;99(7):e33.	Organizational Experience	University of Maryland Medical Center in Baltimore. Six orthopedic trauma devices were categorized for each of the 4 vendors according to cost.	n/a	n/a	n/a	This institution realized cost savings after implementing a "red-yellow-green" tool intended to guide surgeons to select and use lower-cost implants. The initiative resulted in improved preferred-vendor utilization and increased completion among vendors.	VA
46	Patrinely JR Jr, Walker SH, Glassman GE et al. The importance of financial metrics in physician funding and performance evaluation. *Plast Reconstr Surg.* 2021;147(5):1213–1218.	Organizational Experience	Two tertiary medical centers departments of surgery.	n/a	n/a	n/a	Identifies the importance of using key performance indicators including equipment cost and cost savings potential in equipment requests.	VA

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
47	Ross S, Lier D, Mackinnon G, Bentz C, Rakowski G, Capstick VA. Can a simple 'cost-awareness' campaign for laparoscopic hysterectomy change the use and costs of disposable surgical supplies? Pre-post non-controlled study. *BMJ Open.* 2019;9(12):e027099	Organizational Experience	Twelve surgeons at one facility.	n/a	n/a	n/a	Cost awareness campaigns may be associated with reduction in the cost of surgery without negatively impacting OR time or patient length of stay.	VB
48	Park KY, Russell JI, Wilke NP, Marka NA, Nichol PF. Reducing cost and waste in pediatric laparoscopic procedures. *J Pediatr Surg.* 2021;56(1):66–70.	Organizational Experience	Pediatric surgery cost for laparoscopic surgery at the University of Wisconsin American Family Children's Hospital in Madison between January 2016 and March 2019.	n/a	n/a	n/a	Use of a report (that included supply cost per case, high cost, disposable supply utilization, and clinical outcomes) which was given to surgeons resulted in supply cost per case by 43%.	VA
49	Joshi MR, Latham J, Okorogheye G. Use of a flowable haemostat versus an oxidised regenerated cellulose agent in primary elective cardiac surgery: economic impact from a UK healthcare perspective. *J Cardiothoracic Surg.* 2017;12(1):107.	Nonexperimental	NHS (England) reference costs in cardiac surgery 2016.	n/a	n/a	complications avoided, OR time savings, surgical revisions for bleeding avoided, transfusions avoided with use of a hemostatic agent	Despite higher acquisition costs, the use of flowable hemostatic agents achieves cost savings over non-flowable agents in cardiac surgery in all outcomes measured.	IIIB
50	Pesigan P, Chen H, Bajaj AA, Gill HS. Cost savings in urology operating rooms by editing surgeon preference cards. *Qual Manag Health Care.* 2021;30(2):135–137.	Organizational Experience	One organization, 5 urologic surgeons and 4 OR staff over 3 months	n/a	n/a	n/a	Review of opened and unused disposable supplies in the OR and subsequent edits of preference cards resulted in cost savings.	VA
51	Winegar AL, Jackson LW, Sambare TD et al. A surgeon scorecard is associated with improved value in elective primary hip and knee arthroplasty. *J Bone Joint Surg Am.* 2019;101(2):152–159.	Nonexperimental	urban tertiary care center August 2016-May 2017 total joint arthroplasty procedures (n=379)	n/a	n/a	Total direct variable costs and implant costs	Implementation of a surgeon-specific scorecard for joint arthroplasties was associated with a reduced total and direct variable hospital costs, reduced implant costs, decreased variation in costs, and reduced postoperative LOS without compromising clinical outcomes.	IIIA
52	Liu R, Wess A, Kidane B, Srinathan S, Tan L, Buduhan G. A simple "passive awareness" intervention to decrease the cost of thoracoscopic lobectomy. *Updates Surg.* 2021;73(6):2369–2374.	Organizational Experience	Thoracic OR in one organization	n/a	n/a	n/a	Posting a price list for disposable items used for throascopic lobectomy resulted in lower cost per case over time in one institution.	VA
53	Zygourakis CC, Valencia V, Moriates C et al. Association between surgeon scorecard use and operating room costs. *JAMA Surg.* 2017;152(3):284–291.	Nonexperimental	single health system, multi-hospital multidepartment in an urban academic setting from January 1 through December 31 2015.	n/a	n/a	median supply cost per case	Cost feedback to surgeons combined with a small departmental financial incentive, was associated with significantly reduced surgical supply costs without negatively affecting patient outcomes.	IIIA

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
54	Kazmers NH, Judson CH, Presson AP, Xu Y, Tyser AR. Evaluation of factors driving cost variation for distal radius fracture open reduction internal fixation. *J Hand Surg Am* . 2018;43(7):606–614.	Organizational Experience	Single tertiary academic medical center	n/a	n/a	n/a	Cost savings can be realized by organizations when improves in implant costs are prioritized.	VA
55	Koppert T, Tumin D, Tobias JD, Raman VT. Projecting cost containment in the operating room utilizing incentivized strategies to reduce healthcare cost. *Pediatr Qual Saf* . 2019;4(4):e190.	Organizational Experience	One organization, Nationwide Children's Hospital	n/a	n/a	n/a	Simple changes can impact efficiency and cost in healthcare. This organization reduced cost through changes in drug delivery in the OR.	VA
56	Chalmers PN, Kahn T, Broschinsky K et al. An analysis of costs associated with shoulder arthroplasty. *J Shoulder Elbow Surg.* 2019;28(7):1334–1340.	Nonexperimental	361 patients who underwent shoulder arthroplasty	n/a	n/a	patient factors (procedure details), total costs (facility utilization costs and supply costs)	Most short-terms costs are associated with operative costs. Modifiable factors influencing cost were use of bone graft, implant brand, and reverse total shoulder approach	IIIB
57	Chasseigne V, Leguelinel-Blache G, Nguyen TL et al. Assessing the costs of disposable and reusable supplies wasted during surgeries. *Int J Surg.* 2018;53:18–23.	Nonexperimental	French university hospital; 50 routine procedures and 5 non-scheduled procedures	n/a	n/a	cost of opened and unused products in the OR	Reducing wasted supplies could improve the cost efficiency of the OR and decrease its ecological impact.	IIIB
58	Childers CP, Showen A, Nuckols T, Maggard-Gibbons M. Interventions to Reduce Intraoperative Costs: A Systematic Review. *Ann Surg.* 2018;268(1):48-57	Systematic Review	n/a	n/a	n/a	n/a	financial pressures have brought value analysis to the forefront of healthcare discussions, and the activities in the OR will be increasingly scrutinized. Some intraoperative cost-saving interventions appear to be successful without risking patient safety. Significant heterogeneity in cost data limits the ability to compare within and between some intervention categories. The most promising interventions to date involve standardization of operative instruments and cost feedback.	IIIB
59	Denton B. Standardize Physician Cards for Quality, Savings. *Hosp Peer Rev.* 2017;42(6):69-70	Expert Opinion	n/a	n/a	n/a	n/a	Engaging surgeons with data from preference cards can result in cost savings when surgeons are informed about costs.	VC
60	Geppert P, Daily B, Casanova S. Achieving Surgical Supply Savings through Preference Card Standardization. *J Med Syst* . 2020;44(6):1-6	Nonexperimental	359 laparoscopic cholecystectomies at a single institution	n/a	n/a	direct supply cost per case	Preference card standardization in this institution, a heavily consensus-driven academic medical center, was successful in reducing variation and costs for laparoscopic cholecystectomy.	IIIB
61	Glennie RA, Oxner WM, Barry SP, Alant J, Christie S. Will cost transparency in the operating theatre cause surgeons to change their practice? *J Clin Neurosci* . 2019;60:1-6	Nonexperimental	80 neurosurgical and orthopedic spine procedures (cervical or lumbar)	n/a	n/a	cost per procedure	Increasing transparency of implant costs can lead to significant cost savings in the OR but may not be associated with reduction in overall costs.	IIIA

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
62	Goldberg TD, Maltry JA, Ahuja M, Inzana JA. Logistical and Economic Advantages of Sterile-Packed, Single-Use Instruments for Total Knee Arthroplasty. *J Arthroplasty.* 2019;34(9):1876-1883.e2	Nonexperimental	1000 simulated TKA procedures using the Monte Carlo technique	n/a	n/a	cost per procedure for traditional TKA instruments versus single-use instruments	Modeling study suggests that single-use instruments have a compelling potential to help improve the quality and efficiency of delivering TKA procedures, warranting future prospective studies to measure the actual resource and cost savings observed in practice.	IIIB
63	Harvey LFB, Smith KA, Curlin H. Physician Engagement in Improving Operative Supply Chain Efficiency Through Review of Surgeon Preference Cards. *J Minim Invasive Gynecol* . 2017;24(7):1116-1120	Organizational Experience	Twenty-one gynecologic surgeons	n/a	n/a	n/a	A one-time review of preference cards resulted in a decrease in the number of items that were stocked, transported, counted, returned in the OR. Surgeon involvement in preference card management can result in reduced waste and cost.	VA
64	Ibrahim AM, Dimick JB. Use of an operating room scorecard—keeping score and cutting costs. *JAMA Surg.* 2017;152(3):291.	Expert Opinion	n/a	n/a	n/a	n/a	When given the right information, surgeons can be key players in reducing health care costs.	VA
65	Ishii L, Demski R, Ken Lee,K.H., et al. Improving healthcare value through clinical community and supply chain collaboration. *Healthc (Amst*). 2017;5(1-2):1-5. doi:https://dx.doi.org/10.1016/j.hjdsi.2016.03.003	Organizational Experience	Three service lines in one organization (spine, joint, blood management)	n/a	n/a	n/a	Collaboration in physician-led teams resulted in vendor-capping model that resulted din cost savings in spine and joint services.	VA
66	Kynaston JW, Smith T, Batt J. Cost awareness of disposable surgical equipment and strategies for improvement: cross sectional survey and literature review. *J Perioper Pract.* 2017;27(10):211-216	Nonexperimental	48 clinicians in a UK hospital	n/a	n/a	knowledge of cost for 13 commonly-used OR supplies	Demonstrates a lack of cost awareness among healthcare professionals in the UK with regards to disposable surgical supplies.	IIIA
67	Standardization Can Help Lower Costs Related to Supply Chain Expenses. *Strategic Insights for Health System News.* November 20, 2019	Expert Opinion	n/a	n/a	n/a	n/a	The average hospital spends $12.1 million more than it needs annually and wasteful spending could be reduced through standardization efforts.	VA
68	Zhao B, Tyree GA, Lin TC, et al. Effects of a Surgical Receipt Program on the Supply Costs of Five General Surgery Procedures. *J Surg Res.* 2019;236:110-118	Organizational Experience	A single-institution, multi-hospital retrospective study comparing trends in per-case supply costs for five commonly-performed general surgery procedures before and after the implementation of an institution-wide surgical receipt program	n/a	n/a	n/a	An automated and operationalized surgeon-directed cost feedback system (emailed receipts for case cost after every procedure) can be a useful tool to control surgical supply expenses.	VA
69	ECRI Institute. Use of reprocessed single-use medical devices. *Healthcare Risk Control.* July 30 , 2015.	Expert Opinion	n/a	n/a	n/a	n/a	Guidance article informs about FDA regulation of reprocessed SUDs and discusses factors that US health care facilities should consider regarding use of SUDs reprocessed by FDA-registered third party firms.	VA

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
71	*State Operations Manual Appendix A: Survey Protocol, Regulations and Interpretive Guidelines for Hospitals.* Rev. 200 ed. Centers for Medicare & Medicaid Services (CMS); 2020	Regulatory	n/a	n/a	n/a	n/a	Survey protocol intended to be used by surveyors who evaluate hospitals that participate in Medicare.	n/a
72	*State Operations Manual Appendix L: Guidance for Surveyors: Ambulatory Surgical Centers.* Rev. 200 ed. Centers for Medicare & Medicaid Services (CMS); 2020.	Regulatory	n/a	n/a	n/a	n/a	Survey protocol intended to be used by surveyors who evaluate ambulatory surgery centers that participate in Medicare.	n/a
73	Surgical and related services. Subchapter II: Laser, light-based technologies, and other energy-emitting equipment. In: Accreditation Handbook for Ambulatory Health Care. Vol 41. Skokie, IL: Accreditation Association for Ambulatory Health Care (AAAHC); 2020:94–97.	Accreditation	n/a	n/a	n/a	n/a	For freestanding ambulatory surgery centers, handbook is intended to communicate AAAHC policies and procedures, and to assist organizations in assessing compliance with AAAHC standards, and offers tools for improvement.	n/a
74	How healthcare executives make buying decisions. *Healthc Financ Manage.* 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
75	The Hospital Value-Based Purchasing (VBP) Program. Centers for Medicare & Medicaid Services. https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/HVBP/Hospital-Value-Based-Purchasing. Accessed June 9, 2022	Regulatory	n/a	n/a	n/a	n/a	Describes the VBP program which rewards acute care hospitals with incentive payment for the quality of care provided in the inpatient hospital setting. Recognizes hospitals that provide high-quality care at a lower cost to Medicare.	n/a
76	Hospital Value-Based Purchasing Program. Hospital quality initiative. https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Hospital-Value-Based-Purchasing-. Accessed June 9, 2022.	Regulatory	n/a	n/a	n/a	n/a	Describes updates to the VBP program which includes quality domains and weights for clinical outcomes, person/community engagement, safety, and efficiency/cost reduction.	n/a
77	Bosko T, Dubow M, Koenig T. Understanding value-based incentive models and using performance as a strategic advantage. J Healthc Manag. 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
78	Eiferman D, Bhakta A, Khan S. Implementation of a shared-savings program for surgical supplies decreases inventory cost. *Surgery.* 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

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
79	Farrokhi FR, Gunther M, Williams B, Blackmore CC. Application of lean methodology for improved quality and efficiency in operating room instrument availability. *J Healthc Qual.* 2015;37(5):277-286	Organizational Experience	conducted at the Virginia Mason Medical Center	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
80	Mills M. The Need for Interoperability in the Perioperative Environment. *AORN J.* 2019;110(4):363-365	Expert Opinion	n/a	n/a	n/a	n/a	Interoperability is required in the OR for systems that share and interpret clinical data. Perioperative leaders are uniquely positioned to advocate for equipment purchase that meets interoperability demands at the organizational level, and can advocate for interoperability in built systems.	VA
81	Wireless medical devices. US Food and Drug Administration. https://www.fda.gov/medical-devices/digital-health-center-excellence/wireless-medical-devices. Updated September 4, 2018. Accessed June 8, 2022.	Regulatory	n/a	n/a	n/a	n/a	The Federal Communications Commission (FCC) oversees the use of the public Radio Frequency (RF)spectrum within which RF wireless technologies operate. The FDA's policies on wireless medical devices are coordinated with the FCC and provide medical device manufacturers with more predictability and a better understanding of regulatory requirements for medical devices that utilize these technologies.	n/a
82	Wireless medical telemetry systems. US Food and Drug Administration. https://www.fda.gov/medical-devices/wireless-medical-devices/wireless-medical-telemetry-systems. Updated September 4, 2018. Accessed June 8, 2022.	Regulatory	n/a	n/a	n/a	n/a	The Federal Communications Commission (FCC) established the Wireless Medical Telemetry Service (WMTS) by allocating specific frequency bands exclusively for wireless medical telemetry. The WMTS set aside 14 MHz of spectrum in three defined frequency bands of: 608-614 MHz, 1395-1400 MHz, and 1427-1432 MHz for primary or co-primary use by eligible wireless medical telemetry users.	n/a
83	Radio frequency identification (RFID). US Food and Drug Administration. https://www.fda.gov/radiation-emitting-products/electromagnetic-compatibility-emc/radio-frequency-identification-rfid. Updated September 17, 2018. Accessed June 8, 2022.	Regulatory	n/a	n/a	n/a	n/a	The FDA is not aware of any adverse events associated with RFID. However, there is concern about the potential hazard of electromagnetic interference (EMI) to electronic medical devices from radio transmitters like RFID. EMI is a degradation of the performance of equipment or systems caused by an electromagnetic disturbance.	n/a

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
85	FDA informs patients, providers and manufacturers about potential cybersecurity vulnerabilities in certain medical devices with Bluetooth low energy [News Release]. US Food and Drug Administration. https://www.fda.gov/news-events/press-announcements/fda-informs-patients-providers-and-manufacturers-about-potential-cybersecurity-vulnerabilities-0. Published March 3, 2020. Accessed June 8, 2022.	Regulatory	n/a	n/a	n/a	n/a	Alert from FDA that describes cybersecurity concerns around "SweynTooth" - a wireless communication technology that allows medical devices to pair and exchange information - that if exploited could allow an unauthorized users to crash the device, stop it from working or access device functions normally only available to the authorized user.	n/a
86	Yuan S, Fernando A, Klonoff DC. Standards for Medical Device Cybersecurity in 2018. *J Diabetes Sci Technol* . 2018;12(4):743-746	Position Statement	n/a	n/a	n/a	n/a	Summary of consensus statements for the management of medical device cybersecurity	IVB
87	Davis-Smith C. *Aquisition Guide for Clinical Technology Equipment.* Association for the Advancement of Medical Instrumentation (AAMI); 2019	Expert Opinion	n/a	n/a	n/a	n/a	Guide focused on the process of acquiring clinical technology equipment.	VA
88	ECRI Institute. Flaws in medical device networking can lead to delayed or inappropriate care. Hazard #9--top 10 health technology hazards for 2018. Health Devices. November 1 , 2017	Expert Opinion	n/a	n/a	n/a	n/a	Patient safety hazard identification that provides examples of problematic networking, incomplete data, and consequences for care. Provinces recommendations to mitigate risk for these technology failures.	VA
89	Franke S, Rockstroh M, Hofer M, Neumuth T. The intelligent OR: design and validation of a context-aware surgical working environment. *Int j comput assist radiol surg* . 2018;13(8):1301-1308	Expert Opinion	n/a	n/a	n/a	n/a	Presents technology as a product that can provide environmental clinical support with interoperability as a prerequisite.	VA
90	Kuehn BM. Pacemaker Recall Highlights Security Concerns for Implantable Devices. *Circulation.* 2018;138(15):1597-1598	Expert Opinion	n/a	n/a	n/a	n/a	Describes hacking risk for medical devices (cardiac pacemaker) and advises that cybersecurity for devices should be treated as a continuous quality improvement process.	VA
91	Pfeiffer JH, Kasparick M, Strathen B, et al. OR.NET RT: how service-oriented medical device architecture meets real-time communication. *Biomed Tech* (Berl). 2018;63(1):81-93	Expert Opinion	n/a	n/a	n/a	n/a	Technical description of networking and interoperability issues in the OR using the OR.NET approach.	VA
92	Top 10 Health Technology Hazards for 2021: Expert Insights from Health Devices. Plymouth Meeting, PA: ECRI; 2021.	Expert Opinion	n/a	n/a	n/a	n/a	Produced each year by ECRI's device evaluation group, the Top 10 Health Technology Hazards list (1) identifies the potential sources of danger that we believe warrant the greatest attention for the coming year and (2) offers practical recommendations for reducing the risks.	VA
93	Rocchio BJ. Achieving cost reduction through data analytics. *AORN J.* 2016;104(4):320-325	Organizational Experience	Conducted at Mercy with system headquarters in Chesterfield, MO	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

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
94	AORN position statement on environmental responsibility. AORN, Inc. https://www.aorn.org/guidelines/clinical-resources/position-statements. Revised March 2020. Accessed June 8, 2022.	Position Statement	n/a	n/a	n/a	n/a	Perioperative RNs have a responsibility to participate and support environmental practices.	IVB
95	Yates EF, Bowder AN, Roa L, et al. Empowering Surgeons, Anesthesiologists, and Obstetricians to Incorporate Environmental Sustainability in the Operating Room. *Ann Surg.* 2021;273(6).	Literature Review	n/a	n/a	n/a	n/a	Climate change adversely impacts patient health, and disproportionately impacts the most vulnerable patients. Surgeons, anesthesia professionals, obstetricians contribute to the problem through their resource-intensive work in the OR and are uniquely positioned to lead efforts to improve the environmental sustainability of the OR.	VA
96	Denny NA. Operating Room Waste Reduction. *AANA J.* 2019;87(6):477-482	Nonexperimental	2 OR suites in Rochester MN - Mayo Clinic Hospital	n/a	n/a	anesthesia supply waste (laryngoscope blades/handles and ET tubes)	Implementation of a protocol aimed at reducing anesthesia supply waste resulted in a significant improvement in the number of supplies wasted.	IIIA
97	Kaplan S, Sadler B, Little K, Franz C, Orris P. Can sustainable hospitals help bend the health care cost curve. Issue Brief *(Commonw Fund)* . 2012;29:1-14	Nonexperimental	Data obtained at 4 separate hospitals	n/a	n/a	Resource consumption and waste generation	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
98	Van Demark RE, Smith VJS, Fiegen A. Lean and Green Hand Surgery. *J Hand Surg* (USA). 2018;43(2):179-181	Organizational Experience	Single organization hand procedures	n/a	n/a	n/a	Implementation of a "lean and green" approach to hand surgery including reduced need for preoperative testing, WALANT, and a pared-down back table setup resulted in significant cost savings while maintaining quality care and a high level of patient satisfaction.	VA
99	Southorn T, Norrish AR, Gardner K, Baxandall R. Reducing the carbon footprint of the operating theatre: a multicentre quality improvement report. *J Perioper Pract.* 2013;23(6):144-146	Organizational Experience	Two hospitals in UK	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
100	Wormer BA, Augenstein VA, Carpenter CL, et al. The green operating room: simple changes to reduce cost and our carbon footprint. *Am Surg.* 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
101	ECRI Institute. Introduction to hospital waste management. *Healthcare Risk Control.* May 1 , 2011.	Expert Opinion	n/a	n/a	n/a	n/a	Guidance for health care leaders for hospital waste management principals and practices.	VB

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
102	Zygourakis CC, Yoon S, Valencia V, et al. Operating room waste: disposable supply utilization in neurosurgical procedures. *J Neurosurg* . 2017;126(2):620-625	Organizational Experience	58 neurosurgical procedures at the University of California San Francisco in August 2015	n/a	n/a	n/a	There is large variation and significant magnitude of OR waste in neurosurgical procedures. At the authors' institution, they recommend price transparency, education about OR waste to surgeons and nurses, preference card reviews, and clarification of supplies that should be opened versus available as needed to reduce waste.	VA
103	McGain F, Story D, Lim T, McAlister S. Financial and environmental costs of reusable and single-use anaesthetic equipment. *Br J Anaesth* . 2017;118(6):862–869.	Nonexperimental	Life cycle assessment model for anesthesia equipment (reusable versus single use)	n/a	n/a	cost, CO2 equivalents, and water consumption	For an Australian hospital with six operating rooms, converting from single-use to reusable anesthetic equipment saved more than AUD$30 000 annually, but increased the CO2 emissions by almost 10%. The CO2 offset is highly dependent on the power source mix, while water consumption is greater for reusable equipment.	IIIA
104	Cleaning fluid seeping into electrical components can lead to equipment damage and fires. Hazard #9: 2019 top 10 health technology hazards. *Health Devices* . 2018	Expert Opinion	n/a	n/a	n/a	n/a	ECRI reports multiple instances in which cleaning fluid seeping into electrical components has led to equipment damage or fire. Incidents have involved infusion pumps, OR tables, infant warmers, and electrical equipment such as light switches and power supplies. When cleaning electrical equipment, staff should follow manufacturer instructions, they should avoid spraying fluids directly onto the equipment, and they should use appropriate cloths, wipes, and sponges (squeezing out excess liquid before use)	VA
105	Insufficient training of clinicians on operating room technologies puts patients at increased risk of harm. Hazard #5: top 10 health technology hazards for 2016. *Health Devices.* 2015	Expert Opinion	n/a	n/a	n/a	n/a	ECRI Institute estimates that approximately 70% of accidents involving a medical device can be attributed to user error or the technique of use. Many of these incidents could have been avoided if users had a better understanding of the instructions for use and device operation. Facilities should make training a key part of the acquisition process for new OR technologies, as well as an ongoing consideration for existing technologies.	VA
106	Lagoo J, Singal R, Berry W, et al. Development and Feasibility Testing of a Device Briefing Tool and Training to Improve Patient Safety During Introduction of New Devices in Operating Rooms: Best Practices and Lessons Learned. *J Surg Res.* 2019;244:579-586.	Organizational Experience	30 surgeons, 15 device representatives, 30 nurses	n/a	n/a	n/a	Use of the Device Briefing Tool can prepare representatives to train surgeons and nurses in patient safety and quality improve-ment is necessary to fully leverage and empower representatives to become agents of change around safety culture.	VB
107	Dubin JR, Simon SD, Norrell K, Perera J, Gowen J, Cil A. Risk of Recall Among Medical Devices Undergoing US Food and Drug Administration 510(k) Clearance and Premarket Approval, 2008-2017. *JAMA Network Open* . 2021;4(5):e217274-e217274	Nonexperimental	medical devices that received PMA or 510k between 1/1/2008 and 12/31/2017	n/a	n/a	recall rates for medical devices with either PMA or 510k	Study suggests that high-risk medical devices approved via PMA are associated with a greater risk of recall than previously reported. Strengthening post marketing surveillance strategies and pivotal trials may improve device safety.	IIIA

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
108	Ghobadi CW, Janetos TM, Tsai S, et al. Approval-Adjusted Recall Rates of High-Risk Medical Devices from 2002-2016 Across Food and Drug Administration Device Categories. *Issues Law Med.* 2019;34(1):77-92	Nonexperimental	Medical devices cleared by the FDA between 2002 and 2016	n/a	n/a	recall rates for medical devices with either PMA or 510k	From 11/2002 to 12/2016, high-risk medical device recall events occurred on average 35 times per year, increasing each year. More advanced post-market surveillance activities would allow for earlier identification and risk mitigation of emerging safety signals.	IIIA
109	Healy EM, Braender LJ, Zalewski TA. A provider's guide to managing a medical device recall. *J Health Life Sci Law.* 2018;11(2):88–102.	Expert Opinion	n/a	n/a	n/a	n/a	Creating an effective recall system requires establishing a multidisciplinary approach when drafting policies and procedures, providing regular training for staff, maintaining quality communication with patients when a recall occurs, and staying informed about recalls of FDA-regulated medical devices.	VA
110	Ibrahim AM, Dimick JB. Monitoring Medical Devices: Missed Warning Signs Within Existing Data. *JAMA* . 2017;318(4):327-328	Expert Opinion	n/a	n/a	n/a	n/a	Rather than duplicate efforts and collect more data, health care leaders should renew their focus on making better use of available data. An example in which this is readily apparent involves the monitoring of medical devices	VA
111	ECRI. Medical device reporting. *Health Syst Risk Manage* . July 24 , 2020.	Expert Opinion	n/a	n/a	n/a	n/a	ECRI summary of FDA MDR processes, and action recommendations for organizations to establish and implement an MDR program.	VA
112	Sarkissian A. An exploratory analysis of US FDA Class I medical device recalls: 2014-2018. *J Med Eng Technol.* 2018;42(8):595–603.	Nonexperimental	871 FDA Class I medical device recalls	n/a	n/a	recall reporting system quality	The clause classification system in the MDR needs revision and there might be a case for more than one classification scheme. Devising a recall severity measure and improving and standardizing the recalls database are other important issues.	IIIA
114	ECRI. Responding to and learning from device problems. *Health Syst Risk Manage.* March 6 , 2020.	Expert Opinion	n/a	n/a	n/a	n/a	outlines suggestions to improve device problem investigation including identifying and preparing investigation coordinators, creating a plan for device-related incidents, and preparedness across the organization.	VA
115	Talati, Rushi K., Gupta, Ankur S., Xu, Shuai alati RK, Gupta AS, Xu S, Ghobadi CW. Major FDA medical device recalls in ophthalmology from 2003 to 2015. *Can J Ophthalmol.* 2018;53(2):98-103	Expert Opinion	n/a	n/a	n/a	n/a	Class I recalls surrounding ophthalmology are relatively infrequent compared to other medical specialties. However, given the impact of Class I recalls in the field, ophthalmologists have an impetus to advocate for stronger device regulation particularly in the context of post-marketing surveillance.	VA
116	Vajapey SP, Li M. Medical Device Recalls in Orthopedics: Recent Trends and Areas for Improvement. *J Arthroplasty* . 2020;35(8):2259-2266	Expert Opinion	n/a	n/a	n/a	n/a	Orthopedic device recalls remain a significant concern and constitute, on average,16.6% of all class II medical device recalls from 2015 to 2019. Manufacturing companies can reduce the number of orthopedic device recalls by improving their device design, manufacturing, and packaging stages of the production cycle.	VA

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
117	Janetos TM, Ghobadi CW, Xu S, Walter JR. Overview of high-risk medical device recalls in obstetrics and gynecology from 2002 through 2016: implications for device safety. *Am J Obstet Gynecol.* 2017;217(1):42-46.e1	Expert Opinion	n/a	n/a	n/a	n/a	Strengthening post marketing surveillance mechanisms is acritical step forward in ensuring device safety and mitigating impact against high-risk recalls. However, postmarketingsurveillance alone cannot replace the role of high-quality clinical studies prior to the approval and market entry for medical devices.	VA
118	ACOG Committee Opinion No. 769 Summary: Reprocessed Single-Use Devices. *Obstet Gynecol.* 2019;133(3):600-601	Expert Opinion	n/a	n/a	n/a	n/a	Obstetrician–gynecologists are encouraged to report adverse events and outcomes associated with medical devices to the U.S. Food and Drug Administration's Manufacturer and User Facility Device Experience(MAUDE) database.	VA
119	522 Postmarket Surveillance Studies Database. US Food and Drug Administration. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm. Accessed June 8, 2022.	Regulatory	n/a	n/a	n/a	n/a	Section 522 of the Federal Food, Drug and Cosmetic Act (the act) gives the FDA the authority to require a manufacturer to conduct post market surveillance of a class II or class III device that meets any of these criteria: -Its failure would be reasonably likely to have serious adverse health consequences. -It is expected to have significant use in pediatric populations. -It is intended to be implanted in the body for more than one year. -It is intended to be a life-sustaining or life-supporting device used outside a device user facility.	n/a
120	AccessGUDID (Global Unique Device Identification Database). National Library of Medicine. https://accessgudid.nlm.nih.gov. Accessed June 8, 2022.	Regulatory	n/a	n/a	n/a	n/a	FDA's unique device identification system (UDI system) is designed to adequately identify devices through distribution and use.1 Its requirements were designed to be phased in over seven years according to established compliance dates based primarily on device classification. Searchable database	n/a
121	MAUDE - Manufacturer and User Facility Device Experience [Database]	Regulatory	n/a	n/a	n/a	n/a	The MAUDE database houses medical device reports submitted to the FDA by mandatory reporters (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers.	n/a

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
122	MedSun: Medical Product Safety Network. https://www.fda.gov/medical-devices/medical-device-safety/medsun-medical-product-safety-network. Updated 2020. Accessed 7/12, 2021	Regulatory	n/a	n/a	n/a	n/a	adverse event reporting program launched in 2002 by the U.S. Food and Drug Administration's Center for Devices and Radiological Health (CDRH). The primary goal for MedSun is to work collaboratively with the clinical community to identify, understand, and solve problems with the use of medical devices.	n/a
123	Post-Approval Studies (PAS) Database. US Food and Drug Administration. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma_pas.cfm. Accessed June 8, 2022.	Regulatory	n/a	n/a	n/a	n/a	The FDA has the authority to require sponsors to perform a post-approval study (or studies) at the time of approval of a premarket approval (PMA), humanitarian device exemption (HDE), or product development protocol (PDP) application. Post-approval studies can provide patients, health care professionals, the device industry, the FDA and other stakeholders information on the continued safety and effectiveness (or continued probable benefit, in the case of an HDE) of approved medical devices. This database allows you to search Post-Approval Study information by applicant or device information.	n/a
124	CDRH transparency: Total Product Life Cycle (TPLC). US Food and Drug Administration. https://www.fda.gov/about-fda/cdrh-transparency/cdrh-transparency-total-product-life-cycle-tplc. Updated September 6, 2018. Accessed June 8, 2022.	Regulatory	n/a	n/a	n/a	n/a	The Total Product Life Cycle (TPLC) database integrates premarket and post market data about medical devices. It includes information pulled from CDRH databases including Premarket Approvals (PMA), Premarket Notifications (510[k]), Adverse Events, and Recalls. The TPLC database is refreshed as each of the individual data sources is updated.	n/a