REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
1	Infections associated with reprocessed duodenoscopes. US Food and Drug Administration. https://www.fda.gov/medical-devices/reprocessing-reusable-medical-devices/infections-associated-reprocessed-duodenoscopes. Updated June 30, 2022. Accessed July 25, 2022.	Regulatory	n/a	n/a	n/a	n/a	FDA's ongoing activities related to infections associated with duodenoscopes.	n/a
2	Rubin ZA, Kim S, Thaker AM, Muthusamy VR. Safely reprocessing duodenoscopes: current evidence and future directions. Lancet Gastroenterol Hepatol. 2018;3(7):499-508.	Literature Review	n/a	n/a	n/a	n/a	At present, efforts are best focused on emphasizing rigorous performance of the manual cleaning components of the reprocessing cycle including initial staff training, ongoing competency assessment, and reinforcement of best practices, as well as ensuring adequate drying before storage. However, the current high-level disinfection process is likely to undergo changes that involve both device redesign and alteration of the reprocessing techniques, including a potential move towards full sterilization rather than disinfection. of all devices.	VA
3	Jung M, Beilenhoff U. Hygiene: the looming Achilles heel in endoscopy. Visc Med. 2016;32(1):21-28.	Literature Review	n/a	n/a	n/a	n/a	In some cases insufficient cleaning or drying supported the outbreak. In the majority of cases, outbreaks occurred despite the apparently appropriate reprocessing protocols being in use. Microlesions were identified on a number of endoscopes, which supported the growth of bacteria. Strict adherence to manufacturers' recommendations is essential. The outcome quality should be evaluated by regular audits, validation of reprocessing procedures and microbiological surveillance.	VA

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4	Muscarella LF. Use of ethylene-oxide gas sterilisation to terminate multidrug-resistant bacterial outbreaks linked to duodenoscopes. BMJ Open Gastroenterol. 2019;6(1):e000282.	Literature Review	n/a	n/a	n/a	n/a	Measures that can mitigate the impact of reprocessing challenges and reduce the risk of a duodenoscope transmitting MDROs include the use of EO gas sterilization, removing the implicated device from use, re-training staff about proper cleaning, microbiological culturing and returning the device to the manufacturer for evaluation, servicing and/or repair.	VA
5	O'Horo JC, Farrell A, Sohail MR, Safdar N. Carbapenem-resistant Enterobacteriaceae and endoscopy: an evolving threat. Am J Infect Control. 2016;44(9):1032-1036.	Systematic Review	n/a	n/a	n/a	n/a	Seven distinct outbreaks were identified in the published literature; 5 associated with duodenal endoscopy, 2 associated with cystoscopy and ureteroscopy. Several investigators noted difficulties in cleaning protocols surrounding difficult to access components, such as the elevator on duodenoscopes. The published investigations did not report any failures of sterilization. It is unclear if routine reprocessing was ineffective, or difficult to execute properly.	IIIB
6	Rahman MR, Perisetti A, Coman R, Bansal P, Chhabra R, Goyal H. Duodenoscope-associated infections: update on an emerging problem. Dig Dis Sci. 2019;64(6):1409-1418.	Literature Review	n/a	n/a	n/a	n/a	Reports of duodenoscope-related outbreaks despite compliance with established guidelines have prompted professional and government bodies to revisit existing guidelines and offer supplementary recommendations for duodenoscope processing.	VA

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7	Snyder GM. Introduction to transmission of infection: potential agents transmitted by endoscopy. Gastrointest Endosc Clin N Am. 2020;30(4):611-618.	Literature Review	n/a	n/a	n/a	n/a	Studies have demonstrated persistent endoscope contamination of endoscopes despite appropriate reprocessing techniques. The risk of endoscope contamination and therefore transmission of pathogen will likely remain given the intrinsic nature of the exposure to endogenous flora with the ability to form biofilms and the surface characteristics of the endoscopes themselves. Identifying potential pathogens beyond the most commonly identified bacteria—K pneumoniae, E coli, and P aeruginosa—will require changes to sampling techniques.	VA
8	Aumeran C, Poincloux L, Souweine B, et al. Multidrug-resistant Klebsiella pneumoniae outbreak after endoscopic retrograde cholangiopancreatography. Endoscopy. 2010;42(11):895-899.	Organizational Experience	16 patients who underwent ERCP and identified with ESBL-producing K pneumoniae, France	n/a	n/a	n/a	Environmental investigations found no contamination of the washer-disinfectors or the surfaces of the endoscopy rooms. Routine surveillance cultures of endoscopes were repeatedly negative during the outbreak but the epidemic strain was finally isolated from one duodenoscope by flushing and brushing the channels. Practice audits showed that manual cleaning and drying before storage were insufficient. Strict adherence to reprocessing procedures ended the outbreak.	VA
9	Casini B, Tuvo B, Marciano E, et al. Improving the reprocessing quality of flexible thermolabile endoscopes: how to learn from mistakes. Int J Environ Res Public Health. 2021;18(5):2482.	Organizational Experience	Case report of 2 patients who developed carbapenemase-producing Klebsiella pneumoniae infections after they underwent ERCP procedures; Epidemiologic investigation including duodenoscopes, gastroscopes, and colonoscopes; Italy	n/a	n/a	Microbiological surveillance	After 2 patients developed infections, an audit of endoscope reprocessing was performed and crucial issues were highlighted. Corrective actions led to a reduction in the contaminated endoscopes. Risk assessment at every stage of the process is important for the prevention of infections associated with the use of endoscopes.	VA

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10	Frias M, Tsai V, Moulton-Meissner H, et al. Notes from the field: New Delhi metallo-β-lactamase-producing Escherichia coli associated with endoscopic retrograde cholangiopancreatography–Illinois, 2013. MMWR Morbid Mortal Wkly Rep. 2014;62(51-52):1051.	Case Report	n/a	n/a	n/a	n/a	From March to July 2013, nine patients with positive cultures for NDM-producing Escherichia coli were identified in northeastern Illinois. Health-care facilities with CRE outbreaks should consider the possibility of ERCP-related transmission. If ERCP-related transmission of CRE is suspected, reprocessing and preventative maintenance procedures for ERCP endoscopes should be evaluated in consultation with the manufacturer of the endoscope and automated endoscope reprocessor, if used.	VA
11	Epstein L, Hunter JC, Arwady MA, et al. New Delhi metallo-beta-lactamase-producing carbapenem-resistant Escherichia coli associated with exposure to duodenoscopes. JAMA. 2014;312(14):1447-1455.	Nonexperimental	Patients with duodenoscope exposure in one hospital, United States	n/a	n/a	NDM-producing E coli infections	After the hospital changed its processing procedure to sterilization via ethylene oxide, no additional cases were identified.	IIIA
12	Hennequin C, Aumeran C, Robin F, Traore O, Forestier C. Antibiotic resistance and plasmid transfer capacity in biofilm formed with a CTX-M-15-producing Klebsiella pneumoniae isolate. J Antimicrob Chemother. 2012;67(9):2123-2130.	Nonexperimental	Isolates of an ESBL-type CTX-M-15-producing K pneumoniae that infected 16 patients who underwent ERCP and 1 duodenoscope, laboratory, France	n/a	n/a	Virulence factors, ability to form biofilm, antibiotic tolerance, plasmid transfer	This strain of K pneumoniae that was implicated in an outbreak of clinical infections related to ERCP was notable for its ability to transfer its plasmid, especially in biofilm conditions.	IIIA

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13	Humphries RM, Yang S, Kim S, et al. Duodenoscope-related outbreak of a carbapenem-resistant Klebsiella pneumoniae identified using advanced molecular diagnostics. Clin Infect Dis. 2017;65(7):1159-1166.	Organizational Experience	9 patients who were diagnosed with carbapenem-resistant K pneumoniae infections, 179 patients who underwent ERCP, tertiary care hospital, United States	n/a	n/a	Cultures from patients and duodenoscopes, reprocessing practices	Molecular testing ultimately identified 17 patients with carbapenem-resistant K pneumoniae isolates, including 9 with infections, 7 asymptomatic carriers who had undergone ERCP, and 1 additional patient who had been hospitalized in India and was probably the initial carrier. Two case-control studies established a point-source outbreak associated with 2 specific duodenoscopes. A field investigation of the use, reprocessing, and storage of duodenoscopes did not identify deviations from US Food and Drug Administration or manufacturer recommendations for reprocessing.	VA
14	Kim S, Russell D, Mohamadnejad M, et al. Risk factors associated with the transmission of carbapenem-resistant Enterobacteriaceae via contaminated duodenoscopes. Gastrointest Endosc. 2016;83(6):1121-1129.	Nonexperimental	115 patients who underwent ERCP with either 1 of 2 contaminated duodenoscopes, United States	n/a	n/a	CRE active infection or colonization	In patients undergoing ERCP with a contaminated duodenoscope, biliary stent placement, a diagnosis of cholangiocarcinoma, and active inpatient status are associated with an increased risk of CRE transmission.	IIIB
15	Kola A, Piening B, Pape U, et al. An outbreak of carbapenem-resistant OXA-48–producing Klebsiella pneumonia associated to duodenoscopy. Antimicrob Resist Infect Control. 2015;4:8.	Case Report	n/a	n/a	n/a	n/a	Carbapenem-resistant K pneumoniae (CRKP) was cultured from 12 patients staying on 4 different wards. There was a spatial relationship between 6 of the cases which were located on the same wards. The remaining 6 cases were all related to ERCP which was performed with the same duodenoscope. The outbreak ended after the endoscope was sent to the manufacturer for maintenance. Environmental sources or medical personnel also contributed to the outbreak.	VA
16	Naryzhny I, Silas D, Chi K. Impact of ethylene oxide gas sterilization of duodenoscopes after a carbapenem-resistant Enterobacteriaceae outbreak. Gastrointest Endosc. 2016;84(2):259-262.	Organizational Experience	GI laboratory, United States	n/a	n/a	n/a	The addition of ETO sterilization and frequent monitoring with cultures reduced duodenoscope contamination and eliminated clinical infections.	VA

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17	Qiu L, Zhou Z, Liu Q, Ni Y, Zhao F, Cheng H. Investigating the failure of repeated standard cleaning and disinfection of a Pseudomonas aeruginosa–infected pancreatic and biliary endoscope. Am J Infect Control. 2015;43(8):e43-e46.	Case Report	n/a	n/a	n/a	n/a	Three cases of patients who developed P aeruginosa infections after ERCP. A polluted duodenoscope was cleaned and disinfected multiple times with the standard procedure but still tested positive for P aeruginosa.	VA
18	Rauwers AW, Troelstra A, Fluit AC, et al. Independent root-cause analysis of contributing factors, including dismantling of 2 duodenoscopes, to investigate an outbreak of multidrug-resistant Klebsiella pneumoniae. Gastrointest Endosc. 2019;90(5):793-804.	Organizational Experience	102 patients who underwent ERCP, The Netherlands	n/a	n/a	n/a	Cultures were available of 81 patients, yielding 27 multidrug-resistant K pneumoniae (MRKP)-infected or -colonized patients. Ten patients developed an MRKP-related active infection. Identical MRKP isolates were cultured from channel flushes of two duodenoscopes. The review revealed 4 major abnormalities: miscommunication about reprocessing, undetected damaged parts, inadequate repair of duodenoscope damage, and duodenoscope design abnormalities, including the forceps elevator, elevator lever, and instrumentation port sealing.	VA
19	Robertson P, Smith A, Anderson M, et al. Transmission of Salmonella enteritidis after endoscopic retrograde cholangiopancreatography because of inadequate endoscope decontamination. Am J Infect Control. 2017;45(4):440-442.	Case Report	n/a	n/a	n/a	n/a	Outbreak of Salmonella enteritidis affecting 4 inpatients who underwent ERCP. The cause was attributed to inadequate decontamination of an on-loan endoscope used over a weekend. This report highlights the risks of using on-loan endoscopes, particularly regarding their commissioning and adherence to disinfection protocols.	VA
20	Ross AS, Baliga C, Verma P, Duchin J, Gluck M. A quarantine process for the resolution of duodenoscope-associated transmission of multidrug-resistant Escherichia coli. Gastrointest Endosc. 2015;82(3):477-483.	Organizational Experience	32 patients who underwent ERCP and found culture positive for E coli, hospital, United States	n/a	n/a	n/a	No breach in HLD protocol or infection control practices was identified. The clonal strain of E coli was identified in culture on 4 of 8 duodenoscopes, 3 of which required critical repairs despite lack of obvious malfunction. The defect rate in high-level disinfection of duodenoscopes was 2% over a 1-year period. The implemented quality improvements, subsequent to which 1625 ERCPs have been performed, were successful in halting the outbreak.	VA

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21	Shenoy ES, Pierce VM, Walters MS, et al. Transmission of mobile colistin resistance (mcr-1) by duodenoscope. Clin Infect Dis. 2019;68(8):1327-1334.	Case Report	2 patients, 20 healthcare contacts, 2 household contacts, 1 duodenoscope, tertiary academic health center and community setting, United States	n/a	n/a	n/a	Two patients had highly related mcr-1–positive K pneumoniae isolated from clinical cultures; a duodenoscope was the only identified epidemiological link despite no identifiable breaches in reprocessing or infection control practices. Duodenoscope design flaws leading to transmission of MDROs persist despite recent initiatives to improve device safety. Reliable detection of colistin resistance is currently challenging for clinical laboratories.	VA
22	Smith ZL, Oh YS, Saeian K, et al. Transmission of carbapenem-resistant Enterobacteriaceae during ERCP: time to revisit the current reprocessing guidelines. Gastrointest Endosc. 2015;81(4):1041-1045.	Organizational Experience	Academic medical center, United States	n/a	n/a	n/a	Facility uses ethylene oxide sterilization only when an endoscope (side or forward viewing) is used in a patient known to be infected or colonized with CRE or who resides in a facility known to have residents infected or colonized with CRE.	VA
23	Verfaillie CJ, Bruno MJ, Voor in 't Holt AF, et al. Withdrawal of a novel-design duodenoscope ends outbreak of a VIM-2-producing Pseudomonas aeruginosa. Endoscopy. 2015;47(6):493-502.	Organizational Experience	30 patients who cultured positive for VIM-2-producing P aeruginosa (22 underwent ERCP with the same model of duodenoscope), tertiary care hospital, The Netherlands	n/a	n/a	n/a	The new design of duodenoscope with a fixed distal cap contributed to the outbreak. The design was thought to lead to faster and easier cleaning, however the fixed cap hampered adequate reprocessing and the integrity of the construction of the o-ring was not validated.	VA
24	Wendorf KA, Kay M, Baliga C, et al. Endoscopic retrograde cholangiopancreatography–associated AmpC Escherichia coli outbreak. Infect Control Hosp Epidemiol. 2015;36(6):634-642.	Nonexperimental	32 case patients who underwent ERCP and developed AmpC-producing E coli infections, hospital, United States	n/a	n/a		The outbreak occurred despite no identified breaches in reprocessing of the endoscopes. Even after enhancing endoscope reprocessing with meticulous manual cleaning, enteric bacteria continued to be recovered from endoscope elevator channels.	IIIA
25	Kenters N, Huijskens EGW, Meier C, Voss A. Infectious diseases linked to cross-contamination of flexible endoscopes. Endosc Int Open. 2015;3(4):e259-e265.	Literature Review	n/a	n/a	n/a	n/a	Overview of publications about case reports and outbreaks related to contamination of flexible endoscopes. Transmission of microorganisms are mostly related to the use of defective equipment, endoscope reprocessing failures, and noncompliance with recommended guidelines.	VA

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26	Bajolet O, Ciocan D, Vallet C, et al. Gastroscopy-associated transmission of extended-spectrum beta-lactamase-producing Pseudomonas aeruginosa. J Hosp Infect. 2013;83(4):341-343.	Organizational Experience	4 patients, 1 gastroscope, teaching hospital, France	n/a	n/a	n/a	Gastroscope was culture positive for MDR-P aeruginosa. Observations identified deviations of insufficient initial cleaning, shortened immersion and brushing time, insufficient channel flushing, and insufficient drying prior to storage. Since withdrawing the gastroscope and strict adherence to processes, no further cases have been identified.	VA
27	Reddick E. Investigation of Salmonellosis outbreak following a hospital endoscopy: a public health case study. Can J Infect Control. 2017;32(3):156-159.	Organizational Experience	3 patients, 1 colonoscope, community hospital, Canada	n/a	n/a	n/a	No significant infection prevention and control lapses were identified at the endoscopy suite. Reprocessing methods and verification, including documentation, were found to be adequate. However, the epidemiological investigation implicated the endoscope as being the likely source of transmission of S enteritidis for the three patients.	VA
28	Flexible bronchoscopes and updated recommendations for reprocessing: FDA Safety Communication. US Food and Drug Administration. https://www.fda.gov/medical-devices/safety-communications/flexible-bronchoscopes-and-updated-recommendations-reprocessing-fda-safety-communication?utm_medium=email&utm_source=govdelivery. Published June 25, 2021. Updated 2021. Accessed July 25, 2022.	Regulatory	n/a	n/a	n/a	n/a	The FDA is reminding health care facilities and staff responsible for reprocessing bronchoscopes and their accessories about the importance of carefully following the manufacturer's reprocessing instructions.	n/a

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29	Mehta AC, Muscarella LF. Bronchoscope-related "superbug" infections. Chest. 2020;157(2):454-469.	Literature Review	n/a	n/a	n/a	n/a	Several factors were identified that can adversely affect a bronchoscope's reprocessing and pose a risk of transmission of MDROs, including use of a damaged or inadequately serviced bronchoscope and formation of an inaccessible biofilm. Recommendations are provided to improve the safety of flexible bronchoscopes, including supplementing their reprocessing with an enhanced measure such as sterilization when warranted, and strict adherence to a periodic servicing and maintenance schedule consistent with the manufacturer's instructions.	VA
30	Carvalho NFGD, Rodrigues Mestrinari AC, Brandao A, et al. Hospital bronchoscopy-related pseudo-outbreak caused by a circulating Mycobacterium abscessus subsp. massiliense. J Hosp Infect. 2018;100(3):e138-e141.	Nonexperimental	28 patients who underwent bronchoscopy and water samples from 4 bronchoscopes automated endoscope reprocessing machines, and direct from the water supply, Brazil	n/a	n/a	Cultures for M. abscessus subsp. bolletii	Mycobacterium abscessus subsp. massiliense isolated from 28 patients, water from one bronchoscope and water from four automated endoscope reprocessing machines presented high similarity by pulsed-field gel electrophoresis. This strain was not found in the water supply, and it was hypothesized that an infected patient contaminated the bronchoscope, with further false-positive cultures from subsequent patients. Reparative and control measures were effective as no further M. abscessus subsp. massiliense isolates have been identified in the hospital bronchoscopy unit.	IIIB
31	Galdys AL, Marsh JW, Delgado E, et al. Bronchoscope-associated clusters of multidrug-resistant Pseudomonas aeruginosa and carbapenem-resistant Klebsiella pneumoniae. Infect Control Hosp Epidemiol. 2019;40(1):40-46.	Nonexperimental	33 patients who underwent bronchoscopy in the medical intensive care unit, United States	n/a	n/a	Bronchoscope and clinical bacterial isolated, molecular typing with pulsed-field gel electrophoresis	Surveillance of bronchoscope-derived clinical culture data was important for early detection of this outbreak, and whole genome sequencing was important for the confirmation of findings. Visualization of bronchoscope lumens to confirm integrity should be a critical component of device reprocessing.	IIIB

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32	Guimarães T, Chimara E, do Prado GVB, et al. Pseudooutbreak of rapidly growing mycobacteria due to Mycobacterium abscessus subsp bolletii in a digestive and respiratory endoscopy unit caused by the same clone as that of a countrywide outbreak. Am J Infect Control. 2016;44(11):e221-e226.	Organizational Experience	3 patients who underwent bronchoscopy and has a positive culture for M abscessus, large tertiary care teaching hospital, Brazil	n/a	n/a	n/a	Cross-transmission due to poor disinfection as well as resistance to glutaraldehyde may play roles in the spread of MAB01 M abscessus subsp bolletii, which may have a unique resistance to the environment and adaption to human hosts. However the water supply may have played a role. Attention is needed to ensure the quality of water used to rinse disinfected equipment.	VA
33	Seidelman JL, Wallace RJ, Iakhiaeva E, et al. Mycobacterium avium pseudo-outbreak associated with an outpatient bronchoscopy clinic: lessons for reprocessing. Infect Control Hosp Epidemiol. 2019;40(1):106-108.	Case Report	n/a	n/a	n/a	n/a	Identified a pseudo-outbreak of Mycobacterium avium in an outpatient bronchoscopy clinic following an increase in clinic procedure volume was terminated by increasing the frequency of AER filter changes from quarterly to monthly. Filter changing schedules should depend on use rather than fixed time intervals.	VA
34	Alipour N, Karagoz A, Taner A, et al. Outbreak of hospital infection from biofilm-embedded pan drug-resistant Pseudomonas aeroginosa, due to a contaminated bronchoscope. J Prev Med (Wilmington) 2017;2(2):1.	Organizational Experience	15 patients who underwent bronchoscopy, Turkey	n/a	n/a	n/a	Outbreak of Colistin pan drug-resistant P aeruginosa was caused by a contaminated bronchoscope and was terminated by the implementation of a revised disinfection protocol for bronchoscopes.	VA
35	Dickson A, Kondal P, Hilken L, Helgesen M, Sjolin W, Jensen D. Possible pseudotransmission of Enterobacter cloacae associated with an endobronchial ultrasound scope. Am J Infect Control. 2018;46(11):1296-1298.	Case Report	n/a	n/a	n/a	n/a	Despite a functioning EBUS scope without OEM-identified defects and adherence to reprocessing steps, it appears that bacterial contamination and transmission may exist with scopes that have a working channel. Scopes with working channels that retain biofilm and microorganisms after reprocessing place the next patient at risk of infection.	VA

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36	Infections associated with reprocessed urological endoscopes–letter to health care providers. US Food and Drug Administration. https://www.fda.gov/medical-devices/letters-health-care-providers/infections-associated-reprocessed-urological-endoscopes-letter-health-care-providers?utm_medium=email&utm_source=govdelivery. Published April 1, 2021. Accessed July 25, 2022.	Regulatory	n/a	n/a	n/a	n/a	The FDA is investigating numerous medical device reports describing patient infections and other possible contamination issues associated with reprocessing urological endoscopes, including cystoscopes, ureteroscopes and cystourethroscopes. Health care providers should follow the cystoscope manufacturer's reprocessing instructions, not use a device that has failed a leak test, develop schedules for routine device inspection and maintenance, and discuss the potential benefits and risks associated with procedures involving reprocessed urological endoscopes with patients.	n/a
37	Botana-Rial M, Leiro-Fernández V, Núñez-Delgado M, et al. A pseudo-outbreak of Pseudomonas putida and Stenotrophomonas maltophilia in a bronchoscopy unit. Respiration. 2016;92(4):274-278.	Organizational Experience	15 patients who underwent bronchoscopy, Spain	n/a	n/a	Bacterial cultures	Pseudo-outbreak related to a contaminated bronchoscope because of inadequate installation of the AER for used new water lines and because the new tubes were connected to the AER. The antibacterial filters of the AER used tap water, and this may have contained low levels of microorganisms.	VA
38	Chang CL, Su LH, Lu CM, Tai FT, Huang YC, Chang KK. Outbreak of ertapenem-resistant Enterobacter cloacae urinary tract infections due to a contaminated ureteroscope. J Hosp Infect. 2013;85(2):118-124.	Nonexperimental	15 patients who underwent ureteroscopy, 70 specimens from environmental objects and personnel, regional teaching hospital, Taiwan	n/a	n/a	Surveillance cultures, PFGE typing, PCR and sequencing	The pathogen (E cloacae) was identified from two subsequent surveillance cultures and was not eliminated until ethylene oxide sterilization was added to the disinfection protocol.	IIIB

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39	Kumarage J, Khonyongwa K, Khan A, Desai N, Hoffman P, Taori SK. Transmission of multi-drug resistant Pseudomonas aeruginosa between two flexible ureteroscopes and an outbreak of urinary tract infection: the fragility of endoscope decontamination. J Hosp Infect. 2019;102(1):89-94.	Nonexperimental	40 patients who underwent flexible ureteroscopy, large tertiary care center, United Kingdom	n/a	n/a	Patient infection, endoscope cultures and inspection, audit of procedures	Thirteen patients developed clinical infections linked to two flexible ureteroscopes. The first ureteroscope was likely colonized from a known infected patient and the second ureteroscope after use on another patient infected by the first. Risk factors identified include surface cuts, stretching and puckering of the outer cover in both ureteroscopes, absence of bedside cleaning, overnight delay between the ureteroscopy and decontamination, inadequate drying after decontamination and non-traceability of connector valves.	IIIB
40	Zhang Y, Zhou H, Jiang Q, Wang Q, Li S, Huang Y. Bronchoscope-related Pseudomonas aeruginosa pseudo-outbreak attributed to contaminated rinse water. Am J Infect Control. 2020;48(1):26-32.	Organizational Experience	Pseudo-outbreak, tertiary care teaching hospital, China	n/a	n/a	n/a	Pseudo-outbreak of P aeruginosa associated with bronchoscope, for which connecting tube was the hidden reservoir for contaminating bronchoscopes. Measures are needed to control the bacterial load in final rinsing water to protect reusable equipment from contamination in reprocessing and cleaning.	VA
41	Sorbets E, Evrevin M, Jumas-Bilak E, et al. An outbreak of Pseudomonas aeruginosa urinary tract infections following outpatient flexible cystoscopy. Am J Infect Control. 2019;47(12):1510-1512.	Organizational Experience	11 patients who underwent cystoscopy and developed P aeruginosa urinary tract infections, France	n/a	n/a	n/a	The investigation of an outbreak of Pseudomonas aeruginosa urinary tract infections after ambulatory cystoscopies identified a damaged cystoscope contaminated by P aeruginosa and acting as a relay object.	VA
42	Ofstead CL, Buro BL, Hopkins KM, Eiland JE, Wetzler HP, Lichtenstein DR. Duodenoscope-associated infection prevention: a call for evidence-based decision making. Endosc Int Open. 2020;8(12):e1769-e1781.	Literature Review	n/a	n/a	n/a	n/a	There is substantial evidence that duodenoscope reprocessing does not reliably eliminate soil or bioburden, allowing potential pathogens to remain on endoscopes. Evidence suggests that infections could be expected to occur in as few as 1 in 1,765 or as many as 10% of ERCP procedures when contaminated duodenoscopes are used.	VA

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43	Rutala WA, Kanamori H, Sickbert-Bennett E, Weber DJ. What's new in reprocessing endoscopes: are we going to ensure "the needs of the patient come first" by shifting from disinfection to sterilization? Am J Infect Control. 2019;47S:A62-A66.	Expert Opinion	n/a	n/a	n/a	n/a	Professional organizations and a consensus standards organization must clarify the term "critical," as stated earlier, which would facilitate the transition from disinfection to sterilization for endoscopes. Technologies to allow this change to occur are being developed and FDA-cleared and should be used when acceptable in terms of sterilization performance, scope performance (for disposable scopes), cost, throughput, and compatibility of materials (eg, adhesives) to sterilization technology.	VA
44	The FDA is recommending transition to duodenoscopes with innovative designs to enhance safety: FDA Safety Communication. US Food and Drug Administration. https://www.fda.gov/medical-devices/safety-communications/use-duodenoscopes-innovative-designs-enhance-safety-fda-safety-communication. Published August 29, 2019. Updated 2022. Accessed July 25, 2022.	Regulatory	n/a	n/a	n/a	n/a	The FDA continues to recommend that hospitals and endoscopy facilities transition to innovative duodenoscope designs to help improve cleaning and reduce contamination between patients, including designs with disposable caps or distal ends.	n/a
45	Alfa MJ. Medical instrument reprocessing: current issues with cleaning and cleaning monitoring. Am J Infect Control. 2019;47S:A10-A16.	Literature Review	n/a	n/a	n/a	n/a	There has been a paradigm shift in reprocessing of medical devices, with increased emphasis on a quality management systems approach that requires validated cleaning instructions from manufacturers and ongoing monitoring by reprocessing personnel to ensure adequacy of cleaning.	VA

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46	Guideline for design and maintenance of the surgical suite. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 2022:87-118.	Guideline	United States	n/a	n/a	n/a	Provides guidance on the design of the surgical suite; security measures; safety measures during new construction or renovation; planning for utility service interruption; restoration of the surgical suite to full functionality after a utility failure; maintenance of structural surfaces; and design, monitoring, and maintenance of the heating, ventilation, and air conditioning (HVAC) system.	IVA
47	Guideline for sterilization. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 2022:1059-1088.	Guideline	United States	n/a	n/a	n/a	Provides guidance for sterilizing reusable medical devices to be used in perioperative and procedural settings.	IVA
48	Guideline for care and cleaning of surgical instruments. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 2022:417-456.	Guideline	United States	n/a	n/a	n/a	Provides guidance for cleaning surgical instruments, including point-of-use treatment, transport, decontamination, inspection, and general care of reusable medical devices (eg, surgical instruments).	IVA
49	Guideline for manual chemical high-level disinfection. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 2022:329-356.	Guideline	United States	n/a	n/a	n/a	Provides guidance to health care personnel for performing safe and effective manual chemical high level disinfection of reusable semicritical items and preventing patient and health care worker injury associated with the handling and use of liquid chemical high-level disinfectants (HLDs).	IVA
50	Guideline for sterilization packaging systems. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 2022:603-622.	Guideline	United States	n/a	n/a	n/a	Provides guidance to perioperative personnel for evaluating, selecting, and using sterilization packaging systems and for packaging the items to be sterilized and subsequently used in operative and other invasive procedures.	IVA
51	Guideline for medical device and product evaluation. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 2022:781-790.	Guideline	United States	n/a	n/a	n/a	Provides guidance to perioperative team members for developing and implementing a process for evaluating FDA–cleared medical devices and products for use in the perioperative setting.	IVA

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52	ANSI/AAMI ST91:2021—Flexible and Semi-Rigid Endoscope Processing in Health Care Facilities. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2021.	Guideline	United States	n/a	n/a	n/a	The objective of this standard is to provide guidelines for precleaning, transport, leak testing, cleaning, high-level disinfection, liquid chemical sterilization, packaging, sterilization, and storage of flexible and semi-rigid endoscopes.	IVC
53	Professional Handbook. Flexible Endoscopes: Cleaning and Disinfection. Version 4.1. Steering Group for Flexible Endoscope Cleaning and Disinfection. https://www.infectiepreventieoplei dingen.nl/downloads/SFERDHandb ook4_1.pdf. Published September 2017. Accessed July 25, 2022.	Expert Opinion	The Netherlands	n/a	n/a	n/a	Flexible endoscope quality manual in which the existing regulations for the cleaning and disinfection of flexible endoscopes is translated into a practical standard text. Includes a verification and release procedure, a complaints and recall procedure, and an audit and control system.	VA
54	AORN Position Statement on the Value of the Perioperative Nurse Educator. AORN, Inc; 2021. https://www.aorn.org/guidelines/c linical-resources/position-statements. Published June 30, 2021. Accessed July 25, 2022.	Position Statement	n/a	n/a	n/a	n/a	The perioperative nurse educator is essential in promoting interdisciplinary collaboration and communication.	IVB
55	MAUDE: Manufacturer and User Facility Device Experience. US Food and Drug Administration. https://www.accessdata.fda.gov/sc ripts/cdrh/cfdocs/cfmaude/search. cfm. Accessed July 25, 2022.	Regulatory	n/a	n/a	n/a	n/a	FDA MAUDE (Manufacturer and User Facility Device Experience) Database	n/a
56	AAMI TIR 30:2011/(R)2016—A Compendium of Processes, Materials, Test Methods, and Acceptance Criteria for Cleaning Reusable Medical Devices. Association for the Advancement of Medical Instrumentation. Arlington VA: Association for the Advancement of Medical Instrumentation; 2016.	Expert Opinion	n/a	n/a	n/a	n/a	This report is intended as a resource for manufacturers of medical devices who must validate the instructions for reprocessing that they include with their devices. The report also discusses some of the underlying problems and challenges associated with validating a cleaning method.	VA

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57	Rutala WA, Weber DJ; Healthcare Infection Control Practices Advisory Committee. Centers for Disease Control and Prevention. Guideline for Disinfection and Sterilization in Healthcare Facilities; 2008. Centers for Disease Control and Prevention. https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf. Updated May 2019. Accessed July 25, 2022.	Guideline	United States	n/a	n/a	n/a	Recommendations on the preferred methods for cleaning, disinfection and sterilization of patient-care medical devices and for cleaning and disinfecting the healthcare environment.	IVA
58	Reprocessing medical devices in health care settings: validation methods and labeling. Guidance for industry and Food and Drug Administration staff. US Food and Drug Administration. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling. 2015. Updated June 13, 2018. Accessed July 25, 2022.	Regulatory	n/a	n/a	n/a	n/a	This guidance provides recommendations for the formulation and scientific validation of reprocessing instructions for reusable medical devices.	n/a
59	AORN Position Statement on Environmental Responsibility. AORN, Inc. https://www.aorn.org/guidelines/clinical-resources/position-statements. Revised March 2020. Accessed July 25, 2022.	Position Statement	n/a	n/a	n/a	n/a	The interdisciplinary health care community serves as a steward of the environment by seeking knowledge about climate and health effects and assessing health care work environments for opportunities to reduce waste, conserve natural resources, and prevent exposure to hazardous materials.	IVB

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60	Health technical memorandum 01-06: Management and decontamination of flexible endoscopes. Part C: operational management. National Health Service England. https://www.england.nhs.uk/publication/management-and-decontamination-of-flexible-endoscopes-htm-01-06. Updated June 30, 2016. Accessed July 25, 2022.	Guideline	United Kingdom	n/a	n/a	n/a	Part C 'Operational management' gives guidance on operational responsibility together with advice on the procurement and operation of an endoscope washer-disinfector (EWD).	IVB
61	ASGE Technology Committee, Parsi MA, Sullivan SA, et al. Automated endoscope reprocessors. Gastrointest Endosc. 2016;84(6):885-892.	Expert Opinion	n/a	n/a	n/a	n/a	AERs can enhance the efficiency, consistency, and reliability of endoscope reprocessing by automating and standardizing several important reprocessing steps, thereby reducing the possibility of human error. Use of AERs reduces exposure of reprocessing personnel to harmful chemical germicides and may lessen health problems attributed to reprocessing of endoscopes. The use of AERs for endoscope reprocessing is therefore strongly recommended by the ASGE.	VA
62	Loyola M, Babb E, Bocian S, et al. Standards of infection prevention in reprocessing of flexible gastrointestinal endoscopes. Gasteroenterol Nurs. 2020;43(3):E142-E158.	Guideline	United States	n/a	n/a	n/a	Proper reprocessing of endoscopes and accessories is critical to the safe and successful treatment of patients.	IVB
63	Day LW, Muthusamy VR, Collins J, et al. Multisociety guideline on reprocessing flexible GI endoscopes and accessories. Gastrointest Endosc. 2021;93(1):11.	Guideline	United States	n/a	n/a	n/a	This guideline contains expanded details related to the critical reprocessing steps of cleaning and drying and incorporates recent evidence as it pertains to improving the reprocessing of GI endoscopes.	IVA

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64	Endoscope Reprocessing Manual. 2nd ed. Chicago, IL: Healthcare Sterile Processing Association; 2021.	Expert Opinion	n/a	n/a	n/a	n/a	Developed to provide the healthcare professionals that handle and reprocess endoscopes with a better understanding of how these devices should be transported, cleaned, tested, inspected, high-level disinfected or sterilized according to manufacturer's instructions for use and industry standards and guidelines.	VA
65	American Urological Association. Joint AUA/SUNA White Paper on Reprocessing of Flexible Cystoscopes. Linthicum, MD: American Urological Association; 2018.	Expert Opinion	n/a	n/a	n/a	n/a	Overview of guidelines for reprocessing flexible cystoscopes. Some cystoscopes have a proprietary seal that precludes leak testing, check the IFU. Most AERs were developed for GI endoscopes, so confirm compatibility with cystoscopes before processing. Use of OPA is contraindicated for patients with a history of bladder cancer due to risk for anaphylaxis-like reactions with repeated cystoscopy.	VA
66	Mehta AC, Prakash UBS, Garland R, et al. American College of Chest Physicians and American Association for Bronchology consensus statement: prevention of flexible bronchoscopy-associated infection. Chest. 2005;128(3):1742-1755.	Consensus	n/a	n/a	n/a	n/a	Recommendations for prevention of flexible bronchoscopy-associated infections. Infections are infrequent, but all episodes are preventable.	IVB
67	Gonzalez JA, Vanzieleghem T, Dumazy A, et al. On-site comparison of an enzymatic detergent and a non-enzymatic detergent-disinfectant for routine manual cleaning of flexible endoscopes. Endosc Int Open. 2019;7(4):e412-e420.	Quasi-experimental	12 endoscopes (4 colonoscopes, 4 gastroscopes, 2 duodenoscopes, 2 bronchoscopes), Belgium	Manual cleaning with a non-enzymatic detergent disinfectant	Manual cleaning with an enzymatic detergent	ATP	Cleaning with enzymatic detergent provided more consistent and improved cleaning of endoscopes.	IIB

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68	da Costa Luciano C, Olson N, Tipple AFV, Alfa M. Evaluation of the ability of different detergents and disinfectants to remove and kill organisms in traditional biofilm. Am J Infect Control. 2016;44(11):e243-e249.	Quasi-experimental	Pegs in 96 well format, laboratory, Canada	Buildup biofilm (Pseudomonas aeruginosa, Enterococcus faecalis) created by the minimum biofilm eradication concentration model	Exposure to detergents (enzymatic and nonenzymatic) and disinfectants (glutaraldehyde, accelerated hydrogen peroxide, OPA) using the manufacturers' use-dilution, exposure time, and temperature. Controls with no detergent and no HLD.	Bacterial culture, protein, carbohydrate assay, microscopy	If biofilm accumulates in flexible endoscope channels during repeated rounds of reprocessing, then neither the detergent nor high-level disinfectant will provide the expected level of bacterial removal or killing.	IIA
69	Stiefel P, Mauerhofer S, Schneider J, Maniura-Weber K, Rosenberg U, Ren Q. Enzymes enhance biofilm removal efficiency of cleaners. Antimicrob Agents Chemother. 2016;60(6):3647-3652.	Quasi-experimental	Simulated biofilm of P aeruginosa and S aureus in 96 well plates, laboratory, Switzerland	A new cleaner (deconex Prozyme Active) containing four enzymes in a novel base formulation	9 comparable commercial products (base formulations without enzymes, enzymes, cleaners)	Removal of biofilm (crystal violet staining), TOSI test, cleaning performance using EN ISO 15883	The addition of enzymes to the base formulation had a clear beneficial effect on the efficiency of biofilm removal.	IIB
70	Alfa MJ, Singh H, Nugent Z, et al. Simulated-use polytetrafluorethylene biofilm model: repeated rounds of complete reprocessing lead to accumulation of organic debris and viable bacteria. Infect Control Hosp Epidemiol. 2017;38(11):1284-1290.	Quasi-experimental	5 new endoscope channels made of PTFE material, laboratory, Canada	Soiled overnight on 5 successive days with artificial test soil (E faecalis, P aeruginosa). Each day, cleaning assisted with a pump using a brush or pull-through cleaner and detergent, then AER with peracetic acid.	Enzymatic or nonenzymatic detergents; bristle brush or pull-through cleaner; positive control	Residuals visualized by scanning electron microscopy, ATP, protein, viable bacteria count	Surviving E faecalis and P aeruginosa were only detected when the non-enzymatic detergent was used, emphasizing the importance of the detergent used for endoscope channel reprocessing. Preventing biofilm formation is critical because not all current reprocessing methods can reliably eliminate viable bacteria within the biofilm matrix.	IIC
71	When to consider single-use endoscopes. ECRI. https://www.ecri.org/components/HDJournal/Pages/When-to-Consider-Single-Use-Endoscopes.aspx?tab=1. Published July 3, 2019. Updated April 14, 2022. Accessed July 25, 2022.	Expert Opinion	n/a	n/a	n/a	n/a	Facilities may find single-use endoscopes to be valuable if they are concerned about issues such as cross-contamination, access to reprocessing facilities or sterile storage, capital investment cost and recurring costs associated with reusable endoscopes, or rapid access to endoscopes.	VA

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72	Barron SP, Kennedy MP. Single-use (disposable) flexible bronchoscopes: the future of bronchoscopy? Adv Ther. 2020;37(11):4538-4548.	Literature Review	n/a	n/a	n/a	n/a	During the COVID-19 pandemic, single use flexible bronchoscopes have the potential to create a safer working environment in situations where aerosol generating procedures such as bronchoscopy or intubation are unavoidable.	VA
73	Eber E, Goussard P. Bronchoscopy precautions and recommendations in the COVID-19 pandemic. Paediatr Respir Rev. 2021;37:68-73.	Literature Review	n/a	n/a	n/a	n/a	When available, single use flexible bronchoscopes may be considered for use as the instruments can be discharged in the PICU, compared to a re-useable bronchoscope that needs be to send for cleaning. Reusable bronchoscopes should be placed into a sealed bag before being transported for cleaning and disinfection.	VA
74	McGrath BA, Ruane S, McKenna J, Thomas S. Contamination of single-use bronchoscopes in critically ill patients. Anaesthesia. 2017;72(1):36-41.	Nonexperimental	20 single use bronchoscopes used on ICU patients, university hospital, United Kingdom	n/a	n/a	Bacterial culture	Single use bronchoscopes should not be re-used on the same patient, as clinically significant growth of microorganisms occurs frequently, despite cleaning (saline flush, nonenzymatic sponge, saline flush).	IIIC
75	Su ZT, Huang MM, Matlaga BR, Hutfless S, Koo K. A micro-costing analysis of outpatient flexible cystoscopy: implications for adoption of single-use flexible cystoscopes. World J Urol. 2021;39(11):4275-4281.	Nonexperimental	United States	n/a	n/a	Micro-cost analysis	The cost of reprocessing reusable cystoscopes represents a large fraction of the total cost per procedure, especially for high-volume facilities. It may be economical to adopt single-use cystoscopes specifically for stent removal procedures, especially for lower-volume facilities.	IIIA
76	Young JA, Garden EB, Al-Alao O, et al. Disposable versus reusable cystoscopes: a micro-costing value analysis in high-volume and low-volume urology practices. Urology Pract 2021;8(4):466-471.	Nonexperimental	1,984 cystoscopy procedures at a high-volume multi-provider practice, 245 cystoscopy procedures at a low-volume single-provider practice, United States	n/a	n/a	Micro-cost analysis	Per-use costs favor reusable cystoscopes. At the high-volume multi-provider practice, per-case cost for reusable amounted to $65.98 compared to $227.18 for single-use, with reusable equipment more cost-effective after 294 cystoscopies. At the low-volume single-provider practice, the per-case cost for reusable was $232.62 compared to $461.18 for single-use, with reusable equipment more cost-effective after 19 cases.	IIIB

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77	Beebe SC, Jenkins LC, Posid T, Knudsen BE, Sourial MW. Single-use grasper integrated flexible cystoscope for stent removal: a micro-costing analysis-based comparison. J Endourol. 2020;34(8):816-820.	Nonexperimental	1775 cystoscopy procedures (n = 871 stent removal with reusable cystoscope) between February 2016 and February 2017/ United States	n/a	Reusable flexible cystoscope (Olympus CYF-VH digital) vs. single use flexible cystoscope (Isiris)	Purchase cost, repair fee (1 year contract), reprocessing cost, labor cost, sterilization equipment (Sterrad) and accessory cost	Per use cost favors reusable cystoscope for stent removal ($161.85 reusable vs $200 single use) after 704 procedures.	IIIB
78	Kenigsberg AP, Gold S, Grant L, Lotan Y. The economics of cystoscopy: a microcost analysis. Urology. 2021;157:29-34.	Organizational Experience	3,739 flexible cystoscopies, urology clinic, United States	n/a	n/a	Micro-cost analysis	There is a considerable contribution of capital equipment, maintenance, labor and supplies to cost of cystoscopy with profitability highly depend on volume of cystoscopies performed for each cystoscope. Use of AER results in higher cost than HLD. Cost-effectiveness of disposable scopes needs to be determined but will vary by clinic volumes and site of practice.	VA
79	Martin CJ, McAdams SB, Abdul-Muhsin H, et al. The economic implications of a reusable flexible digital ureteroscope: a cost-benefit analysis. J Urol. 2017;197(3):730-735.	Organizational Experience	Single use ureteroscope, reusable ureteroscopes sterilized by hydrogen peroxide gas plasma, academic hospital, United States	n/a	n/a	Cost	Disposable ureteroscope may be cost beneficial at centers with a lower case volume per year. However, institutions with a high volume of cases may find reusable ureteroscopes cost beneficial.	VA
80	Larsen S, Kalloo A, Hutfless S. The hidden cost of colonoscopy including cost of reprocessing and infection rate: the implications for disposable colonoscopes. Gut. 2020;69(2):197-200.	Organizational Experience	25 colonoscope reprocessing procedures over 3 days, high-volume outpatient endoscopy referral center, United States	n/a	n/a	Micro-cost analysis	Cost per colonoscopy for purchase, maintenance, and reprocessing ranges from US$188.64 at high volume centers to $501.16 at low volume centers. Low volume centers are most likely to achieve cost savings with disposable colonoscopes.	VA
81	Bang JY, Sutton B, Hawes R, Varadarajulu S. Concept of disposable duodenoscope: at what cost? Gut. 2019;68(11):1915-1917.	Organizational Experience	Endoscopy center, United States	n/a	n/a	n/a	The per-procedure cost of a disposable duodenoscope in the United States can vary from $797 to $1547 for centers performing at the 75th percentile of ERCP procedure volume and from $1318 to $2068 for centers performing at the 25th percentile of procedure volume, based on infection rates of 0.4% to 1%, respectively.	VA

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82	Taguchi K, Usawachintachit M, Tzou DT, et al. Micro-costing analysis demonstrates comparable costs for LithoVue compared to reusable flexible fiberoptic ureteroscopes. J Endourol. 2018;32(4):267-273.	Nonexperimental	23 patients who underwent flexible ureteroscopy, academic medical center, United States	n/a	Single use ureteroscope (n= 9, Reusable flexible ureteroscope (n = 14)	Micro-cost analysis	The acquisition cost of a single use ureteroscope was higher per case compared to reusable fiberoptic ureteroscopes, although there were savings in labor, consumables, and repair. The total cost per case were comparable.	IIIB
83	Travis H, Ehlers L, Thornton J. The total cost of reusable duodenoscopes: are single-use duodenoscopes the future of ERCP? Pharmacoeconomics. 2020;5(1)3-5.	Organizational Experience	7 endoscopy units in the same health system, United States	n/a	n/a	Micro-cost analysis	Single-use duodenoscopes might be cost-effective at most facilities due to the risk of infection and costs associated with reprocessing and maintaining reusable duodenoscopes.	VA
84	Marchini GS, Torricelli FC, Batagello CA, et al. A comprehensive literature-based equation to compare cost-effectiveness of a flexible ureteroscopy program with single-use versus reusable devices. Int Braz J Urol. 2019;45(4):658-670.	Systematic Review	n/a	n/a	n/a	n/a	Developed an evidence-based equation that will allow future comparisons of flexible ureteroscopy program cost-effectiveness with reusable versus single-use scopes worldwide.	IIIA
85	Ventimiglia E, Godinez AJ, Traxer O, Somani BK. Cost comparison of single-use versus reusable flexible ureteroscope: a systematic review. Turk J Urol. 2020;46(Suppl 1):S40-S45.	Systematic Review	n/a	n/a	n/a	n/a	An important local and international variation in costs exists for both reusable and single use flexible ureteroscopes in terms of acquisition, maintenance, and repair costs. Reusable scopes have high acquisition and ancillary (e.g. repair, involved personnel) costs. Only recently single use ureteroscopes were shown to have a similar efficacy as compared with reusable devices. In high-volume centers, with proper training for reusable ureteroscopes management, the cost per case of reusable and single-use scopes are overlapping ($1,212–$1,743 versus $1,300–$3,180 per procedure), which makes it important to precisely know the caseload, repair bills, and added expenses when negotiating purchase prices, repair prices, and warranty conditions for scopes.	IIIA

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86	Ventimiglia E, Somani BK, Traxer O. Flexible ureteroscopy: reuse? Or is single use the new direction? Curr Opin Urol. 2020;30(2):113-119.	Systematic Review	n/a	n/a	n/a	n/a	Since their introduction, single use flexible ureteroscopes have gained widespread popularity. Despite their ability at addressing reusable ureteroscope limitations, high-cost and a substantial lack of evidence are still limiting their routine adoption.	IIIA
87	Edenharter GM, Gartner D, Pförringer D. Decision support for the capacity management of bronchoscopy devices: optimizing the cost-efficient mix of reusable and single-use devices through mathematical modeling. Anesth Analg. 2017;124(6):1963-1967.	Expert Opinion	n/a	n/a	n/a	n/a	To determine the optimum mix of single-use and reusable bronchoscopy devices effectively and efficiently, managers can enter their hospital-specific parameters such as demand and prices into this decision support tool.	VA
88	Oderda M, Antolini J, Falcone M, Lacquaniti S, Fasolis G. Cost-effectiveness analysis of a single-use digital flexible cystoscope for double J removal. Urologia. 2020;87(1):29-34.	Organizational Experience	127 patients who underwent in-office cystoscopy JJ stent removal with Isiris, Italy	n/a	n/a	n/a	The procedure was successful in all cases except for one, where the device did not work due to the failure of the grasper and had to be replaced. Overall, the performance of Isiris was judged by the physician “very good” and “good” in 90.6% of the cases. Both median pain and invasiveness felt by the patient were 0. The mean cost of procedure was estimated at €361 for in-office stent removal with Isiris, and €1.126.8 for stent removal in OR with a reusable flexible cystoscope. 64 h of OR time was saved.	VA
89	Bang JY, Hawes R, Varadarajulu S. Equivalent performance of single-use and reusable duodenoscopes in a randomised trial. Gut. 2021;70(5):838-844.	RCT	98 patients who underwent ERCP procedures, United States	Single use duodenoscope (n = 48)	Reusable duodenoscope (n = 50)	Number of attempts to cannulate duct, technical performance, adverse events	Given the overall safety profile and similar technical performance, single-use duodenoscopes represent an alternative to reusable duodenoscopes for performing low-complexity ERCP procedures in experienced hands.	IB
90	Ross AS, Bruno MJ, Kozarek RA, et al. Novel single-use duodenoscope compared with 3 models of reusable duodenoscopes for ERCP: a randomized bench-model comparison. Gastrointest Endosc. 2020;91(2):396-403.	RCT	4 duodenoscopes, 6 expert endoscopists at 2 sites, laboratory, United States	EXALT Model D single-use duodenoscope	3 different models of reusable duodenoscopes	Completion of 4 ERCP tasks	A new single-use duodenoscope was used to simulate 4 ERCP tasks in an anatomic model, with performance ratings and completion times comparable with 3 models of reusable duodenoscopes.	IB

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91	Muthusamy VR, Bruno MJ, Kozarek RA, et al. Clinical evaluation of a single-use duodenoscope for endoscopic retrograde cholangiopancreatography. Clin Gastroenterol Hepatol. 2020;18(9):2108-2117.e3.	Quasi-experimental	73 patients who underwent ERCP, 6 tertiary referral centers, United States	Use of a single-use duodenoscope to perform roll in maneuver (13 patients) and ERCP (60 patients)	n/a	Ability to complete roll in maneuver or study ERCP procedure, crossover to a reusable scope, endoscopist satisfaction, serious adverse events	In a case-series study, we found that expert endoscopists can complete ERCPs of a wide range of complexity using a single-use duodenoscope for nearly all cases.	IIB
92	Mager R, Kurosch M, Höfner T, Frees S, Haferkamp A, Neisius A. Clinical outcomes and costs of reusable and single-use flexible ureterorenoscopes: a prospective cohort study. Urolithiasis. 2018;46(6):587-593.	Nonexperimental	68 reusable and 68 single-use ureterorenoscopes, tertiary referral center, Germany	n/a	n/a	Cost analysis	Showed equal clinical effectiveness of reusable and single-use flexible ureterorenoscopes. Reusable scopes have high initial investments, and lower costs per procedure. Partially overlapping ranges of costs for single-use and reusable scopes stress the importance to precisely know the expenses and caseload when negotiating purchase prices, repair prices and warranty conditions.	IIIB
93	Usawachintachit M, Isaacson DS, Taguchi K, et al. A prospective case-control study comparing lithovue, a single-use, flexible disposable ureteroscope, with flexible, reusable fiber-optic ureteroscopes. J Endourology. 2017;31(5):468-475.	Nonexperimental	180 patients who underwent ureteroscopy, academic medical center, United States	n/a	Single-use (n = 115) and reusable (n = 65) fiber-optic ureteroscopes	Procedural outcomes, operative times, time spent in the hospital	A single-use ureteroscope represents a feasible alternative to reusable ureteroscopes with a comparably low rate of scope failure. Its use shortens procedure duration, a finding that warrants further investigation.	IIIB
94	Trindade AJ, Copland A, Bhatt A, et al. Single-use duodenoscopes and duodenoscopes with disposable end caps. Gastrointest Endosc. 2021;93(5):997-1005.	Expert Opinion	n/a	n/a	n/a	n/a	Several technologies discussed in this document are anticipated to eliminate or reduce exogenous infections during endoscopy requiring a duodenoscope. Although disposable duodenoscopes can eliminate exogenous ERCP-related risk of infection, data regarding effectiveness are needed outside of expert centers. Additionally, with more widespread adoption of these new technologies, more data regarding functionality, medical economics, and environmental impact will accrue.	VA

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95	Saleem N, Ali F, Kamal F, Sherman S, Gromski M. FDA-approved innovative duodenoscope designs: reports from the manufacturer and user facility device experience (MAUDE) database. Tech Innov Gastrointest Endosc. 2021;24(2):211-213.	Case Report	>300 reports in the FDA MAUDE database from 2015 to 2021, United States	n/a	n/a	n/a	The most common reported device was the duodenoscope with single use distal tip attachment. For all reports, detachment/dislodgement of a device component made up 26.3% of reported events, while microbial contamination of the device (mostly on routine microbiological testing by the user facility) made up 18.6% of reported events.	VC
96	Ofosu A, Ramai D, Mozell D, et al. Analysis of reported adverse events related to single use duodenoscopes and duodenoscopes with detachable endcaps. Gastrointest Endosc. 2022;96(1)67-72.	Case Report	195 reports in the FDA MAUDE database from 2018 to 2021, United States	n/a	n/a	n/a	Among the duodenoscopes with detachable endcaps, most device issues related to bacterial contamination (52 reports), followed by issues with device use (31 reports), detachment /separation of the device (25 reports), and crack/dent in device material (16 reports). Ninety reports of microbial contamination of duodenoscopes were identified of which P aeruginosa was most common.	VC
97	Pasquale L, Maurano A, Cengia G, et al. Infection prevention in endoscopy practice: comparative evaluation of re-usable vs single-use endoscopic valves. Infect Prev Pract. 2021;3(2):100123.	Nonexperimental	219 samples (203 reusable and 16 single-use valves) used in 1121 endoscopies (567 reusable and 554 single-use), 11 endoscopy units, Italy	n/a	n/a	Microbial culture, cost, procedure success	Microbiological analysis of the rinse liquid of reprocessed reusable valves identified various surviving micro-organisms and highlighted their potential pathogenicity. Such data suggest that sterile single-use valves may be safer than re-usable valves, and have comparable performance.	IIIC
98	Ofstead CL, Wetzler HP, Doyle EM, et al. Persistent contamination on colonoscopes and gastroscopes detected by biologic cultures and rapid indicators despite reprocessing performed in accordance with guidelines. Am J Infect Control. 2015;43(8):794-801.	Organizational Experience	60 encounters with 15 endoscopes, large GI endoscopy unit, United States	n/a	n/a	Reprocessing compliance, visual inspection, aerobic cultures, ATP, protein, carbohydrate, hemoglobin	In this study, GI endoscopes were highly contaminated during clinical use, and residual organic materials including viable organisms, persisted despite reprocessing in accordance with guidelines.	VA

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
99	Behnia MM, Amurao K, Clemons V, Lantz G. Pseudo-outbreak of Stenotrophomonas maltophilia and Acinetobacter baumannii by a contaminated bronchoscope in an intensive care unit. TANAFFOS. 2010;9(3):44-49.	Organizational Experience	6 patients who underwent bronchoscopy, 1 bronchoscope, ICU, United States	n/a	n/a	n/a	Two patients with Acinetobacter and 4 patients with Stenotrophomonas positive lavage samples were identified over 2 month period and all patients had bronchoscopy with the same bronchoscope. Cultures of the scope revealed it was contaminated and was not properly decontaminated between procedures. There were no further cases after revising and implementing a more strict protocol for processing bronchoscopes.	VB
100	ANSI/AAMI ST79:2017. Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2017.	Guideline	United States	n/a	n/a	n/a	This recommended practice covers steam sterilization in health care facilities. The recommendations are intended to promote sterility assurance and to guide health care personnel in the proper use of processing equipment.	IVC
101	Essential elements of a reprocessing program for flexible endoscopes: recommendations of the Healthcare Infection Control Practices Advisory Committee. Centers for Disease Control and Prevention. https://www.cdc.gov/hicpac/pdf/Flexible-Endoscope-Reprocessing.pdf. Updated June 28, 2017. Accessed July 25, 2022.	Expert Opinion	n/a	n/a	n/a	n/a	Guidance is provided to assist healthcare facilities, including clinical and administrative staff, to achieve a reliable, high-quality reprocessing program. A toolkit of sample documents accompanies this guidance to help facilities create and maintain the infrastructure to support their flexible endoscope reprocessing program.	VA
102	Smith ZL, Dua A, Saeian K, et al. A novel protocol obviates endoscope sampling for carbapenem-resistant Enterobacteriaceae: experience of a center with a prior outbreak. Dig Dis Sci. 2017;62(11):3100-3109.	Organizational Experience	Academic medical center, United States	CRE screening program, HLD or ethylene oxide sterilization in high-risk settings	n/a	n/a	Implemented a novel protocol, which does not utilize endoscope culturing, to address an outbreak. Using EtO sterilization in high-risk patients has thus far eliminated endoscope associated MDRO transmission, although no CRE infections were noted throughout the institution during the study period.	VB

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103	Spaulding EH. Chemical disinfection of medical and surgical materials. In: Lawrence C, Block SS, eds. Disinfection, Sterilization, and Preservation. Philadelphia, PA: Lea & Febiger, 1968:517-531.	Expert Opinion	n/a	n/a	n/a	n/a	There are three categories of materials: critical items, semicritical items, and noncritical items. Critical items should be sterile. Semicritical items should be sterile or high-level disinfected at a minimum. Noncritical items should be clean or low-level disinfected.	VA
104	Al Qahtani SH, Abdelhamied MH, AlMuhrij AH, et al. Prospective comparative study between the effect of CIDEX®OPA and STERRAD NX on the durability of digital flexible ureteroscope. World J Urol. 2019.	RCT	88 patients who underwent flexible ureteroscopy, Saudi Arabia	Brand new digital flexible ureteroscope (Flex-Xc) HLD with chemical disinfectant (CIDEX® OPA) (n = 59)	Brand new digital flexible ureteroscope (Flex-Xc) sterilized by low-temperature hydrogen peroxide gas plasma (STERRAD NX) (n = 29)	Durability and functionality of the ureteroscopes (total operative time, laser power parameters, maneuverability, visibility scores, laser duration, stone burden), post-operative infection rate, and cost	The HLD ureteroscope was used for a significantly longer total operative time. Laser power was significantly lower in the sterilized ureteroscope. The cost of HLD was significantly less than sterilization (11.14 $ and 42.78 $ per scope). HLD was preferred over sterilization.	IB
105	Guideline for sterile technique. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 2022:1017-1058.	Guideline	United States	n/a	n/a	n/a	Provides guidance on the principles and processes of sterile technique.	IVA
106	Supplemental measures to enhance duodenoscope reprocessing: FDA Safety Communication. US Food and Drug Administration. https://www.fdanews.com/ext/resources/files/08-15/081015-duodenoscopes-fda.pdf?1520541508. Published August 4, 2015. Accessed July 25, 2022.	Regulatory	n/a	n/a	n/a	n/a	FDA is providing a detailed list of supplemental duodenoscope reprocessing measures that emerged from an agency-led expert panel meeting.	n/a
107	Department of Health and Human Services Collaboration. Duodenoscope Surveillance Sampling & Culturing. Reducing the Risks of Infection. US Food and Drug Administration. https://www.fda.gov/media/111081/download. Accessed July 25, 2022.	Expert Opinion	n/a	n/a	n/a	n/a	Protocol for surveillance sampling and culturing of reprocessed duodenoscopes intended as a quality control measure of the adequacy of reprocessing.	VA

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108	Thaker AM, Muthusamy VR, Sedarat A, et al. Duodenoscope reprocessing practice patterns in US endoscopy centers: a survey study. Gastrointest Endosc. 2018;88(2):316-322.	Nonexperimental	249 institutions that perform ERCP, United States	n/a	n/a	Survey of practices and opinions	Although most endoscopy centers have implemented enhanced duodenoscope reprocessing techniques, there is a large variation in practice. Most providers believe that duodenoscope redesign and identifying reprocessing techniques with maximal efficacy are the long-term priorities. Improved adherence to forced-air drying in duodenoscope reprocessing is needed.	IIIB
109	Snyder GM, Wright SB, Smithey A, et al. Randomized comparison of 3 high-level disinfection and sterilization procedures for duodenoscopes. Gastroenterology. 2017;153(4):1018-1025.	RCT	516 duodenoscope samples, 18 duodenoscopes, United States	Double HLD, Sterilization with ethylene oxide	Standard HLD (OPA)	Bacterial cultures (primary: proportion of elevator or working channel samples with 1 or more MDRO; secondary: frequency of contamination with more than 0 and 10 or more CFU of aerobic bacteria)	In a comparison of duodenoscopes reprocessed by sHLD, dHLD, or HLD/ETO, we found no significant differences between groups for MDRO or bacteria contamination. Enhanced disinfection methods (dHLD or HLD/ETO) did not provide additional protection against contamination. However, insufficient events occurred to assess our primary study end-point.	IB
110	Bartles RL, Leggett JE, Hove S, et al. A randomized trial of single versus double high-level disinfection of duodenoscopes and linear echoendoscopes using standard automated reprocessing. Gastrointest Endosc. 2018;88(2):306-313.	RCT	5,850 surveillance culture specimens from 45 duodenoscopes and linear echoendoscopes at 4 facilities, United States	Double HLD (n = 3,052)	Single HLD (n = 2,798)	Microbial growth and high-concern pathogens	Double HLD did not reduce culture positivity rates compared with single HLD in facilities with an already low positive culture rate.	IA
111	Rex DK, Sieber M, Lehman GA, et al. A double-reprocessing high-level disinfection protocol does not eliminate positive cultures from the elevators of duodenoscopes. Endoscopy. 2018;50(6):588-596.	Organizational Experience	56 duodenoscopes, endoscopy center, United States	Initial sterilization with ethylene oxide, then double HLD protocol implemented	n/a	Bacterial culture of elevator	Double HLD resulted in a low rate of positive cultures for known pathogens and for organisms of low pathogenic potential, but did not eliminate these, from duodenoscope elevators. Additional improvements in HLD protocols and/or duodenoscope design are needed.	VA
112	Gromski MA, Sieber MS, Sherman S, Rex DK. Double high-level disinfection versus liquid chemical sterilization for reprocessing of duodenoscopes used for ERCP: a prospective randomized study. Gastrointest Endosc. 2021;93(4):927-931.	RCT	878 post-processing surveillance cultures from duodenoscopes, high-volume referral center, United States	453 cultures from duodenoscopes that underwent double HLD	425 cultures from duodenoscopes that underwent LCS	Microbial cultures	Both methods resulted in a low rate of positive cultures, for all organisms and for high-concern organisms. However, neither process completely eliminated positive cultures.	IA

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113	Molloy-Simard V, Lemyre J, Martel K, Catalone BJ. Elevating the standard of endoscope processing: terminal sterilization of duodenoscopes using a hydrogen peroxide-ozone sterilizer. Am J Infect Control. 2019;47(3):243-250.	Quasi-experimental	Duodenoscope, laboratory and simulated clinical use, Canada	Sterilization in the STERIZONE VP4 Sterilizer after direct inoculation of the duodenoscope	n/a	Recovery of G stearothermophilus	Simulated-use and clinical in-use studies demonstrated the efficacy of a hydrogen peroxide–ozone sterilizer for terminal sterilization of duodenoscopes	IIB
114	McDonnell G, Ehrman M, Kiess, S. Effectiveness of the system 1e liquid chemical sterilant processing system for reprocessing duodenoscopes. Am J Infect Control. 2016;44(6):685-688.	Quasi-experimental	3 different duodenoscope models inoculated with G stearothermophilus, laboratory, United States	Processing in SYSTEM 1E under worst case conditions (end-of-shelf-life, pump output at lowest likely flow rate, UV light at or below acceptable intensity, water at a temperature that would result in shortest total contact time, cycle cancelled after 2.5 minutes of exposure [less than half of the full cycle exposure time])	n/a	Recovery of G stearothermophilus	All devices were successfully liquid chemically sterilized, showing greater than a 6 log reduction of G stearothermophilus spores at every inoculation site of each duodenoscope tested, in less than half the exposure time of the standard cycle.	IIB
115	Almario CV, May FP, Shaheen NJ, et al. Cost utility of competing strategies to prevent endoscopic transmission of carbapenem-resistant Enterobacteriaceae. Am J Gastroenterol. 2015;110(12):1666-1674.	Nonexperimental	Hypothetical cohort of patients hospitalized for symptomatic common bile duct stones (the most common indication for ERCP), United States	n/a	(1) FDA-recommended endoscope reprocessing procedures; (2) endoscope culture and hold; (3) ethylene oxide sterilization; and (4) stop performing ERCP (surgical intervention)	Cost	In institutions with a low CRE prevalence, ERCP with FDA-recommended reprocessing is the most cost-effective approach for mitigating CRE transmission risk. Only in settings with an extremely high CRE prevalence did ERCP with culture and hold become cost-effective.	IIIB
116	Du Rand IA, Blaikley J, Booton R, et al. British Thoracic Society guideline for diagnostic flexible bronchoscopy in adults: accredited by NICE. Thorax. 2013;68(Suppl 1)i1-i44.	Guideline	British	n/a	n/a	n/a	Recommendations for cleaning and disinfection of bronchoscopes.	IVA

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117	2020 guidance on decontamination of equipment for gastrointestinal endoscopy. British Society of Gastroenterology. https://www.bsg.org.uk/clinical-resource/guidance-on-decontamination-of-equipment-for-gastrointestinal-endoscopy. Accessed July 25, 2022.	Guideline	British	n/a	n/a	n/a	Recommendations for the decontamination of flexible endoscopes.	IVC
118	Beilenhoff U, Biering H, Blum R, et al. Reprocessing of flexible endoscopes and endoscopic accessories used in gastrointestinal endoscopy: position statement of the European Society of Gastrointestinal Endoscopy (ESGE) and European Society of Gastroenterology Nurses and Associates (ESGENA)–Update 2018. Endoscopy. 2018;50(12):1205-1234.	Position Statement	n/a	n/a	n/a	n/a	Standards for the reprocessing of flexible endoscopes and endoscopic devices used in gastroenterology.	IVB
119	Infection Prevention and Control Guideline for Flexible Gastrointestinal Endoscopy and Flexible Bronchoscopy. Public Health Agency of Canada. phac-aspc.gc.ca/nois-sinp/guide/endo/pdf/endo-eng.pdf. Published 2010. Accessed July 25, 2022.	Guideline	Canada	n/a	n/a	n/a	This guideline is intended to assist infection prevention and control professionals and all other healthcare providers responsible for using and reprocessing flexible gastrointestinal endoscopes and flexible bronchoscopes in all settings in which endoscopy is performed, whether in hospitals, clinics, physician offices, or stand-alone endoscopy centers.	IVA
120	Cheung DY, Jang BI, Kim SW, et al. Multidisciplinary and multisociety practice guideline on reprocessing flexible gastrointestinal endoscopes and endoscopic accessories. Clin Endosc. 2020;53(3):276-285.	Guideline	Korea	n/a	n/a	n/a	This guideline contains principles and instructions of the reprocessing procedure according to the step by step. Multiple societies and working groups participated to revise.	IVB

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121	Reprocessing re-usable medical devices. In: Standards for Perioperative Nursing in Australia. Vol 1: Clinical Standards. 16th ed. Australian College of Operating Room Nurses. 2020:276-293.	Guideline	Australia	n/a	n/a	n/a	Provides direction for perioperative nurses to develop, implement, and evaluate safe practices detailing the reprocessing of reusable medical devices.	IVB
122	Ofstead C, Wetzler HP, Snyder AK, Horton RA. Endoscope reprocessing methods: a prospective study on the impact of human factors and automation. Gastroenterol Nurs. 2010;33(4):304-311.	Nonexperimental	183 endoscopes; 2 GI centers, 2 multispecialty hospitals, 1 outpatient surgery center; United States	n/a	n/a	Interviews, surveys, and direct observation	Guideline adherence was only 1.4% using manual cleaning methods versus 75.4% using an automated endoscope cleaner and reprocessor. The majority reported health problems (i.e., pain, decreased flexibility, numbness, or tingling). Physical discomfort was associated with time spent reprocessing. Discomfort diminished after installation of automated endoscope cleaners and reprocessors.	IIIA
123	Machida H, Seki M, Yoshioka N, et al. Correlation between outbreaks of multidrug-resistant Pseudomonas aeruginosa infection and use of bronchoscopes suggested by epidemiological analysis. Biol Pharm Bull. 2014;37(1):26-30.	Nonexperimental	Patients who developed MDR-P aeruginosa infections, ED and ICU, university hospital, Japan	n/a	n/a	Risk factors, including bronchoscopy	Bronchoscopy was one of the most important risk factors for MDR-P aeruginosa isolation. Bronchoscope contamination was suspected to cause an outbreak involving 5 patients.	IIIB
124	US Food and Drug Administration. Guidance for industry on enforcement priorities for single-use devices reprocessed by third parties and hospitals. Fed Regist. 2000;65(157):49583-49585.	Regulatory	n/a	n/a	n/a	n/a	Third party and hospital reprocessors of single-use devices are subject to all the regulatory requirements currently applicable to original equipment manufacturers, including premarket submission requirements.	n/a
125	Reusable & single-use medical devices standards: standards for the reprocessing of reusable medical devices and for the use of single-use medical devices in all health care facilities and settings. https://open.alberta.ca/publications/9781460145470. Alberta Government. Updated September 1, 2019. Accessed July 25, 2022.	Guideline	Canada	n/a	n/a	n/a	Standards for the reprocessing of reusable medical devices and for the use of single use medical devices in all health care facilities and settings.	IVB

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126	Decontamination and Reprocessing of Medical Devices for Health-Care Facilities. World Health Organization. https://www.who.int/publications/i/item/9789241549851. Published 2016. Accessed July 25, 2022.	Guideline	International	n/a	n/a	n/a	The aim of this manual is to provide guidance in improving standards in sterile services across health-care facilities worldwide.	IVB
127	Guidelines for Design and Construction of Outpatient Facilities. The Facility Guidelines Institute; 2018.	Guideline	n/a	n/a	n/a	n/a	Provides guidelines for construction including: minimum recommended program, space, risk assessment, infection prevention, architectural detail, and surface and built-in furnishing needs for clinical and support areas of hospitals, rehabilitation facilities, and ambulatory care facilities. It also addresses minimum engineering design criteria for plumbing, electrical, and heating, ventilation, and air-conditioning (HVAC) systems.	IVC
128	Guidelines for Design and Construction of Hospitals. The Facility Guidelines Institute; 2018.	Guideline	n/a	n/a	n/a	n/a	Provides guidelines for construction including: minimum recommended program, space, risk assessment, infection prevention, architectural detail, and surface and built-in furnishing needs for clinical and support areas of hospitals, rehabilitation facilities, and ambulatory care facilities. It also addresses minimum engineering design criteria for plumbing, electrical, and heating, ventilation, and air-conditioning (HVAC) systems.	IVC

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129	Health technical memorandum 01-06: Management and decontamination of flexible endoscopes. Part B: design and installation. National Health Service UK. https://www.england.nhs.uk/publication/management-and-decontamination-of-flexible-endoscopes-htm-01-06. Updated June 30, 2016. Accessed July 25, 2022.	Guideline	United Kingdom	n/a	n/a	n/a	Part B 'Design and installation' gives guidance on the design and fitting of endoscope reprocessing units.	IVB
130	Hota S, Hirji Z, Stockton K, et al. Outbreak of multidrug-resistant Pseudomonas aeruginosa colonization and infection secondary to imperfect intensive care unit room design. Infect Control Hosp Epidemiol. 2009;30(1):25-33.	Organizational Experience	36 patients infected with MDR-P aeruginosa, ICU and transplant units, tertiary care hospital, Canada	n/a	n/a	n/a	This report highlights the importance of biofilm and of sink and patient room design in the propagation of an outbreak and suggests strategies to reduce the risks associated with hospital sinks.	VB
131	Ofstead CL, Hopkins KM, Smart AG, Brewer MK. Droplet dispersal in decontamination areas of instrument reprocessing suites. Am J Infect Control. 2022;50(2)126-132.	Organizational Experience	Large urban hospital, United States	n/a	n/a	Detection of droplets on chemical indicator paper, distance of droplets, PPE exposure to droplets	Droplets traveled at least 3 feet when filling a sink, brushing a ureteroscope, and using a power sprayer to rinse a basin. Some activities dispersed droplets up to 5 feet from the sink. Personal protective equipment was splashed during most activities and did not prevent skin exposure even when properly donned and doffed, especially at the glove-gown interface.	VB
132	Silva CV, Magalhaes VD, Pereira CR, et al. Pseudo-outbreak of Pseudomonas aeruginosa and Serratia marcescens related to bronchoscopes. Infect Control Hosp Epidemiol. 2003;24(3):195-197.	Organizational Experience	41 patients who underwent bronchoscopy and had positive bronchoalveolar lavage samples for P aeruginosa and Serratia marcescens, private hospital, Brazil	n/a	n/a	n/a	The investigation emphasizes the need for ongoing vigilance and highlights the requirement of strict disinfection methods. Delayed recognition of such a pseudo-outbreak could result in sporadic cases of transmission, colonization, and actual infection, plus the additional costs of unnecessary investigations and overtreatment of false-positive cases.	VC

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133	Sivek AD, Davis J, Tremoulet P, et al. Healthcare worker feedback on duodenoscope reprocessing workflow and ergonomics. Am J Infect Control. 2022;30:S0196-6553(22)00055-4.	Nonexperimental	341 health care workers who routinely process duodenoscopes, survey, United States	n/a	n/a	8 survey questions about duodenoscope processing	To enhance duodenoscope cleaning, facilities should provide ample reprocessing work spaces with incorporated height-adjustable work surfaces, train HCWs on validated duodenoscope reprocessing instructions, provide step-by-step instructions for HCWs when duodenoscope cleaning is performed, mentor reprocessing HCWs, and retain experienced staff.	IIIB
134	29 CFR 1910.1030. Bloodborne pathogens. Occupational Safety and Health Administration. https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1030. Accessed July 25, 2022.	Regulatory	n/a	n/a	n/a	n/a	OSHA requirements for preventing occupational exposure to bloodborne pathogens.	n/a
135	Guideline for transmission-based precautions. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 2022:1187-1216.	Guideline	United States	n/a	n/a	n/a	Provides guidance to perioperative RNs for implementing standard precautions and transmission-based precautions (ie, contact, droplet, airborne) to prevent pathogen transmission in the perioperative practice setting. Additional guidance is provided for personal protective equipment (PPE); bloodborne pathogens; immunization; and activities of health care workers with infections, exudative lesions, and nonintact skin.	IVA
136	Kahveci Z, Kilinc-Balci FS, Yorio PL. A simulation study to assess fluid leakage through the glove-gown interface in isolation settings. Am J Infect Control. 2021;49(12):1481-1487.	Quasi-experimental	2 examination gloves with different cuff lengths and 7 isolation gowns, laboratory, United States	Simulated arm movements with a robotic limb while being sprayed with synthetic body fluids	n/a	Fluid penetration	Leakage through the glove-gown interface depends on multiple factors, including glove cuff length and gown cuff design. Gowns with the thumb loop design provided better protection than the elastic cuff design, and the elastic cuff design provided better protection compared to the knit cuff design for a given AAMI PB70 level. More importantly, a substantial penetration through gown fabrics was observed.	IIA

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137	Kilinc-Balci FS, Kahveci Z, Yorio PL. Novel test method for the evaluation of fluid leakage at the glove-gown interface and investigation of test parameters. J Am Coll Surg. 2018;227(6):573-586.	Quasi-experimental	Surgical gowns and extended cuff gloves in the CDC Strategic National Stockpile, laboratory, United States	Simulated arm movements with a robotic limb while soaking and being sprayed with synthetic body fluids	n/a	Fluid penetration	Test results suggest that, with the exception of procedure duration, all parameters significantly affected the amount of fluid leaked at the glove-gown interface. Leakage was higher for soaking when compared to spraying, increased as the exposure duration increased, and was greater with the application of pressure.	IIA
138	Kilinc Balci FS. Isolation gowns in health care settings: laboratory studies, regulations and standards, and potential barriers of gown selection and use. Am J Infect Control. 2016;44(1):104-111.	Expert Opinion	n/a	n/a	n/a	n/a	Isolation gowns offer varying resistance to blood depending on the type of the material, its impermeability-permeability, its wear and tear, and its processing conditions. Although laboratory studies have produced mixed results for the effectiveness of gown use, appropriate gowns are recommended to prevent or reduce exposure to bloodborne pathogens of HCWs.	VA
139	Guideline for surgical attire. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 2022:1089-1106.	Guideline	United States	n/a	n/a	n/a	Provides guidance to perioperative team members for laundering surgical attire; wearing long sleeves, cover apparel, head coverings, and shoes in semirestricted and restricted areas; and cleaning identification badges, stethoscopes, and personal items such as backpacks, briefcases, cell phones, and electronic tablets.	IVA
140	Guideline for hand hygiene. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 20122:303-328.	Guideline	United States	n/a	n/a	n/a	Provides guidance for hand hygiene and surgical hand antisepsis in the perioperative setting.	IVA
141	Akinbobola AB, Amaeze NJ, Mackay WG, Ramage G, Williams C. 'Secondary biofilms' could cause failure of peracetic acid high-level disinfection of endoscopes. J Hosp Infect. 2021;107:67-75.	Quasi-experimental	P aeruginosa biofilms in a 24-well plate, laboratory	Exposure to peracetic acid	Untreated control	Peracetic acid tolerance (biofilm biomass, polysaccharide, protein), Confocal microscopy	Under certain circumstances, recolonization of residual extracellular polymeric substance of P aeruginosa biofilm can cause failure of disinfection of endoscopes, and emphasizes the importance of cleaning endoscopes prior to disinfection.	IIB

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142	Akinbobola AB, Sherry L, Mckay WG, Ramage G, Williams C. Tolerance of Pseudomonas aeruginosa in in-vitro biofilms to high-level peracetic acid disinfection. J Hosp Infect. 2017;97(2):162-168.	Quasi-experimental	P. aeruginosa PA14 planktonic cells, laboratory, UK	Different concentrations of peracetic acid	n/a	Viability (resazurin viability, plate count) and biomass of the P. aeruginosa biofilms (Crystal Violet assay)	Ninety-six-hour P. aeruginosa biofilm survives 5 min treatment with 2000 ppm of peracetic acid, which is the working concentration used in some endoscope washer disinfectors. This implies that disinfection failure of flexible endoscopes might occur when biofilms build up in the lumens of endoscopes.	IIB
143	Cholley AC, Traoré O, Hennequin C, Aumeran C. Klebsiella pneumoniae survival and regrowth in endoscope channel biofilm exposed to glutaraldehyde and desiccation. Eur J Clin Microbiol Infect Dis. 2020;39(6):1129-1136.	Quasi-experimental	Teflon tubing simulating insertion tube of flexible endoscopes, laboratory, France	Soiled with test suspension of Klebsiella pneumoniae, allowed to dry, and exposed to glutaraldehyde	n/a	Bacterial culture	Guidelines on endoscope reprocessing should be strictly followed but once constituted the biofilm in endoscope tubing will be very difficult to eradicate with present practices. Biofilm prevention and thorough mechanical cleaning is important. Contaminated endoscopes should be returned to the manufacturer to remove the biofilm before reuse of the device.	IIB
144	Primo MGB, Tipple AFV, Costa DM, et al. Biofilm accumulation in new flexible gastroscope channels in clinical use. Infect Control Hosp Epidemiol. 2022;43(2):174-180.	Quasi-experimental	7 flexible gastroscopes, endoscopy service of public hospital, Brazil	Replacement of channels with new ones and implementation of revised processing protocol	Baseline, 30 days of clinical use, 60 days of clinical use	Protein testing, bacterial culture, scanning electron microscopy	Extensive biofilm was detected in air, water, and air–water junction channels. All channels showed residual matter, and structural damage was identified in most of them. Residual protein was detected in the air and water channels of all evaluated, except for 1 air channel. Bacteria were recovered from 8 of 21 channels.	IIC
145	Endoscope Disinfection: A Resource-Sensitive Approach. World Gastroenterology Organisation/World Endoscopy Organization. https://www.worldendo.org/wp-content/uploads/2016/03/wgo_weo_endoscope_disinfection.pdf. Published February 2011. Accessed July 25, 2022.	Guideline	International	n/a	n/a	n/a	Resource-sensitive guidelines.	IVC
146	Ling ML, Ching P, Widitaputra A, Stewart A, Sirijindadirat N, Thu LTA. APSIC guidelines for disinfection and sterilization of instruments in health care facilities. Antimicrob Resist Infect Control. 2018;7:25.	Guideline	Asian Pacific	n/a	n/a	n/a	Guidelines and recommendations for the reprocessing of instruments, including flexible endoscopes, in the healthcare setting.	IVA

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
147	Ofstead CL, Heymann OL, Quick MR, Johnson EA, Eiland JE, Wetzler HP. The effectiveness of sterilization for flexible ureteroscopes: a real-world study. Am J Infect Control. 2017;45(8):888-895.	Organizational Experience	17 ureteroscopes, 2 large multispecialty health care facilities, United States	n/a	n/a	Procedural use, repair history, microbial culture samples, observation of reprocessing practices	Flexible ureteroscope reprocessing methods were insufficient and may have introduced contamination. These findings reinforce the need for frequent audits of reprocessing practices and the routine use of cleaning verification tests and visual inspection as recommended in reprocessing guidelines.	VA
148	Infection Control in Endoscopy. 3rd edition. Victoria, Australia: Gastroenterological Society of Australia; 2010.	Guideline	Australia	n/a	n/a	n/a	Guidelines for infection control in endoscopy.	IVB
149	Khan F, Mukhtar S, Marsh H, et al. Evaluation of the pressure leak test in increasing the lifespan of flexible ureteroscopes. Int J Clin Pract. 2013;67(10):1040-1043.	Quasi-experimental	193 patients who underwent ureterorenoscopy with laser fragmentation of renal calculi, hospital, United Kingdom	Use of an ureteroscope with in-built leak test facility	Use of an ureteroscope without an in-built leak test facility	Pressure leak test, repair costs	Pressure leak testing following flexible ureterorenoscopy helped to significantly control costs of maintenance and repair. Newer scopes should have a leak testing mechanism as it prevents further detrimental damage to the scope, build-up of repair costs are avoided and there is an increase in the longevity of these delicate instruments.	IIB
150	Ramsey AH, Oemig TV, Davis JP, Massey JP, Török TJ. An outbreak of bronchoscopy-related Mycobacterium tuberculosis infections due to lack of bronchoscope leak testing. Chest. 2002;121(3):976-981.	Organizational Experience	19 patients who underwent bronchoscopy, 10 of whom contracted TB, United States	n/a	n/a	n/a	A hole in the sheath provided access to a space that was difficult to clean and disinfect. Leak testing should be conducted for each bronchoscope processed.	VC
151	Krishna PD, Statham MM, Rosen CA. Acute glutaraldehyde mucosal injury of the upper aerodigestive tract due to damage to the working channel of an endoscope. Ann Otol Rhinol Laryngol. 2010;119(3):150-154.	Organizational Experience	2 patients who suffered acute glutaraldehyde exposures during office injection procedures, United States	n/a	n/a	n/a	Glutaraldehyde was retained in the endoscope because of a damaged channel.	VB

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152	Ribeiro MM, Graziano KU, Olson N, França R, Alfa MJ. The polytetrafluoroethylene (PTFE) channel model of cyclic-buildup biofilm and traditional biofilm: the impact of friction, and detergent on cleaning and subsequent high-level disinfection. Infect Control Hosp Epidemiol. 2020;41(2):172-180.	Quasi-experimental	Simulated PTFE channels exposed to artificial test soil (P aeruginosa, E faecalis) to develop traditional biofilm and cyclic-buildup biofilm, laboratory, Brazil	Cleaning with enzymatic and alkaline detergents, bristle brush, pull through channel cleaner	Water flush only	Carbohydrate, protein, viable count, ATP, atomic force microscopy	Friction during the cleaning process was a critical parameter regardless of the detergent used for removal of biofilm. Glutaraldehyde effectively killed the remaining microorganisms regardless of the cleaning method used.	IIB
153	Mati MLDM, Guimarães NR, Magalhães PP, Farias LDM, Oliveira ACD. Enzymatic detergent reuse in gastroscope processing: a potential source of microorganism transmission. Rev Lat Am Enfermagem. 2019;(27):e3211.	Nonexperimental	76 samples of enzymatic detergent solutions, endoscopy service, Brazil	n/a	After the 1st, 3rd, and 5th reuse of the enzymatic solution	Microbiological analysis	The reuse of the enzymatic detergent solution is a risk to the safe processing of endoscopic devices, evidenced by its contamination with pathogenic potential microorganisms, since the enzymatic detergent has no bactericidal property and can contribute as an important source for outbreaks in patients under such procedures.	IIIB
154	AAMI TIR34:2014/(R)2017. Water for the Reprocessing of Medical Devices. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2017.	Expert Opinion	n/a	n/a	n/a	n/a	The objective of this TIR is to provide guidelines to personnel involved in medical device reprocessing on the quality of water that should be used in various stages of medical device reprocessing.	VA
155	Quan E, Mahmood R, Naik A, et al. Use of adenosine triphosphate to audit reprocessing of flexible endoscopes with an elevator mechanism. Am J Infect Control. 2018;46(11):1272-1277.	Nonexperimental	4 duodenoscopes and 8 linear echoendoscopes, tertiary referral center, United States	n/a	n/a	ATP	ATP testing is effective in identifying residual organic material and improving quality of manual cleaning of endoscopes with an elevator mechanism. Cleaning efficacy is influenced by reprocessing technicians and location tested on the endoscope. Close attention to the working channel and elevator mechanism during manual cleaning is warranted.	IIIB

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156	Ofstead CL, Wetzler HP, Johnson EA, Heymann OL, Maust TJ, Shaw MJ. Simethicone residue remains inside gastrointestinal endoscopes despite reprocessing. Am J Infect Control. 2016;44(11):1237-1240.	Organizational Experience	20 endoscopes, large ambulatory surgery center, United States	n/a	n/a	Visual inspection with a borescope, FTIR analysis	Fluid containing simethicone remained inside endoscopes despite reprocessing. Simethicone is an inert, hydrophobic substance that may reduce reprocessing effectiveness. Simethicone solutions commonly contain sugars and thickeners, which may contribute to microbial growth and biofilm development. We recommend minimizing the use of simethicone pending further research into its safety.	VA
157	Ofstead CL, Hopkins KM, Eiland JE, Wetzler HP. Widespread clinical use of simethicone, insoluble lubricants, and tissue glue during endoscopy: a call to action for infection preventionists. Am J Infect Control. 2019;47(6):666-670.	Organizational Experience	69 endoscopes, 4 hospitals, United States	n/a	n/a	Microbial cultures, visual inspection, interviewing hospital personnel	Microbial cultures were positive for ≥50% of fully reprocessed endoscopes. Researchers observed cloudy, shimmery fluid resembling simethicone inside channels and under a duodenoscope elevator mechanism. Crystallized white fragments were observed protruding from a gastroscope water jet outlet. Oily, sticky residue was found on endoscopes, and a mass was found inside an endoscopic ultrasound endoscope. Hospital personnel reported the use of simethicone, cooking oil and silicone sprays, and tissue glue during endoscopy.	VA
158	Alfa MJ. Quality systems approach for endoscope reprocessing: you don't know what you don't know! Gastrointest Endosc Clin N Am. 2020;30(4):693-709.	Literature Review	n/a	n/a	n/a	n/a	Once endoscopy reprocessing sites have data from their QMS monitoring, they can implement changes to reduce the use of off-label products that cannot be effectively removed by MIFU cleaning, improve transit time between patient use and cleaning, optimize manual cleaning efficacy prior to HLD, ensure adequate drying for storage, and culture to reduce the risk of infection transmission due to contaminated endoscopes.	VA

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159	Ofstead CL, Hopkins KM. The value of borescopes in detecting damage, soil, fluid, and foreign objects in flexible endoscopes. Biomed Instrum Technol. 2020;54(2):146-152.	Expert Opinion	n/a	n/a	n/a	n/a	Guidance for developing a visual inspection protocol and how to use borescopes.	VA
160	Ofstead CL, Heymann OL, Quick MR, Eiland JE, Wetzler HP. Residual moisture and waterborne pathogens inside flexible endoscopes: evidence from a multisite study of endoscope drying effectiveness. Am J Infect Control. 2018;46(6):689-696.	Organizational Experience	45 endoscopes, 3 multispecialty hospitals, United States	n/a	n/a	Visual examination with borescopes; reprocessing, drying, and storage practices; ATP; microbial cultures	Fluid was detected in 49% of endoscopes. Prevalence of moisture varied significantly by site. High ATP levels were found in 22% of endoscopes, and microbial growth was detected in 71% of endoscopes. Retained fluid was associated with significantly higher ATP levels. Damaged endoscopes were in use at all sites.	VA
161	Ofstead CL, Wetzler HP, Heymann OL, Johnson EA, Eiland JE, Shaw MJ. Longitudinal assessment of reprocessing effectiveness for colonoscopes and gastroscopes: results of visual inspections, biochemical markers, and microbial cultures. Am J Infect Control. 2017;45(2):e26-e33.	Quasi-experimental	22 endoscopes, ambulatory surgery center, United States	More rigorous reprocessing (AER that performed automated cleaning before HLD with 5% peracetic acid; ATP tested and if >200, recleaned and subjected to 2 AER cycles)	Reprocessing using customary practices (bedside precleaning, leak testing, manual cleaning, HLD in AER with 2.5% glutaraldehyde)	Visual inspection with a borescope, microbial cultures, protein test, ATP	At final assessment, all endoscopes had visible irregularities. Researchers observed fluid (95%), discoloration, and debris in channels. ATP levels were higher for gastroscopes than colonoscopes. Eighty-five percent of endoscopes required repair due to findings. Seven-day incubation allowed identification of slow-growing microbes.	IIB
162	Barakat MT, Huang RJ, Banerjee S. Simethicone is retained in endoscopes despite reprocessing: impact of its use on working channel fluid retention and adenosine triphosphate bioluminescence values (with video). Gastrointest Endosc. 2019;89(1):115-123.	Quasi-experimental	6 colonoscopes, 6 gastroscopes, United States	Flushing with varying simethicone concentrations-0.5%, 1%, 3%	No simethicone	Borescope inspection for retained fluid, ATP	Use of medium/high concentrations of simethicone is associated with retention of increased fluid droplets and higher ATP, compared with endoscopes in which water or low concentration simethicone was used. However, simethicone is detectable in endoscopes despite reprocessing, even when it is utilized in low concentrations.	IIB

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163	Thaker AM, Kim S, Sedarat A, Watson RR, Muthusamy VR. Inspection of endoscope instrument channels after reprocessing using a prototype borescope. Gastrointest Endosc. 2018;88(4):612-619.	Nonexperimental	97 inspections of 59 endoscopes, United States	n/a	n/a	Borescope inspection	Internal defects of the instrument channel appear to occur frequently. Manual forced-air drying of the channel appears to be highly effective in eliminating moisture compared with overnight hang drying alone. Video inspection of the endoscope channel may be useful to audit reprocessing performance and to identify damaged endoscopes.	IIIC
164	Alfa MJ, Singh H. Impact of wet storage and other factors on biofilm formation and contamination of patient-ready endoscopes: a narrative review. Gastrointest Endosc. 2020;91(2):236-247.	Literature Review	n/a	n/a	n/a	n/a	There is an immediate need to focus attention on the issue of moisture in endoscope channels during storage (including the potential role of simethicone and other off-label products in preventing cleaning and drying adequacy). Unless a quality systems approach is implemented, accumulation of biofilm in endoscope channels will continue to result in contamination of flexible endoscopes that protects embedded microbes against HLD and low temperature sterilization, which could result in infection transmission.	VA
165	Information about automated endoscope reprocessors (AERs) and FDA's evaluation. US Food and Drug Administration. https://www.fda.gov/medical-devices/reprocessing-reusable-medical-devices/information-about-automated-endoscope-reprocessors-aers-and-fdas-evaluation. Updated November 2, 2021. Accessed July 25, 2022.	Regulatory	n/a	n/a	n/a	n/a	FDA evaluation of automated endoscope reprocessors.	n/a
166	Guideline for electrosurgical safety. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 2022:119-144.	Guideline	United States	n/a	n/a	n/a	Provides guidance for the safe use of electrosurgical units (ESUs), electrocautery devices, and argon-enhanced coagulators.	IVA

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
167	Liu TC, Peng CL, Wang HP, Huang HH, Chang WK. SpyGlass application for duodenoscope working channel inspection: impact on the microbiological surveillance. World J Gastroenterol. 2020;26(26):3767-3779.	Nonexperimental	19 patient-ready duodenoscopes, 2 endoscopy units at tertiary care teaching hospitals, Taiwan	n/a	n/a	Visual inspection findings, ATP, microbiological surveillance	Found abnormal visual inspection findings in patient-ready duodenoscopes, including scratches (52.6%), buckling (78.9%), stains (73.7%), debris (73.7%), and fluids (31.6%). The risk of duodenoscopes of being scratched, buckled, and stained, and accumulating debris was significantly higher at the bending section than at the insertion tube. Multivariate analysis demonstrated that fluids, but not debris, was an independent factor for bacterial culture positivity. Working channel inspection may be added to the current recommendations to identify suboptimal reprocessing or duodenoscopes requiring evaluation, repair, or replacement.	IIIB
168	Barakat MT, Girotra M, Huang RJ, Banerjee S. Scoping the scope: endoscopic evaluation of endoscope working channels with a new high-resolution inspection endoscope (with video). Gastrointest Endosc. 2018;88(4):601-611.	Nonexperimental	68 endoscopes, United States	n/a	Inspection of working channel with a novel flexible inspection endoscope	Channel damage or debris, ATP values	Overall endoscope working channel damage was rated as minimal and/or mild and was consistent with expected wear and tear, mostly superficial scratches and scratches with adherent peel. The extent of damage was not predicted by endoscope age. A few small drops of fluid were noted in 42.6% of endoscopes after reprocessing and drying. The presence of residual fluid predicted higher ATP values. The presence of visualized working channel damage or debris was not associated with elevated ATP.	IIIB

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169	Ofstead CL, Quick MR, Wetzler HP, et al. Effectiveness of reprocessing for flexible bronchoscopes and endobronchial ultrasound bronchoscopes. Chest. 2018;154(5):1024-1034.	Organizational Experience	24 bronchoscopes, 3 large tertiary-care hospitals, United States	n/a	n/a	n/a	After manual cleaning, 100% of bronchoscopes had residual contamination. Microbial growth was found in 14 fully reprocessed bronchoscopes (58%), including mold, Stenotrophomonas maltophilia, and E coli/Shigella species. Visible irregularities were observed in 100% of bronchoscopes, including retained fluid; brown, red, or oily residue; scratches; damaged insertion tubes and distal ends; and filamentous debris in channels. Reprocessing practices were substandard at two of three sites.	VA
170	Ofstead CL, Wetzler HP, Eiland JE, Heymann OL, Held SB, Shaw MJ. Assessing residual contamination and damage inside flexible endoscopes over time. Am J Infect Control. 2016;44(12):1675-1677.	Quasi-experimental	17 endoscopes, ambulatory surgery center, United States	Intervention endoscopes were tested for ATP to verify cleaning effectiveness after manual cleaning, manually recleaned when results exceeded benchmarks, and then cleaned in an AER with peracetic acid HLD	Control endoscopes were bedside precleaned, leak tested, and manually cleaned, followed by 2.5% glutaraldehyde HLD in AER	Microbial culture, visual inspection with borescope	Most GI endoscopes had irregularities that changed over 2 months. Clinical implications of these anomalies are unknown, but internal irregularities and residual fluid may have contributed to residual contamination. ATP tests and borescope examinations allowed damaged and contaminated endoscopes to be identified so they could be re-reprocessed or repaired as needed to prevent biofilm buildup and potential transmission of infection.	IIB
171	Nerandzic M, Antloga K, Litto C, Robinson N. Efficacy of flexible endoscope drying using novel endoscope test articles that allow direct visualization of the internal channel systems. Am J Infect Control. 2020:49(5)614-621.	Quasi-experimental	Transparent inner channels of colonoscope, enteroscope, and ultrasound gastroscope	Dyed water rinse (blue) and alcohol rinse (red), then air via syringe and suction pump as indicated per manufacturer's IFU. Stored in ambient endoscope storage cabinet for 5 days.	Omission of the alcohol flush step; Compressed air drying	Visual inspection	Alcohol flush followed by hanging in an ambient storage cabinet was not effective for drying endoscope channels, and residual liquid was not completely removed after performing the steps of the preoperative inspection of endoscopic channels. The factors impacting effective compressed air drying were channel dependent. For some channels, alcohol increased the time to dry.	IIB

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172	Alfa MJ, Ribeiro MM, da Costa Luciano C, et al. A novel polytetrafluoroethylene-channel model, which simulates low levels of culturable bacteria in buildup biofilm after repeated endoscope reprocessing. Gastrointest Endosc. 2017;86(3):442-451.	Quasi-experimental	5 new endoscope channels made of PFTE material, laboratory, Canada	Soiled over 8 days with repeated biofilm formation (E faecalis, P aeruginosa), rinsing, glutaraldehyde fixation, and rinsing. Dry storage for 26 weeks.	CDC flush method vs flush-brush-flush method	Viable count, scanning electron microscopy, borescope examination	Viable but nonculturable P aeruginosa within the simulated biofilm model are able to recover, which may explain the variability of culture in patient-used endoscopes. Also, friction as part of the collection method may be a critical part of sample collection from endoscope channels.	IIC
173	Alfa MJ, Singh H, Nugent Z, et al. Sterile reverse osmosis water combined with friction are optimal for channel and lever cavity sample collection of flexible duodenoscopes. Front Med (Lausanne). 2017;4:191.	Quasi-experimental	Channels made of PFTE and 2 duodenoscopes, laboratory, Canada	PFTE: soiled over 8 days with artificial test soil (E faecalis, P aeruginosa), rinsed, glutaraldehyde fixation. Channel cut to 5cm segment and attached between two 60cm sterile segments. Duodenoscopes: lever cavity inoculated with E faecalis and E coli.	Rinse with either sterile RO water, phosphate-buffered saline with and without Tween80, Letheen broth, or Dey-Engley broth. Flush only, brush, or pull through.	Bacteria viability, borescope examination	Sterile RO water and the flush-brush-flush extraction method was significantly better for E coli recovery from duodenoscope lever cavities than the CDC flush method. RO water also was significantly better in the PFTE channel model. Borescope examination showed far less residual when friction was part of the extraction protocol.	IIC
174	Olafsdottir LB, Whelan J, Snyder, GM. A systematic review of adenosine triphosphate as a surrogate for bacterial contamination of duodenoscopes used for endoscopic retrograde cholangiopancreatography. Am J Infect Control. 2018;46(6):697-705.	Systematic Review	n/a	n/a	n/a	n/a	Studies measuring ATP before and after manual cleaning and before and after HLD reported a reduction in ATP after the reprocessing stage. Current research does not support the direct substitution of ATP for bacterial culture surveillance of duodenoscopes. Serial ATP measurement may be a useful tool to evaluate the adequacy of manual cleaning and for training of endoscopic reprocessing staff.	IIIB
175	Ridtitid W, Pakvisal P, Chatsuwan T, et al. Performance characteristics and optimal cut-off value of triple adenylate nucleotides test versus adenosine triphosphate test as point-of-care testing for predicting inadequacy of duodenoscope reprocessing. J Hosp Infection. 2020;106(2):348-356.	RCT	400 duodenoscope samples after 100 ERCP procedures, 3 duodenoscopes, Thailand	Three adenylate nucleotides (A3) testing and processing until <200 RLU	ATP testing and processing until <200 RLU	A3 and ATP testing, bacterial culture	A3 and ATP tests provide good performances in predicting bacterial contamination of duodenoscopes for the four-step cleaning process. ATP <40 RLU was helpful in point of care testing, but the limitation of this value is it's inability to detect low numbers of bacteria.	IB

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176	Sethi S, Huang RJ, Barakat MT, Banaei N, Friedland S, Banerjee S. Adenosine triphosphate bioluminescence for bacteriologic surveillance and reprocessing strategies for minimizing risk of infection transmission by duodenoscopes. Gastrointest Endosc. 2017;85(6):1180-1187.	Quasi-experimental	48 patient-used endoscopes, university hospital, United States	Education and competency testing of endoscopy unit and SPD staff	n/a	ATP	ATP testing offers a rapid, inexpensive alternative for detection of endoscope microbial residue. Re-education of endoscopy staff and 2 cycles of cleaning and HLD decreased elevator channel RLUs to levels similar to sterile water and may therefore minimize the risk of transmission of infections by duodenoscopes.	IIB
177	Singh H, Duerksen DR, Schultz G, et al. Impact of cleaning monitoring combined with channel purge storage on elimination of Escherichia coli and environmental bacteria from duodenoscopes. Gastrointest Endosc. 2018;88(2):292-302.	Quasi-experimental	119 duodenoscope samples (59 sealed elevator, 60 nonsealed elevator) from 2 duodenoscope models contaminated with test soil (E faecalis, E coli), laboratory, Canada	Scopes with ATP >200 RLU were recleaned, scopes stored in channel-purge storage cabinet for 1 to 3 days	Extended cleaning and alcohol flush	ATP, bacterial culture	High-concern Gram-negative bacteria but not E faecalis or environmental bacteria can be reliably eliminated by use of the manufacturer's instructions for reprocessing with ATP monitoring of cleaning and channel-purge storage conditions.	IIB
178	McCafferty CE, Abi-Hanna D, Aghajani MJ, et al. The validity of adenosine triphosphate measurement in detecting endoscope contamination. J Hosp Infect. 2018;100(3):e142-e145.	Nonexperimental	17 gastroscopes and 24 colonoscopes, endoscopy unit, Australia	n/a	n/a	Bacterial culture, ATP	Precleaning and manual cleaning were shown to reduce ATP and microbiological load significantly.	IIIB
179	Parohl N, Stiefenhöfer D, Heiligtag S, et al. Monitoring of endoscope reprocessing with an adenosine triphosphate (ATP) bioluminescence method. GMS Hyg Infect Control. 2017;12:Doc04.	Nonexperimental	60 samples from 8 gastroscopes, major university hospital, Germany	n/a	n/a	ATP, microbial cultures	Our data suggest that monitoring of flexible endoscope with ATP can identify a number of different influence factors, like the endoscope condition and the endoscopic procedure, or especially the quality of the bedside flush and manual cleaning before the AER. ATP measurement seems to be a valid technique that allows an immediate repeat of the manual cleaning if the ATP results after manual cleaning exceed the established cutoff of 200 RLU.	IIIB

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180	Schmitt C, Pires Maciel AL, Boszczowski I, et al. Evaluation of adenosine triphosphate test for cleaning assessment of gastroscopes and the effect on workload in a busy endoscopy center. Am J Infect Control. 2018;46(10):1110-1114.	Nonexperimental	24 samples from 10 gastroscopes, endoscopy center, Brazil	n/a	n/a	ATP	After manual cleaning, 58.3% samples had no microbial growth, and in 91.7% samples the protein was undetectable. ATP test was above the cutoff (200 RLU) in 70.8% samples. After the second cleaning, 64.7% gastroscopes still failed the ATP test. The mean time spent to perform manual cleaning and ATP tests was 16 and 8 minutes, respectively. Hence, each test increased the length of time for cleaning plus testing cleanliness by 50%.	IIIC
181	Chang WK, Liu TC, Liu TL, Peng CL, Wang HP. Enhanced manual cleaning efficacy of duodenoscope in endoscopy units: results of a multicenter comprehensive quality control program. Am J Infect Control. 2019;47(10):1233-1239.	Organizational Experience	14 major tertiary care teaching hospitals, Taiwan	Comprehensive quality control program	n/a	ATP	Implementing a comprehensive QC program could enhance the efficacy of manual cleaning in endoscopy units.	VA
182	Luo Y, Yang Q, Li B, Yao Y. Establishment of a quality control circle to reduce biofilm formation in flexible endoscopes by improvement of qualified cleaning rate. J Int Med Res. 2020;48(9):300060520952983.	Organizational Experience	13 healthcare workers on Quality Control Circle (QCC) team, 235 flexible endoscopes (45 ureterorenoscopes, 93 ureterofiberscopes, 97 cystoscopes), urology surgical suite, hospital, China	n/a	n/a	n/a	A QCC was established to implement a 10-step plan-do-check-act model. The baseline ATP monitoring pass rate during reprocessing of 235 flexible endoscopes was 50%. During the study, the qualified rate increased to 85.29% after establishment of the QCC. During reprocessing of 150 flexible endoscopes in the following 6 months, the qualified rate remained at 90%.	VA
183	Washburn RE, Pietsch JJ. Assessment of test methods for evaluating effectiveness of cleaning flexible endoscopes. Am J Infect Control. 2018;46(6):685-688.	Nonexperimental	90 endoscopes, 2 endoscopy units, United States	n/a	n/a	ATP, protein, microbial growth on agar plate, rapid gram-negative culture via assay	This study suggests that if protein is detected post manual cleaning, there is a significant likelihood that protein will also be detected post–high-level disinfection. It also infers that a cleaning verification test is not predictive of microbial growth.	IIIB
184	Alfa M, Fatima I, Olson N. Validation of adenosine triphosphate to audit manual cleaning of flexible endoscope channels. Am J Infect Control. 2013;41(3):245-248.	Quasi-experimental	Duodenoscope contaminated, laboratory, Canada	Soiled with artificial test soil (E faecalis, P aeruginosa), then either fully cleaned, partially cleaned, or not cleaned	n/a	ATP, protein, hemoglobin, and bioburden	Flexible endoscopes that have complete manual cleaning will have <200 relative light units using the ATP test.	IIB

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185	Alfa M, Olson N, Murray B. Comparison of clinically relevant benchmarks and channel sampling methods used to assess manual cleaning compliance for flexible gastrointestinal endoscopes. Am J Infect Control. 2014;42(1):e1-e5.	Quasi-experimental	Clinically used colonoscopes, gastroscopes, and duodenoscopes, Canada	Manual cleaning	Before manual cleaning	Protein, bioburden and ATP	Sampling the suction biopsy channel from the biopsy port to the distal end detected the most residuals from patient-used gastrointestinal endoscopes. The protein and bioburden benchmarks for pump-assisted cleaning can be lowered, but 200 relative light units is still adequate for adenosine triphosphate.	IIA
186	Alfa MJ, Degagne P, Olson N. Worst-case soiling levels for patient-used flexible endoscopes before and after cleaning. Am J Infect Control. 1999;27(5):392-401.	Quasi-experimental	Clinically used bronchoscopes, duodenoscopes, and colonoscopes, Canada	Manual cleaning	Before manual cleaning	Protein, carbohydrate, sodium ion, hemoglobin, bilirubin, endotoxin, bacterial culturing	The data demonstrated that cleaning effectively reduced or eliminated many components of soil, but a substantial amount of viable bacteria and protein remained. Soil that mimics the worst-case composition from patient-used endoscopes would be ideal for simulated use studies for such medical devices.	IIA
187	Alfa MJ, Olson N. Simulated-use validation of a sponge ATP method for determining the adequacy of manual cleaning of endoscope channels. BMC Res Notes. 2016;9:258.	Quasi-experimental	Instrument channel segment of 2 flexible colonoscopes, laboratory, Canada	Soiled with artificial test soil (E faecalis, P aeruginosa), then either fully cleaned, partially cleaned, or not cleaned	n/a	ATP, protein, bacterial residuals	The validated cut off for acceptable manual cleaning was set at ≤100 RLUs.	IIC
188	Gillespie E, Sievert W, Swan M, Kaye C, Edridge I, Stuart RL. Adenosine triphosphate bioluminescence to validate decontamination of endoscopes. J Hosp Infect. 2017;97(4):353-356.	Quasi-experimental	127 endoscopes, Australia	ATP	Culture	ATP, bacterial culture	No elevated levels of ATP >50 RLU were found in cleaned endoscopes. The average ATP result was 4.2 RLU with only one reading at 48 RLU. There was no bacterial growth. ATP testing provides a convenient assessment of endoscopy hygiene to demonstrate safety and quality assurance.	IIB
189	Olafsdottir LB, Wright SB, Smithey A. et al. Adenosine triphosphate quantification correlates poorly with microbial contamination of duodenoscopes. Infect Control Hosp Epidemiol. 2017;38(6):678-684.	Nonexperimental	18 duodenoscopes, tertiary referral center, United States	n/a	n/a	Bacterial culture, ATP	ATP measurements correlate poorly with a microbiologic standard assessing duodenoscope contamination, particularly for elevator mechanism sampling. ATP may reflect biological material other than nonviable aerobic bacteria and may not serve as an adequate marker of bacterial contamination.	IIIB

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190	Batailler P, Saviuc P, Picot-Gueraud R, Bosson JL, Mallaret MR. Usefulness of adenosinetriphosphate bioluminescence assay (ATPmetry) for monitoring the reprocessing of endoscopes. Infect Control Hosp Epidemiol. 2015;36(12):1437-1443.	Nonexperimental	165 samples from endoscopes, France	n/a	n/a	Microbial analysis, ATP	No difference in ATP values was found between microbiologically acceptable and unacceptable samples. ATP cannot be used as an alternative or complementary approach to microbiologic tests for monitoring the reprocessing of endoscopes in France.	IIIB
191	Visrodia K, Hanada Y, Pennington KM, Tosh PK, Topazian MD, Petersen BT. Duodenoscope reprocessing surveillance with adenosine triphosphate testing and terminal cultures: a clinical pilot study. Gastrointest Endosc. 2017;86(1):180-186.	Quasi-experimental	20 clinically used duodenoscopes, endoscopy unit, United States	ATP sampling protocol: ATP >200 = repeated manual cleaning, ATP sampling, HLD, and culture sampling until meeting the benchmark. Duodenoscopes with persistently high ATP were sterilized.	n/a	Aerobic cultures, ATP	ATP sampling appears to correlate poorly with terminal culture results and cannot be recommended as a surrogate for terminal cultures. The performance and interpretation of cultures remains complicated by the potential recovery of environmental contaminants.	IIB
192	ANSI/AAMI ST58:2013/(R)2018—Chemical Sterilization and High-Level Disinfection in Health Care Facilities. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2018.	Guideline	United States	n/a	n/a	n/a	This recommended practice provides guidelines for the selection and use of liquid chemical sterilants/ high-level disinfectants and gaseous chemical sterilizers that have been cleared for marketing by the US FDA for use in health care facilities.	IVC
193	ANSI/AAMI ST41:2008/(R)2018—Ethylene Oxide Sterilization in Health Care Facilities: Safety and Effectiveness. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2018.	Guideline	United States	n/a	n/a	n/a	This recommended practice covers the safe and effective use of ethylene oxide as a sterilant in health care facilities. The provisions of this document are intended to promote sterility assurance, help minimize occupational exposure to ethylene oxide, and guide health care personnel in the proper use of processing equipment.	IVC

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
194	Centers for Disease Control and Prevention. Bronchoscopy-related infections and pseudoinfections—New York, 1996 and 1998. MMWR Morb Mortal Wkly Rep. 1999;48(26):557-560.	Case Report	n/a	n/a	n/a	n/a	The New York State Department of Health received reports of three clusters of culture-positive bronchoscopy specimens obtained in 1996 and 1998 from patients at local health-care facilities. This report summarizes the results of investigations of these clusters, which indicated involvement of Mycobacterium tuberculosis, M. intracellular, or imipenem resistant Pseudomonas aeruginosa.	VA
195	Ofstead CL, Doyle EM, Eiland JE, et al. Practical toolkit for monitoring endoscope reprocessing effectiveness: identification of viable bacteria on gastroscopes, colonoscopes, and bronchoscopes. Am J Infect Control. 2016;44(7):815-819.	Organizational Experience	5 gastroscopes, 5 colonoscopes, 5 bronchoscopes; large academic medical center, United States	n/a	n/a	Microbial cultures with a preassembled toolkit	A preassembled toolkit facilitated the aseptic collection of samples. The laboratory detected bacteria in samples from 60% of patient-ready endoscopes, including gram-positive and gram-negative species. The identification of a waterborne pathogen (S maltophilia) in samples from endoscopes and AER rinse water also prompted reconsideration of endoscope drying practices.	VB
196	Kovaleva J, Degener JE, van der Mei HC. Mimicking disinfection and drying of biofilms in contaminated endoscopes. J Hosp Infect. 2010;76(4):345-350.	Nonexperimental	4 strains of organisms that were isolated from flexible endoscopes that remained contaminated after repeat processing, laboratory, The Netherlands	n/a	n/a	Bacterial culturing	Routine cleaning procedures do not remove biofilm reliably from endoscope channels if the accurate drying procedure is not applied. This may explain the failure of decontamination during endoscope reprocessing.	IIIB
197	Devereaux BM, Athan E, Brown RR, et al. Australian infection control in endoscopy consensus statements on carbapenemase-producing Enterobacteriaceae. J Gastroenterol Hepatol. 2019;34(4):650-658.	Guideline	Australia	n/a	n/a	n/a	Recommendations to ensure the highest possible standards in flexible endoscope reprocessing thereby optimizing patient safety.	IVA
198	Barakat MT, Banerjee S. Novel algorithms for reprocessing, drying and storing endoscopes. Gastrointest Endosc Clin N Am. 2020;30(4):677-691.	Literature Review	n/a	n/a	n/a	n/a	Discusses multiple approaches to enhance and optimize reprocessing, drying, and storage of standard duodenoscopes.	VA

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199	Behm T, Robinson N. Drying and storage of flexible endoscopes: an area of growing concern. Biomed Instrum Technol. 2020;54(3):223-227.	Literature Review	n/a	n/a	n/a	n/a	Endoscope manufacturers and researchers must take the lead to provide complete drying and storage instructions. Drying instructions must be verified to be effective and validated through human factors testing.	VB
200	Kovaleva J. Endoscope drying and its pitfalls. J Hosp Infect. 2017;97(4):319-328.	Literature Review	n/a	n/a	n/a	n/a	There is no conclusive evidence on the length of time endoscopes can be safely stored before requiring redisinfection and before they pose a contamination risk.	VA
201	Tian H, Sun J, Guo S, et al. The effectiveness of drying on residual droplets, microorganisms, and biofilms in gastrointestinal endoscope reprocessing: a systematic review. Gastroenterol Res Pract. 2021;(2021):6615357.	Systematic Review	n/a	n/a	n/a	n/a	Endoscope drying practices may not always effectively remove residual droplets, microorganisms, and biofilms in endoscopes, but existing evidence suggests that automatic drying may be superior to other drying methods, drying for more than 10 min or storing in drying cabinets for more than 72 h, which highlights the importance of strict adherence to drying guidelines to make drying procedures more standardized and automated.	IIIC
202	Alfa MJ, Sitter DL. In-hospital evaluation of contamination of duodenoscopes: a quantitative assessment of the effect of drying. J Hosp Infect. 1991;19(2):89-98.	Nonexperimental	42 duodenoscopes, Canada	n/a	n/a	Bacterial culture	The primary problem with the duodenoscopes was related to overgrowth of Gram-negative rods. The overgrowth was a time-dependent phenomenon. Additional drying time prevented bacterial overgrowth.	IIIA
203	Barakat MT, Huang RJ, Banerjee S. Comparison of automated and manual drying in the elimination of residual endoscope working channel fluid after reprocessing (with video). Gastrointest Endosc. 2019;89(1):124-132.	Quasi-experimental	6 gastroscopes, 6 colonoscopes, 5 linear echoendoscopes, 6 duodenoscopes, United States	Automated device-facilitated drying for 5 minutes and 10 minutes	Manual drying with a forced air gun	Borescope inspection for retained fluid, ATP	Significantly fewer water droplets and delayed ATP bioluminescence values within endoscope working channels after automated drying compared with manual drying. In particular, virtually no retained fluid was evident within endoscope working channels after automated drying for 10 minutes.	IIB

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204	Perumpail RB, Marya NB, McGinty BL, Muthusamy VR. Endoscope reprocessing: comparison of drying effectiveness and microbial levels with an automated drying and storage cabinet with forced filtered air and a standard storage cabinet. Am J Infect Control. 2019;47(9):1083-1089.	Quasi-experimental	3 bronchoscopes, 3 colonoscopes, 3 duodenoscopes; laboratory, United States	Automated drying and storage cabinet	Standard storage cabinet	Moisture via cobalt chloride paper, bacterial culture	Using the automated drying and storage cabinet, internal channels were dry at 1 hour and external surfaces at 3 hours in all endoscopes. With the standard storage cabinet, there was residual internal fluid at 24 hours, whereas external surfaces were dry at 24 hours. An automated cabinet is advantageous for rapid drying of endoscope surfaces and in reducing the risk of microbial growth post reprocessing.	IIC
205	Health technical memorandum 01-06: Management and decontamination of flexible endoscopes. Part D: validation and verification (including storage/drying cabinets). National Health Service England. https://www.england.nhs.uk/publication/management-and-decontamination-of-flexible-endoscopes-htm-01-06. Updated June 30, 2016. Accessed July 25, 2022.	Guideline	United Kingdom	n/a	n/a	n/a	Part D 'Validation and verification' highlights the types of tests and maintenance procedures that are needed to ensure that decontamination has been achieved.	IVB
206	Saliou P, Le Bars H, Payan C, et al. Measures to improve microbial quality surveillance of gastrointestinal endoscopes. Endoscopy. 2016;48(8):704-710.	Nonexperimental	1100 samples (762 GI endoscopes and 338 AERs), teaching hospital, France	n/a	n/a	Microbial culture	Microbial samples should be cultured for more than 2 days to improve the detection of contaminated endoscopes. Particular attention should be paid to endoscopes older than 2 years and to those that are not stored in storage cabinets for heat-sensitive endoscopes.	IIIB
207	Wiktorczyk N, Kwiecińska-Piróg J, Skowron K, et al. Assessment of endoscope cleaning and disinfection efficacy, and the impact of endoscope storage on the microbiological safety level. J Appl Microbiol. 2020;128(5):1503-1513.	Quasi-experimental	Colonoscope and bronchoscope contaminated with test soil (P aeruginosa, E faecium, C sporogenes, C albicans, Aspergillus brasiliensis), laboratory, Poland	Endoscope washer-disinfector (EndoCleaner)	Storage in endoscope storage cabinet	Cleaning efficacy per PN-EN ISO 15883 standard, validity of storage cabinet per PN-EN 16442 standard	Usage of washer-disinfector Endo Cleaner and endoscope storage cabinet ensures the microbiological safety of using endoscopes.	IIB

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208	Minebois C, Saviuc P, Shum J, et al. Evaluation of a new packaging process for non-autoclavable endoscopes: results for the first 100 microbiological samples. J Hosp Infect. 2017;97(4):333-337.	Nonexperimental	38 GI endoscopes (gastroscope, colonoscope, echoendoscope, duodenoscope), academic hospital, France	n/a	n/a	Microbiological sampling, factors associated with sterility maintenance	The probability of having a sterile sample decreased 17-fold when the endoscope was packaged >2 h after leaving the AER compared to an endoscope packaged within 1 h after leaving the AER. The Sure Store process seems capable of satisfactorily maintaining compliance of samples taken from endoscopes stored for up to 15 days.	IIIB
209	Foxcroft L, Monaghan W, Faoagali J. ILL Controlled study of the Lancer FD8 drying/storage cabinet for endoscopes. J.GENCA. 2008;18(2):5-11.	Quasi-experimental	Endoscopes	Drying cabinet	Standard storage cabinet	Bacterial culture	Results confirmed that a 72 hour hold time did not result in any increased bacterial count in the test endoscopes compared with the control endoscopes.	IIB
210	Grandval P, Hautefeuille G, Marchetti B, Pineau L, Laugier R. Evaluation of a storage cabinet for heat-sensitive endoscopes in a clinical setting. J Hosp Infect. 2013;84(1):71-76.	Nonexperimental	25 GI endoscopes (10 gastroscopes, 11 colonoscopes, 4 duodenoscopes), France	n/a	Drying cabinet, standard cabinet	Bacterial culture	Use of the drying cabinet helped maintain the microbiological quality of endoscopes.	IIIB
211	Pineau L, Villard E, Duc DL, Marchetti B. Endoscope drying/storage cabinet: interest and efficacy. J Hosp Infect. 2008;68(1):59-65.	Quasi-experimental	Colonoscope, duodenoscope, enteroscope, France	Contamination with artificial test soil (P aeruginosa)	Storage in a drying cabinet for varying times 12h, 24h, 48h, 72h	Bacterial culture	The results of this study confirm the inherent risk in maintaining a potentially contaminated, wet endoscope in a non-controlled environment.	IIC
212	Wardle E. Endoscope storage cabinets. J.GENCA. 2007;17(3):5-11.	Quasi-experimental	Colonoscope, gastroscope	Various lengths of time endoscopes were stored in cabinet	n/a	Bacterial culture	The results of the study suggest that flexible endoscopes may be stored for up to 72 hours in the cabinet without reprocessing before use.	IIC
213	Hansen C. Best practices for flexible endoscope hang time: an integrative review. Can J Infect Control. 2016;31(2):85-94.	Systematic Review	n/a	n/a	n/a	n/a	Evidence suggested an optimal hang time of 5-7 days, although a longer hang time may be acceptable.	IIIA
214	Schmelzer M, Daniels G, Hough H. Safe storage time for reprocessed flexible endoscopes: a systematic review. JBI Evid Synth. 2015;13(9)187-243.	Systematic Review	n/a	n/a	n/a	n/a	Storage time ranged from two to 56 days, and all 10 studies concluded that endoscopes could safely be stored for the time measured. Seven studies measured microbial growth in all channels; six involved storing the endoscopes for at least three days and five for at least seven days. The contamination rates were low (2% at three days and 4% at seven days) and pathogens were rare.	IIIA

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215	Mallette KI, Pieroni P, Dhalla SS. Bacterial presence on flexible endoscopes vs time since disinfection. World J Gastrointest Endosc. 2018;10(1):51-55.	Nonexperimental	164 samples from 19 gastroscopes, 24 colonoscopes, and 5 duodenoscopes; Canada	n/a	n/a	Bacterial culture, hang time	There was no correlation between hang time and bacterial load. Endoscopes can be stored up to 7 days without requiring reprocessing.	IIIB
216	Scanlon P, Flaherty K, Reilly EA, et al. Association between storage interval and contamination of reprocessed flexible endoscopes in a pediatric gastrointestinal procedural unit. Infect Control Hosp Epidemiol. 2017;38(2):131-135.	Nonexperimental	27 GI endoscopes, pediatric GI procedural unit, United States	n/a	n/a	Bacterial cultures at different time intervals	No endoscopes demonstrated clinically relevant contamination at hang times ranging from 7 to 555 days, and most scopes remained uncontaminated up to 56 days after reprocessing.	IIIB
217	Heroux R, Sheppard M, Wright SB, et al. Duodenoscope hang time does not correlate with risk of bacterial contamination. Am J Infect Control. 2017;45(4):360-364.	Nonexperimental	531 cultures from 18 duodenoscopes, secondary analysis of dataset from DISINFECTS study, United States	n/a	n/a	Bacterial culture	In a large dataset of rigorously collected elevator mechanism and working channel cultures, hang time for ERCP duodenoscopes did not significantly correlate with the probability of duodenoscope contamination with aerobic bacteria. Hang times for duodenoscopes exceeding 7 days may present a negligible additional risk of duodenoscope contamination.	IIIA
218	Lacey V, Good K, Toliver C, Jenkins S, DeGuzman PB. Evaluation of 12-week shelf life of patient-ready endoscopes. Gastroenterol Nurs. 2019;42(2):159-164.	Nonexperimental	4 colonoscopes and two gastroscopes, community hospital, United States	n/a	n/a	Bacteria and fungus culture	Contaminated endoscopes may be related to inadequate disinfection or contamination during storage, not shelf life.	IIIC
219	Troutner JC, Harrell MV, Seelen MT, Daily BJ, Levine WC. Using real-time locating systems to optimize endoscope use at a large academic medical center. J Med Syst. 2020;44(4):71.	Organizational Experience	Large academic medical center, United States	n/a	n/a	n/a	Used a real time location system for endoscopes and found an increase in compliance with 7-day storage from 88.9% to 94.5% and an estimated $17,350 annual cost savings due to more efficient scope management.	VA
220	Guideline for environmental cleaning. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 2022:181-212.	Guideline	United States	n/a	n/a	n/a	Provides guidance on the selection and use of cleaning products, cleaning procedures, personnel education and competency verification, and monitoring cleanliness through performance improvement processes.	IVA

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
221	Position Statement: Management of Endoscopic Accessories, Valves, and Water and Irrigation Bottles in the Gastroenterology Setting. Society of Gasteroenterology Nurses and Associates, Inc. https://www.sgna.org/Portals/0/Management%20Endoscopic%20Accessories%20Valves%20Water%20Irrigation%20bottles.pdf?ver=2018-08-20-141307-367. Published May 2002. Updated August 2018. Accessed July 25, 2022.	Position Statement	n/a	n/a	n/a	n/a	Infection prevention should be a guiding factor in selecting endoscopic accessories, valves, and water bottles because cross-contamination can transmit infection.	IVB
222	Jouck D, Magerman K, Bruckers L, et al. Reusable endoscopic water bottles: is daily renewal really necessary? J Hosp Infect. 2018;100(3):e135-e137.	Nonexperimental	179 samples from water bottles in a gastrointestinal endoscopy unit, tertiary hospital, Belgium	n/a	n/a	Bacterial culture, duration of use (days)	Bacterial growth from the water samples included mainly skin flora, Stenotrophomonas maltophilia, Sphingomonas species, and P aeruginosa. Reuse of water bottles for more than one day is inadequate because >9 cfu/100 mL was detected in 17% of samples after only one day of water bottle use. It would be contradictory to use less stringent measures for these water bottles and to tolerate a high number of micro-organisms with a potential risk for patient safety. Stricter guidelines may be right to recommend replacing water bottles after each endoscopy session.	IIIB
223	Ofstead CL, Hopkins KM, Quick MR, Brooks KB, Eiland JE, Wetzler HP. A systematic review of disposable sheath use during flexible endoscopy. AORN J. 2019;109(6):757-771.	Systematic Review	n/a	n/a	n/a	n/a	The evidence showed that sheaths were durable and yielded faster endoscope turnover times because their reusable components did not require HLD or sterilization. Patients generally did not experience greater discomfort during procedures in which sheaths were used. Microbial cultures of sheathed endoscopes were negative or similar to unsheathed endoscopes.	IIIB

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224	Rutala WA, Weber DJ, Society for Healthcare Epidemiology of America. Guideline for disinfection and sterilization of prion-contaminated medical instruments. Infect Control Hosp Epidemiol. 2010;31(2):107-117.	Guideline	United States	n/a	n/a	n/a	Use standard cleaning and high-level disinfection protocols for reprocessing endoscopes (except neurosurgical endoscopes with central nervous system contact), because these devices can become contaminated only with no-risk materials.	IVA
225	Health technical memorandum 01-06: Management and decontamination of flexible endoscopes. Part A: policy and management. National Health Service England. https://www.england.nhs.uk/publication/management-and-decontamination-of-flexible-endoscopes-htm-01-06. Updated June 30, 2016. Accessed July 25, 2022.	Guideline	United Kingdom	n/a	n/a	n/a	Part A 'Policy and management' sets the Department of Health's policy context and discusses the Essential Quality Requirements and Best Practice recommendations for an endoscope decontamination service. Transmissible spongiform encephalopathy (TSE) infectious agents are discussed and guidance is given on the management and handling of an endoscope after it has been used on a patient at increased risk of vCJD.	IVB
226	Kampf G, Jung M, Suchomel M, Saliou P, Griffiths H, Vos MC. Prion disease and recommended procedures for flexible endoscope reprocessing—a review of policies worldwide and proposal for a simplified approach. J Hosp Infect. 2020;104(1):92-110.	Literature Review	n/a	n/a	n/a	n/a	Thus far, no case of CJD or vCJD transmitted by a contaminated flexible endoscope has been reported. In addition, no studies were found measuring prion protein on flexible endoscopes, either after use in a patient with proven or suspected prion disease. Therefore, it is still unknown whether an endoscope harbors prion protein on its inner and outer surfaces after use in a patient with prion disease.	VA
227	Preventing cross-contamination in endoscope processing: FDA Safety Communication. US Food and Drug Administration. http://wayback.archive-it.org/7993/20170722213023/https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm190273.htm. Published November 19, 2009. Archived July 22, 2017. Accessed July 25, 2022.	Regulatory	n/a	n/a	n/a	n/a	The FDA cautions healthcare facilities about the risks to patients if flexible endoscopes are not processed properly, and recommends steps to reduce risk.	n/a

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228	Beilenhoff U. Europe-wide curriculum for endoscope reprocessing. Gastrointestinal Nurs. 2020;18(Suppl 1):S4-S5.	Consensus	n/a	n/a	n/a	n/a	The qualification and competencies of the reprocessing staff is a key issue in infection prevention, patient and staff safety. Therefore, ESGENA developed a European Core Curriculum for reprocessing flexible thermo labile endoscopes.	IVB
229	Kenters N, Tartari E, Hopman J, et al. Worldwide practices on flexible endoscope reprocessing. Antimicrob Resist Infect Control. 2018;7:153.	Nonexperimental	165 respondents from 39 countries	n/a	n/a	50 question survey assessing stakeholder involvement, assessment of perceived risks, and processing process	Most facilities 82% have a standard operating procedure. There is, however a lot of variation within the flexible endoscope reprocessing practices observed. The need for regular training and education of reprocessing practitioners were identified by 50% of the respondents as main concerns. A standardized education and training program with a competency assessment is essential to prevent reprocessing lapses and improve patient safety.	IIIB
230	Suresh S, Pande M, Patel K, et al. Education, training, and knowledge of infection control among endoscopy technicians and nurses. Am J Infect Control. 2021;49(6):836-839.	Qualitative	88 endoscopy technicians and nurses, United States	n/a	n/a	Survey of experience, training, and knowledge in infection control	While self-reported confidence in endoscope reprocessing was high (9 out of 10), knowledge of best practices in this regard lagged (average assessment score of 62%).	IIIB
231	Jolly JD, Hildebrand EA, Branaghan RJ. Better instructions for use to improve reusable medical equipment (RME) sterility. Hum Factors. 2013;55(2):397-410.	RCT	36 students in psychology classes at a large university, United States	Participants reprocessed an endoscope using new instructional aids (n = 24)	Participants reprocessed an endoscope using manufacturer-provided visual aids (n = 12)	Endoscope reprocessing performance	When given an instructional aid designed with human factors principles, participants were able to more successfully complete the reprocessing task. This resulted in an endoscope that was more likely to be safe for use on patients.	IB

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
232	State Operations Manual Appendix L–Guidance For Surveyors: Ambulatory Surgical Centers. Rev 206, 6-17-22. Centers for Medicare and Medicaid Services. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107ap_l_ambulatory.pdf. Accessed July 25, 2022.	Regulatory	n/a	n/a	n/a	n/a	CMS conditions for coverage for ASCs.	n/a
233	State Operations Manual Appendix A: Survey Protocol, Regulations and Interpretive Guidelines for Hospitals. Rev 206, 6-17-22. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107ap_l_ambulatory.pdf. Accessed July 25, 2022.	Regulatory	n/a	n/a	n/a	n/a	CMS condition of participation for hospitals.	n/a

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234	Guideline for team communication. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 2022:1155-1186.	Guideline	United States	n/a	n/a	n/a	This document provides guidance for improving perioperative team communication through a culture of safety that incorporates team training, simulation training, standardized transfer of patient information (commonly referred to as hand overs or hand offs), briefings, time outs, surgical safety checklists, and debriefings.	IVA
235	Quick Safety 33: Improperly sterilized or HLD equipment—a growing problem. The Joint Commission. https://www.jointcommission.org/resources/news-and-multimedia/newsletters/newsletters/quick-safety/quick-safety-issue-33-improperly-sterilized-or-hld-equipment--a-growing-problem/improperly-sterilized-or-hld-equipment--a-growing-problem/#.YuQL9z3MKM8. Published May 2017. Accessed July 25, 2022.	Accreditation	n/a	n/a	n/a	n/a	Information to help leaders address the growing problem of improperly sterilized or HLD equipment.	n/a
236	Higa JT, Ross AS. Duodenoscope as a vector for transmission. Gastrointest Endosc Clin N Am. 2020;30(4):653-663.	Literature Review	n/a	n/a	n/a	n/a	Advancements in endoscope technology and design are needed to ensure greater safety for patients undergoing ERCP and endoscopic ultrasound. Interim solutions have emerged to include enhanced cleaning methods, quality metrics and redundancy built into the reprocessing procedures, exhaustive informed consent, and routine maintenance of endoscopes. Staff training and competency must also be prioritized; however, other implementable and wholly important measures include skill task alignment, ergonomic workspace optimization, and a feedback process.	VA

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237	Washburn R, Chami E, Keskimaki A, Starr P. Tales from the auditors: what we learned from endoscope auditing. Am J Infect Control. 2020;48(1):86-88.	Expert Opinion	n/a	n/a	n/a	n/a	Advice from auditing teams who visit all locations with a standardized tool, review the entire workflow, and evaluate every step, from point of use through storage.	VB
238	Alfa MJ, Singh H. Contaminated flexible endoscopes: review of impact of channel sampling methods on culture results and recommendations for root-cause analysis. Infect Control Hosp Epidemiol. 2022;3(5):623-638.	Literature Review	n/a	n/a	n/a	n/a	The investigative approach recommended in this review will ensure that monitoring of manual cleaning and monitoring of dry storage are routinely assessed to ensure that they are not overlooked as part of the quality process for endoscope reprocessing.	VA
239	Teter J, Zenilman ME, Wachter P; Johns Hopkins Medicine Cleaning, Disinfection and Sterilization, Clinical Community. Assessment of endoscope reprocessing using peer-to-peer assessment through a clinical community. Jt Comm J Qual Patient Saf. 2016;42(6):265-270.	Organizational Experience	5 GI endoscopy sites (3 hospital-based, 2 freestanding ASC), United States	n/a	n/a	n/a	A nonpunitive and collaborative peer methodology was successful in capturing and sharing best practices in endoscopy areas.	VA
240	Armellino D, Cifu K, Wallace M, et al. Implementation of remote video auditing with feedback and compliance for manual-cleaning protocols of endoscopic retrograde cholangiopancreatography endoscopes. Am J Infect Control. 2018;46(5):594-596.	Organizational Experience	Community teaching hospital, United States	n/a	n/a	n/a	The use of remote video auditing to document manual processing of ERCP endoscopes is a feasible approach and feedback and reeducation increased manual-cleaning compliance from 53.1% to 98.9%.	VA
241	Armellino D. Ongoing discovery of high-level disinfection of endoscope practices and the use of performance improvement methodologies to improve processes. Jt Comm J Qual Patient Saf. 2016;42(6):262-264.	Organizational Experience	Community teaching hospital, United States	n/a	n/a	n/a	Large health system experience with quality improvement of HLD practices and ERCP endoscopes. Conducted an assessment (site-specific infection preventionist and HLD area-specific management) and then implemented changes on the basis of the evaluation of practices in HLD locations in which reprocessed endoscopes were identified. Also implemented remote video auditing technology.	VA

REFERENCE #	CITATION	EVIDENCE TYPE	SAMPLE SIZE/ POPULATION	INTERVENTION(S)	CONTROL/ COMPARISON	OUTCOME MEASURE(S)	CONCLUSION(S)	CONSENSUS SCORE
242	Reporting problems with reusable medical devices or reprocessing. US Food and Drug Administration. https://www.fda.gov/medical-devices/reprocessing-reusable-medical-devices/reporting-problems-reusable-medical-devices-or-reprocessing. Accessed July 25, 2022.	Regulatory	n/a	n/a	n/a	n/a	Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices.	n/a
243	Van Wicklin SA. Microbiological culture surveillance of flexible endoscopes: a systematic review. Can J Infect Control. 2016;31(2):79-84.	Systematic Review	n/a	n/a	n/a	n/a	Routine microbiological surveillance culturing is supported in the literature as an effective method for monitoring the effectiveness and quality of processing, reinforcing best practices, evaluating the effectiveness of corrective interventions, and detecting endoscopes requiring service; however, there is also evidence to show that surveillance cultures may be ineffective as a method for preventing transmission of infection from flexible endoscopes.	IIIB
244	Higa JT, Choe J, Tombs D, Gluck M, Ross AS. Optimizing duodenoscope reprocessing: rigorous assessment of a culture and quarantine protocol. Gastrointest Endosc. 2018;88(2):223-229.	Quasi-experimental	4,307 cultures from 28 duodenoscopes over a 3 year period, United States	Changes to cleaning practices, withdrawal of a high-frequency culture-positive duodenoscope	n/a	Bacterial culture	High-concern organisms were isolated from 33 of these cultures, resulting in a .697% high-level disinfection defect rate. Withdrawal of duodenoscopes with a high rate of culture positivity and optimizing manual cleaning practices have contributed to an overall decline in the high-level disinfection defect rate. A stringent culture and quarantine protocol allowed identification of the culprit endoscopes.	IIB

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245	Ellison Jr PL, Freeman J, Elmunzer BJ, Cote GA, Brock AS. Review of duodenoscope infection prevention practices at the Medical University of South Carolina. Gastroenterol Nurs. 2020;43(6):E214-E216.	Organizational Experience	8 duodenoscopes at Medical University of South Carolina, United States	n/a	n/a	n/a	Implemented FDA recommended periodic microbiologic surveillance (2 separate cultures from 2 duodenoscopes every 2 months). The initial results of the surveillance cultures are negative for any multidrug-resistant organisms; however, other centers should consider implementing surveillance cultures into their reprocessing practices and closely monitoring for future endoscope infection prevention modalities.	VA
246	Ma GK, Pegues DA, Kochman ML, et al. Implementation of a systematic culturing program to monitor the efficacy of endoscope reprocessing: outcomes and costs. Gastrointest Endosc. 2018;87(1):104-109.	Organizational Experience	Large teaching hospital, United States	n/a	n/a	n/a	This 16-month evaluation of a systematic endoscope culturing program identified a low rate of positive cultures after elevator lever endoscope reprocessing. All positive cultures were with non-enteric microorganisms. The program was of modest cost and identified reprocessing procedures that may have led to a low rate of positive cultures.	VA
247	Mark JA, Underberg K, Kramer RE. Results of duodenoscope culture and quarantine after manufacturer-recommended cleaning process. Gastrointest Endosc. 2020;91(6):1328-1333.	Nonexperimental	280 samples from duodenoscopes, pediatric teaching hospital, United States	n/a	n/a	Bacterial culture	Eighteen percent of duodenoscopes had a positive culture after initial HLD. Repeated HLD was 86% and 75% effective at eliminating initial and repeat positive cultures, respectively. Initial HLD per manufacturer recommendations is not always effective at eliminating bacterial contamination. Additional steps are necessary to decrease risks of duodenoscope-transmitted infections.	IIIB
248	Paula H, Tribl B, Presterl E, Diab-El Schahawi M. Prospective microbiologic evaluation of the forceps elevator in closed-channel duodenoscopes after reprocessing. Am J Infect Control. 2017;45(2):121-125.	Organizational Experience	237 samples from duodenoscopes, tertiary-care university teaching hospital, Austria	n/a	n/a	Microbial cultures	Thorough reprocessing in combination with microbiologic surveillance at a large institution may successfully overcome endoscope design shortcomings, but duodenoscope design must accommodate reprocessing in settings less optimal than a tertiary university hospital.	VA

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249	Rauwers AW, Voor In 't Holt, AF, Buijs JG, et al. High prevalence rate of digestive tract bacteria in duodenoscopes: a nationwide study. Gut. 2018;67(9):1637-1645.	Nonexperimental	155 duodenoscopes, 73 centers that perform ERCP, The Netherlands	n/a	n/a	Bacterial cultures	In 39% of all Dutch ERCP centers, at least one patient-ready duodenoscope with contamination of any microorganism over 20 CFU was identified. Fifteen per cent of the duodenoscopes harbored GI or oral organisms, indicating residual organic material of previous patients, that is, failing of disinfection. These results suggest that the present reprocessing and process control procedures are not adequate and safe.	IIIA
250	Troiano G, Lo Nostro A, Calonico C, et al. Microbiological surveillance of flexible bronchoscopes after a high-level disinfection with peracetic acid: preliminary results from an Italian teaching hospital. Ann Ig. 2019;31(1):13-20.	Nonexperimental	218 samples from bronchoscopes, pulmonology unit at teaching hospital, Italy	n/a	n/a	Microbial culture	Staphylococci were found in 15.7% of all samples and Pseudomonas in 5%. Results similar to other literature. Bronchoscopy hygiene should be part of a complex strategy of surveillance and control of infections.	IIIC
251	Valeriani F, Agodi A, Casini B, et al. Potential testing of reprocessing procedures by real-time polymerase chain reaction: a multicenter study of colonoscopy devices. Am J Infect Control. 2018;46(2):159-164.	Nonexperimental	111 colonoscopes, 10 hospitals, Italy	n/a	n/a	Microbial culture, PCR testing	An PCR-based method allowed identification of both contaminated (n = 59) and fully reprocessed endoscopes (n = 52) with high sensibility (98%) and specificity (98%), within 3-4 hours, in contrast to the 24- 72 hours needed for a classic microbiology test.	IIIB
252	Cristina ML, Sartini M, Schinca E, et al. Is post-reprocessing microbiological surveillance of duodenoscopes effective in reducing the potential risk in transmitting pathogens? Int J Environ Res Public Health. 2019;17(1):140.	Organizational Experience	124 samples from 4 duodenoscopes, endoscopy unit, Italy	n/a	n/a	Microbiological surveillance	Three duodenoscopes presented a high level of contamination with "high-concern" micro-organisms, some of which were multidrug-resistant. The highest values of contamination regarded the species P. aeruginosa, K. pneumoniae, and A. baumannii. Since the cultures were repeatedly positive on three successive occasions, the contaminated devices were sent to the manufacturer for evaluation. Audits were carried out with the personnel responsible for reprocessing and only one case of non-conformity was found.	VA

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253	Legemate JD, Kamphuis GM, Freund JE, et al. Pre-use ureteroscope contamination after high level disinfection: reprocessing effectiveness and the relation with cumulative ureteroscope use. J Urol. 2019;201(6):1144-1151.	Nonexperimental	389 procedures performed using 20 ureteroscopes, tertiary referral center, The Netherlands	n/a	n/a	Microbial samples, UTI symptoms	Ureteroscopes were contaminated after HLD 12% of the time. In 2.3% of all procedures, contamination was caused by uropathogens. Contamination implies flaws in the reprocessing process, and frequent audits of the process need to be strengthened to ensure patient safety.	IIIB
254	Cattoir L, Vanzieleghem T, Florin L, et al. Surveillance of endoscopes: comparison of different sampling techniques. Infect Control Hosp Epidemiol. 2017;38(9):1062-1069.	Quasi-experimental	Channels made of PTFE (N= 20), endoscopes (N = 40) [10 gastroscopes, 10 colonoscopes, 5 duodenoscopes, 5 echoendoscopes, 10 bronchoscopes], laboratory, Belgium	4 sampling techniques: flushing with sterile physiological saline (PHYS), flushing with neutralizing pharmacopeia diluent (NPD), and 2 flush-brush-flush techniques using PHYS in combination with the Olympus single-use, dual-ended cleaning brush or the PULL THRU brush.	n/a	ATP, bacterial culture	Physiological saline flushing combined with PULL THRU brush to sample endoscopes generated higher ATP values and increased the yield of microbial surveillance culture. Consequently, the acceptance rate of endoscopes based on a defined CFU limit was significantly lower when the saline + PULL THRU method was used instead of saline alone.	IIB
255	De Wolfe TJ, Safdar N, Meller M, et al. A prospective, randomized comparison of duodenoscope reprocessing surveillance methods. Can J Gastroenterol Hepatol. 2019;(2019):1959141.	RCT	248 samples from duodenoscopes, United States	Surveillance protocol developed by University of Wisconsin Hospitals and Clinics (UWHC) (n = 119) [Swab elevator, immerse terminal end into broth, flush lumen with saline]	CDC sampling and surveillance protocol 2015 (n = 129) [Brush terminal end, flush lumen with sterile water]	Bacterial culture, time, cost	The UWHC protocol provides similar detection rates as the CDC protocol, had a shorter processing time and was lower cost to perform.	IB
256	Gazdik MA, Coombs J, Burke JP, Lopansri BK. Comparison of two culture methods for use in assessing microbial contamination of duodenoscopes. J Clin Microbiol. 2016;54(2):312-316.	Quasi-experimental	Two duodenoscopes soiled with artificial test soil plus mucin (E coli, K pneumoniae, P aeruginosa, E faecium), laboratory, United States	Modified protocol for duodenoscope sampling (European Society of Gastroenterology [ESGE])	Interim CDC protocol for duodenoscope sampling	Bacterial culture to determine sampling efficiency	Implementation of this protocol may increase the feasibility of duodenoscope surveillance for microbiology laboratories and endoscopy departments.	IIB

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257	Ji XY, Ning PY, Fei CN, Liu J, Liu H, Song J. The importance of sampling technique and rinse water for assessing flexible gastrointestinal endoscope reprocessing: a 3-year study covering 59 centers. Am J Infect Control. 2020;48(1):19-25.	RCT	237 flushing channel samples and 110 final rinse water samples, 59 endoscope centers, China	Flush-brush-flush sampling method (FBFSM)	Pump-assisted sampling method (PASM); conventional flushing method	Residual bacterial contamination	The problem of the residual microorganisms of the post reprocessing endoscope was serious; many endoscopes had failed to meet the national standard. Sampling technique and final rinse water were critical for endoscope reprocessing verification. PASM and FBFSM could improve efficiency for recovering microorganisms. The endoscope centers should implement the national standard and strictly use purified water for the final rinse.	IB
258	Sohn SY, Alfa MJ, Lai R, Tabani Y, Labib ME. Turbulent fluid flow is a novel closed-system sample extraction method for flexible endoscope channels of various inner diameters. J Microbiol Methods. 2020;168:105782.	Quasi-experimental	PTFE tubes contaminated with test soil (P aeruginosa, E faecalis, C albicans), laboratory, United States	Turbulent Fluid Flow (TFF)	Flush (F), Flush brush flush (FBF)	Microbial cultures	The novel TFF method for extraction of samples from colonoscope channels is a more effective method than the existing FBF and F methods.	IIB
259	Okamoto N, Sczaniecka A, Hirano M, et al. A prospective, multicenter, clinical study of duodenoscope contamination after reprocessing. Infect Control Hosp Epidemiol. 2022:1-9. doi: 10.1017/ice.2021.525	Nonexperimental	859 newer-model and 850 older-model duodenoscopes, 16 sites, United States	n/a	n/a	Microbial cultures, environmental cultures	Overall high-concern organism contamination rate of 5.3% in nonoutbreak settings using FDA/CDC/ASM guideline.	IIIB