

Guideline for Processing Flexible Endoscopes
Evidence Table

	A	C	D	E	F	I	J	K	L	M	N
	REFERENCE NUMBER	CITATION	PURPOSE	CONSENSUS SCORE	RESULTS AND CONCLUSIONS	EVIDENCE TYPE	POPULATION	INTERVENTIONS	COMPARISON	SAMPLE SIZE	OUTCOME MEASURE
1	1	Alvarado CJ, Reichelderfer M. APIC guideline for infection prevention and control in flexible endoscopy. Association for Professionals in Infection Control. Am J Infect Control. 2000;28(2):138-155.	To provide guidance for infection prevention and control in flexible endoscopy.	IVB	These guidelines represent minimum standards of care. Facilities may wish to adopt more stringent criteria. The recommendations should be followed for all patients, regardless of whether they are suspected or known to be infected.	Guideline	Health care providers and others with an interest in endoscopy associated infection	N/A	N/A	N/A	N
2	2	Infections associated with reprocessed flexible bronchoscopes: FDA safety communication. US Food and Drug Administration. http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm462949.htm . Accessed December 9, 2015.	To share preliminary information regarding infections associated with the use of reprocessed flexible endoscopes.	VA	The FDA has undertaken an ongoing, comprehensive investigation into infections associated with reprocessed reusable medical devices to better understand the critical factors contributing to device-associated patient infection and how to best mitigate them.	Expert opinion	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
3	3	Preventing cross-contamination in endoscope processing: FDA safety communication. US Food and Drug Administration. http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm190273.htm . Accessed December 9, 2015.	To caution healthcare facilities about the risks to patients if flexible endoscopes and their accessories are not processed correctly.	VB	Recommended steps are provided to reduce these risks.	Expert opinion	Health care providers and others with an interest in effective reprocessing and preventing endoscopy-related infection	N/A	N/A	N/A	N/A
4	4	Gastmeier P, Vonberg RP. Klebsiella spp. in endoscopy-associated infections: we may only be seeing the tip of the iceberg. Infection. 2014;42(1):15-21.	To perform a systematic search of the medical literature in order to elucidate the epidemiology of <i>Klebsiella</i> spp. In endoscopy-associated outbreaks.	VA	The following key conclusions can be drawn from the results of this review: 1) strict adherence to infection control guidelines for reprocessing endoscopes is necessary; 2) alertness to the possibility of pathogen transmission after endoscopy is required; 3) prospective studies using indicator species are necessary to determine the true risk of pathogen transmission caused by endoscopic procedures.	Literature review	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	Epidemiology of <i>Klebsiella</i> spp. In endoscopy-associated outbreaks
5	5	Kampf B, Makowski T, Weiss H, et al. ESGE newsletter. Definition of "endoscope families" as used in EN ISO 15883-4. Endoscopy. 2013;45(2):156-157.	To provide a definition for endoscope families.	VB	The classification criteria for endoscope families were based on the significant characteristics of endoscopes, including the number, construction, and purpose of the different endoscope channels and their clinical applications.	Expert opinion	Health care providers and others with an interest in processing endoscopes	N/A	N/A	N/A	N/A
6	6	Design of endoscopic retrograde cholangiopancreatography (ERCP) duodenoscopes may impede effective cleaning: FDA safety communication. US Food and Drug Administration. http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm434871.htm . Accessed December 9, 2015.	To communicate that the design of the ERCP may impede effective cleaning.	VA	Closely follow the manufacturer's recommendations. Meticulously clean the elevator mechanism.	Expert opinion	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
7	7	Boylu U, Oommen M, Thomas R, Lee BR. In vitro comparison of a disposable flexible ureteroscope and conventional flexible ureteroscopes. J Urol. 2009;182(5):2347-2351.	To compare and evaluate the objective characteristics of a disposable flexible ureteroscope and six established commercially available ureteroscopes.	IIIB	The disposable flexible ureteroscope has acceptable active tip deflection, field of view and flow rate compared to those of other flexible ureteroscopes on the market.	Nonexperimental	Flexible ureteroscopes	Disposable ureteroscopes	Deflection/Field of view/Flow rate/Cost	7	N/A
8	8	Piepho T, Werner C, Noppens RR. Evaluation of the novel, single-use, flexible aScope for tracheal intubation in the simulated difficult airway and first clinical experiences. Anaesthesia. 2010;65(8):820-825.	To compare the Ambu®aScope™ with a standard flexible intubating scope.	VB	Although the performance of the AmbuScope is acceptable, it does not meet the current quality of standard flexible intubation scopes.	Case report	Anesthetists with clinical experience in fiberoptic intubation	Use of AmbuScope	Reusable versus disposable	21	Successful intubation
9											

Guideline for Processing Flexible Endoscopes
Evidence Table

	A	C	D	E	F	I	J	K	L	M	N
	REFERENCE NUMBER	CITATION	PURPOSE	CONSENSUS SCORE	RESULTS AND CONCLUSIONS	EVIDENCE TYPE	POPULATION	INTERVENTIONS	COMPARISON	SAMPLE SIZE	OUTCOME MEASURE
1	9	Pujol E, Lopez AM, Valero R. Use of the Ambu® aScope in 10 patients with predicted difficult intubation. Anaesthesia. 2010;65(10):1037-1040.	To assess the use of the AmbuaScope in 10 patients with predicted difficult intubation.	VB	The procedure was easy and successful in nine patients. However, the limited time of use did not permit intubation in one patient. The limited image resolution that can be expected of a single-use system and the absence of a suction channel are other limitations.	Case report	Adult patients with predicted difficult intubation	Use of AmbuaScope	Reusable versus disposable	10	Successful intubation
10	10	Tvede MF, Kristensen MS, Nyhus-Andreasen M. A cost analysis of reusable and disposable flexible optical scopes for intubation. Acta Anaesthesiol Scand. 2012;56(5):577-584.	To provide a cost analysis of reusable and disposable flexible optical scopes for intubation.	VA	The total cost of an intubation is greater when using disposable compared with reusable equipment.	Organizational experience: financial	University Hospital	Cost analysis	Reusable versus disposable	30	Cost effectiveness
11	11	Guidelines for Design and Construction of Hospitals and Outpatient Facilities. Chicago, IL: Facility Guidelines Institute; 2014.	To provide guidelines for design and construction of hospitals and outpatient facilities.	IVC	This document comprises four parts: 1) considerations applicable to all hospitals and outpatient facilities, 2) facilities where inpatient care is provided, 3) facilities where outpatient care is provided, and 4) American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE) Standard 170-2013: Ventilation of Health Care Facilities.	Guideline	Individuals with an interest in guidelines for construction of hospitals and outpatient facilities.	N/A	N/A	N/A	N/A
12	12	ANSI/AAMI ST91:2015 Flexible and Semi-rigid Endoscope Processing in Health Care Facilities. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2015.	To provide guidelines for pre-cleaning, leak testing, cleaning, packaging (where indicated), storage, high-level disinfecting, and/or sterilizing of flexible gastrointestinal (endoscopes, flexible bronchoscopes, flexible ear, nose, and throat, surgical flexible endoscopes (eg, flexible endoscopes), and semi-rigid operative endoscopes (eg, choledochoscopes) in health care facilities.	IVC	This document addresses functional and physical design criteria for endoscope processing areas, education, training, and competency verification, and other personnel considerations, processing recommendations, installation, care, and maintenance of automated processing equipment, quality control, and quality process improvement.	Guideline	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
13	13	Health Service Executive Advisory Group. HSE Standards and Recommended Practices for Endoscope Reprocessing Units. Tipperary, Ireland: HSE; 2012.	To provide guidance for all relevant staff in the public health service who work in Central Decontamination Units, and other relevant staff with responsibility for decontamination of reusable invasive medical devices.	IVB	The Standards and Recommended Practices are a guide to the practices required in the decontamination of reusable invasive medical devices in Central Decontamination Units, based on current requirements and professional best practice.	Guideline	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
14	14	CLARIFICATION: requirements for an endoscopy equipment processing room. Jt Comm Perspect. 2012;32(3):13-14.	To clarify elements of performance for endoscopy equipment processing rooms.	VA	Clarification is provided regarding room configuration, layout, and ventilation.	Expert opinion	Health care facilities and others who reprocess endoscopes	N/A	N/A	N/A	N/A
15	15	Infection Control in Endoscopy. 3rd ed. Victoria, Australia: Gastroenterological Society of Australia and the Gastroenterological Nurses College of Australia; 2010.	To provide updated guidelines for prevention of infection in endoscopy.	IVB	The mantra of, "clean it, clean it, clean it" remains unchanged. Extending the duration that most endoscopes can be used after reprocessing to 72 hours is the most significant change, although this comes with a strong caveat that storage and testing requirements must be carefully followed.	Guideline	Endoscope users	N/A	N/A	N/A	N/A
16	16	Society of Gastroenterology Nurses and Associates. Standards of infection control in reprocessing of flexible gastrointestinal endoscopes. Gastroenterol Nurs. 2013;36(4):293-303.	To provide standards of infection control in reprocessing of flexible gastrointestinal endoscopes	IVB	Diligence in application of all steps of reprocessing remains paramount in the safe delivery of endoscopic services.	Guideline	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
17											

Guideline for Processing Flexible Endoscopes
Evidence Table

	A	C	D	E	F	I	J	K	L	M	N
	REFERENCE NUMBER	CITATION	PURPOSE	CONSENSUS SCORE	RESULTS AND CONCLUSIONS	EVIDENCE TYPE	POPULATION	INTERVENTIONS	COMPARISON	SAMPLE SIZE	OUTCOME MEASURE
1	17	Hookey L, Armstrong D, Enns R, Matlow A, Singh H, Love J. Summary of guidelines for infection prevention and control for flexible gastrointestinal endoscopy. <i>Can J Gastroenterol.</i> 2013;27(6):347-350.	To provide an executive summary of the Canadian guidelines for reprocessing flexible endoscopes and endoscopy equipment.	VA	The recommendations for infection prevention and control for flexible gastrointestinal endoscopy are intended for all individuals with responsibility for endoscopes in all settings where endoscopy is performed.	Case report	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
18	18	Du Rand IA, Blaikley J, Booton R, et al. British Thoracic Society guideline for diagnostic flexible bronchoscopy in adults. <i>Thorax.</i> 2013;68(Suppl 1):i1-i44.	To provide guidance for diagnostic flexible bronchoscopy in adults.	IVA	This guideline provides a detailed, evidence-based and practical overview of best practices.	Guideline	Health care providers and others with an interest in safe practices for bronchoscopy	N/A	N/A	N/A	N/A
19	19	World Gastroenterology Organisation/World Endoscopy Organization. Endoscopy Disinfection—A Resource-Sensitive Approach. World Endoscopy Organisation. http://www.worldendo.org/assets/downloads/pdf/guidelines/wgo_weo_endoscope_disinfection.pdf . Accessed December 9, 2015.	To provide global guidelines for processing flexible endoscopes.	IVC	There is evidence that disinfection techniques are less well adhered to in developing countries.	Guideline	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
20	20	Guidance on decontamination of equipment for gastrointestinal endoscopy. 2014. British Society of Gastroenterology. http://www.bsg.org.uk/clinical-guidance/general/guidelines-for-decontamination-of-equipment-for-gastrointestinal-endoscopy.html . Accessed December 9, 2015.	To provide guidance for decontamination of equipment for gastrointestinal endoscopy	IVA	In addition to an introduction and historical perspective, guidance is provided for preventing transmission of infection at endoscopy, decontamination of endoscopes, traceability, and other considerations. Also included is guidance for determining relevance of transmissible spongiform encephalopathies to endoscopic practice, disinfectants, endoscope washer disinfectors, drying and storage cabinets, special situations, and infection control.	Guideline	Health care providers and others using and processing flexible endoscopes	N/A	N/A	N/A	N/A
21	21	Professional Standard Handbook Cleaning and Disinfection Flexible Endoscopes. Version 3.1 ed. The Netherlands: Steering Group for Flexible Endoscope Cleaning and Disinfection; 2014.	To provide guidelines for cleaning and disinfection of flexible endoscopes.	IVB	The existing regulations for the cleaning and disinfection of flexible endoscopes is provided in addition to a verification and release procedure, and an audit and control system.	Guideline	Endoscope users	N/A	N/A	N/A	N/A
22	22	Beilenhoff U, Neumann CS, Rey JF, et al. ESGEESGENA Guideline: cleaning and disinfection in gastrointestinal endoscopy. <i>Endoscopy.</i> 2008;40(11):939-957.	To provide guidance for reprocessing of endoscopes and endoscope accessories used in gastrointestinal endoscopy.	IVC	The guideline focuses on flexible endoscopes and the accessories used in gastrointestinal endoscopy. It addresses important aspects of safety in endoscopy with emphasis on avoiding infection that may result from inadequate processing. It also provides technical protocols.	Guideline	Health care providers and others reprocessing gastrointestinal endoscopes	N/A	N/A	N/A	N/A
23	23	Formal Interpretations: Guidelines for Design and Construction of Hospitals and Outpatient Facilities, 2014. Facility Guidelines Institute. http://fgiguidelines.org/pdfs/FGI-interps_2014Guidelines_141222.pdf . Accessed December 9, 2015.	To provide explanatory information to those who use the guidelines.	VA	Clarification is provided relative to the sterile processing room.	Expert opinion	Health care providers and others with an interest in construction and design for endoscope processing	N/A	N/A	N/A	N/A
24											

Guideline for Processing Flexible Endoscopes
Evidence Table

	A	C	D	E	F	I	J	K	L	M	N
	REFERENCE NUMBER	CITATION	PURPOSE	CONSENSUS SCORE	RESULTS AND CONCLUSIONS	EVIDENCE TYPE	POPULATION	INTERVENTIONS	COMPARISON	SAMPLE SIZE	OUTCOME MEASURE
1	24	Choice Framework for local Policy and Procedures 01-06—Decontamination of flexible endoscopes: Policy and management. 2013. UK Department of Health. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/192522/Decontamination_of_flexible_endoscopes.pdf . Accessed December 9, 2015.	To provide a suite of evidence-based policy and guidance documents on the management and decontamination of reusable medical devices.	IVB	To discuss the principles and methods used in the test described and detailed.	Guideline	Health care providers and others processing flexible endoscopes	N/A	N/A	N/A	N/A
25	25	Choice Framework for local Policy and Procedures 01-06—Decontamination of flexible endoscopes: Design and installation. 2013. UK Department of Health. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/148560/CFPP_01-06_Design_and_installation_Final.pdf . Accessed December 9, 2015.	To provide a suite of evidence-based policy and guidance documents on the management and decontamination of reusable medical devices.	IVB	To provide guidance on the design and fitting of endoscope reprocessing units.	Guideline	Health care providers and others processing flexible endoscopes	N/A	N/A	N/A	N/A
26	26	Burlingame BL. Airflow in endoscope cleaning rooms [Clinical Issues]. AORN J. 2013;98(5):541-542.	To provide guidance for airflow in endoscopy cleaning rooms.	VA	The airflow in the decontamination room should be negative. If the design is a single room containing a decontamination area and a clean area separated by a barrier, the airflow direction can be neutral to the surrounding areas.	Expert opinion	Health care providers and others interested in safe practices for endoscope processing	N/A	N/A	N/A	N/A
27	27	Mehta AC, Prakash UBS, Garland R, et al. American College of Chest Physicians and American Association for Bronchoscopy Consensus Statement: Prevention of flexible bronchoscopy-associated infection. Chest. 2005;128(3):1742-1755.	To summarize data from the literature regarding the extent of infection related to bronchoscopy and principles related to maintenance and disinfection of endoscopes.	IVC	Review of the literature suggests that all episodes are preventable. Review of the literature also points out several flaws in current practices.	Clinical practice guideline	Health care personnel processing bronchoscopes	N/A	N/A	N/A	N/A
28	28	Hota S, Hirji Z, Stockton K, et al. Outbreak of multidrug-resistant <i>Pseudomonas aeruginosa</i> colonization and infection secondary to imperfect intensive care unit room design. Infect Control Hosp Epidemiol. 2009;30(1):25-33.	To describe an outbreak of multi-drug resistant <i>Pseudomonas aeruginosa</i> infection resulting from colonization of hand hygiene sink drains in a recently constructed tertiary care medical/surgical intensive care unit.	VB	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.	Case report	Health care providers and others with an interest in room design related to hospital sink placement	N/A	N/A	N/A	N/A
29	29	Siegel JD, Rhinehart E, Jackson M, Chiarello L; Healthcare Infection Control Practices Advisory Committee. 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings. Am J Infect Control. 2007;35(10 Suppl 2):S65-S164.	This document is intended for use by infection control staff, healthcare epidemiologists, healthcare administrators, nurses, other healthcare providers, and persons responsible for developing, implementing, and evaluating infection control programs for healthcare settings across the continuum of care.	IVA	This updated guideline responds to changes in healthcare delivery and addresses new concerns about transmission of infectious agents to patients and healthcare workers in the United States and infection control. The primary objective of the guideline is to improve the safety of the nation's healthcare delivery system by reducing the rates of healthcare-associated infections.	Guideline	Health care providers and others with an interest in preventing health care-associated infections	N/A	N/A	N/A	N/A
30	30	ASGE Ensuring Safety in the Gastrointestinal Endoscopy Unit Task Force; Calderwood AH, Chapman FJ, et al. Guidelines for safety in the gastrointestinal endoscopy unit. Gastrointest Endosc. 2014;79(3):363-372.	To provide guidelines for safety in the gastrointestinal endoscopy unit.	IVB	Safety in endoscopy units begins with clear and effective leadership that fosters a culture of safety including team work, open communication, and efforts to minimize adverse events. The document also provides a summary of key strategies to maintain safety in the endoscopy unit.	Guideline	Health care providers and others with an interest in endoscopy	N/A	N/A	N/A	N/A
31											

Guideline for Processing Flexible Endoscopes
Evidence Table

	A	C	D	E	F	I	J	K	L	M	N
	REFERENCE NUMBER	CITATION	PURPOSE	CONSENSUS SCORE	RESULTS AND CONCLUSIONS	EVIDENCE TYPE	POPULATION	INTERVENTIONS	COMPARISON	SAMPLE SIZE	OUTCOME MEASURE
1	31	Overview of health care HVAC systems. In: HVAC Design Manual for Hospitals and Clinics. 2nd ed. Atlanta, GA: American Society of Heating, Refrigerating and Air-Conditioning Engineers; 2013.	To provide guidance for individuals involved in the design, installation, and commissioning of HVAC systems for hospitals and clinics.	IVC	This text covers: environmental comfort, infection control, energy conservation, life safety, operation and maintenance, design strategies known to meet applicable standards and guidelines, disaster planning, temperature, humidity, air exchange, and pressure requirements for various types of rooms found in hospitals and clinics.	Guideline	Health care providers and others with an interest in parameters for HVAC systems in health care facilities	N/A	N/A	N/A	N/A
32	32	Guideline for a safe environment of care, part 2. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 2015:265-290.	This document provides guidance for the design of the building structure; movement of patients, personnel, supplies, and equipment through the suite; safety during construction; environmental controls (eg, heating, ventilation, air conditioning); maintenance of structural surfaces; power failure response planning; security; and control of noise and distractions.	IVA	The physical design and environment of the perioperative suite should support safe patient care, workplace safety, and security.	Guideline	Perioperative RNs	N/A	N/A	N/A	N/A
33	33	Table 7.1: Design parameters. In: ANSI/ASHRAE/ASHE 170-2013: Ventilation of Health Care Facilities. Atlanta, GA: American Society of Heating, Refrigerating and Air-Conditioning Engineers; 2013.	To define ventilation system design requirements that provide environmental control for comfort, asepsis, and odor in health care facilities.	IVC	The requirements in this standard apply to patient-care areas and related support areas within health care facilities, including hospitals, nursing facilities, and outpatient facilities. The standard considers chemical, physical, and biological contamination that can affect the delivery of medical care to patients; and the safety of patients, health care workers, and visitors.	Guideline	Health care providers and others with an interest in parameters for ventilation systems in health care facilities	N/A	N/A	N/A	N/A
34	34	Interpretation IC 170-2013-4 of ANSI/ASHRAE/ASHE Standard 170-2013 Ventilation of Health Care Facilities. Atlanta, GA: American Society of Heating, Refrigerating and Air-Conditioning Engineers; January 27, 2015.	To provide guidance for interpretation of pressure relationship for sterile processing areas.	IVC	The space may be treated as a sub-sterile service area, as indicated in Table 7-1.	Guideline	Health care providers and others with an interest in design of ventilation systems	N/A	N/A	N/A	N/A
35	35	Guideline for prevention of transmissible infections. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 2015:419-454.	This document provides guidance to perioperative RNs in implementing standard precautions and transmission-based precautions (ie, contact, droplet, airborne) to prevent infection in the perioperative practice setting. Additional guidance is provided for bloodborne pathogens; personal protective equipment; health care-associated infections and multidrug-resistant organisms; immunization; and activities of health care workers with infections, exudative lesions, and nonintact skin.	IVA	Protecting patients and health care practitioners from potentially infectious agent transmission continues to be a primary focus of perioperative registered nurses. The prevention and control of multidrug-resistant organisms requires that all health care organizations implement, evaluate, and adjust efforts to decrease the risk of transmission	Guideline	Health care providers and others with an interest in preventing transmissible infections	N/A	N/A	N/A	N/A
36	36	Tan HL, Lo PLC, Eng CTP. Bronchoscopy during SARS: perspectives from a non-SARS designated hospital. J Bronchol. 2006;13(4):223-225.	To discuss care of a SARS patient undergoing bronchoscopy.	VB	There is a need for respiratory protection when attending to patients with SARS.	Expert opinion	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
37											

Guideline for Processing Flexible Endoscopes
Evidence Table

	A	C	D	E	F	I	J	K	L	M	N
	REFERENCE NUMBER	CITATION	PURPOSE	CONSENSUS SCORE	RESULTS AND CONCLUSIONS	EVIDENCE TYPE	POPULATION	INTERVENTIONS	COMPARISON	SAMPLE SIZE	OUTCOME MEASURE
1	37	Occupational Safety and Health Act of 1970 (Public Law 91-596, December 29, 1970, as amended through January 1, 2004). Occupational Safety and Health Administration. https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=OSHACT&p_id=2743 . Accessed December 9, 2015.		Reg							
38	38	29 CFR 1910.1200: Hazard Communication. 2011. Occupational Safety and Health Administration. https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=standards&p_id=10099 . Accessed December 9, 2015.		Reg							
39	39	Industrial Ventilation: A Manual of Recommended Practice for Design. Cincinnati, OH: ACGIH; 2013.	To provide guidance for engineers and industrial hygienists to design and evaluate industrial ventilation systems.	IVC	These updated recommended practices address design aspects of industrial ventilation systems.	Guideline	Health care providers and others with an interest in design of ventilation systems	N/A	N/A	N/A	N/A
40	40	ANSI/AAMI ST58: Chemical Sterilization and Highlevel Disinfection in Health Care Facilities. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2013.	To provide guidelines for the selection and use of liquid chemical sterilants, high-level disinfectants, and gaseous chemical sterilizers that have been cleared for use in hospitals and other health care facilities.	IVC	The guidelines are intended to assist health care personnel in the safe and effective use of gaseous chemical sterilizing systems, liquid chemical sterilants, high-level disinfectants, and associated equipment.	Guideline	Health care providers and others using liquid chemical sterilants, high-level disinfectants, and gaseous chemical sterilizers in hospitals and health care facilities	N/A	N/A	N/A	N/A
41	41	ANSI/AAMI ST41: Ethylene Oxide Sterilization in Health Care Facilities: Safety and Effectiveness. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2012.	To provide guidelines for ethylene oxide sterilization processing in hospitals and other health care facilities.	IVC	The guidelines are intended to promote sterility assurance and to assist health care personnel in the use of processing equipment. The guidelines are also intended to help ensure the safe use of ethylene oxide by defining equipment and procedures, including ventilation recommendations and emission controls, to minimize personnel exposure to ethylene oxide or its residuals.	Guideline	Health care providers and others using ethylene oxide sterilization in hospitals and health care facilities	N/A	N/A	N/A	N/A
42	42	Guideline for a safe environment of care, part 1. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 2015:239-264.	This document provides guidance for providing a safe environment of care related to patients and perioperative personnel and the equipment used in the perioperative environment.	IVA	Guidance is provided on musculoskeletal injury, fire safety, electrical equipment, clinical and alert alarms, blanket- and solution-warming cabinets, medical gas cylinders, waste anesthesia gases, latex, chemicals including methyl methacrylate bone cement, and hazardous waste.	Guideline	Health care providers and others with an interest in providing a safe environment of care	N/A	N/A	N/A	N/A
43											

Guideline for Processing Flexible Endoscopes
Evidence Table

	A	C	D	E	F	I	J	K	L	M	N
	REFERENCE NUMBER	CITATION	PURPOSE	CONSENSUS SCORE	RESULTS AND CONCLUSIONS	EVIDENCE TYPE	POPULATION	INTERVENTIONS	COMPARISON	SAMPLE SIZE	OUTCOME MEASURE
1	43	Guideline for high-level disinfection. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 2015:601-614.	To provide guidance for achieving safe and effective high-level disinfection of reusable instruments and equipment.	IVB	High-level disinfection is a process that kills all microorganisms with the exception of high numbers of bacterial spores and prions. High-level disinfectants have the capability to inactivate the hepatitis B and C viruses, HIV, and <i>Mycobacterium tuberculosis</i> , but do not inactivate the virus-like prion that causes Creutzfeldt-Jakob disease. Government-registered high-level disinfection agents kill vegetative bacteria, tubercle bacilli, some spores and fungi, and lipid and nonlipid viruses, given appropriate concentration, submersion, and contact time.	Guideline	Perioperative RNs	N/A	N/A	N/A	N/A
44	44	ASGE Quality Assurance In Endoscopy Committee; Petersen BT, Chennat J, et al. Multisociety guideline on reprocessing flexible gastrointestinal endoscopes: 2011. Gastrointest Endosc. 2011;73(6):1075-1084.	To provide guidelines for reprocessing flexible gastrointestinal endoscopes.	IVA	Compliance with accepted guidelines for reprocessing endoscopes is critical to the safety and success of their use. When these guidelines are followed, pathogen transmission can be effectively prevented. Increased efforts and resources should be directed to improve compliance with these guidelines. Further research in the area of endoscope processing should be encouraged.	Guideline	Health care providers and others with an interest in endoscopy	N/A	N/A	N/A	N/A
45	45	Rutala WA, Weber DJ; the Healthcare Infection Control Practices Advisory Committee (HICPAC). Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. Atlanta, GA: Centers for Disease Control and Prevention; 2008.	To provide evidence-based recommendations on the preferred methods for cleaning, disinfection and sterilization of patient care medical devices and for cleaning and disinfecting the healthcare environment.	IVA	Disinfection and sterilization are essential for ensuring that medical and surgical instruments do not transmit infectious pathogens to patients. Because sterilization of all patient care items is not necessary, health care policies must identify, primarily on the basis of the items' intended use, whether cleaning, disinfection, or sterilization is indicated.	Guideline	Health care providers and others using and processing flexible endoscopes	N/A	N/A	N/A	N/A
46	46	SGNA Practice Committee 2013-14. Guideline for use of high-level disinfectants and sterilants for reprocessing flexible gastrointestinal endoscopes. Gastroenterol Nurs. 2015;38(1):70-80.	To provide information about the properties of the main ingredients of high-level disinfectants, their safe and effective use, and their compatibility with endoscopes	IVB	All high-level disinfectants and sterilants require adherence to published reprocessing protocols to maintain the integrity of the equipment, while providing the patient with endoscopic instruments that are safe and effective.	Guideline	Health care providers and others using high-level disinfection for endoscope reprocessing	N/A	N/A	N/A	N/A
47	47	ANSI/IESNA RP-29-06: Lighting for Hospitals and Health Care Facilities. RP-29-06 ed. New York, NY: Illuminating Engineering Society of North America; 2006.	To provide guidelines for good lighting, stimulate the producers of lighting equipment, and inspire the designers of lighting systems so that the sick and infirm will have a more comfortable and enjoyable recovery environment.	IVC	Engineers must continually seeks ways to introduce new technology developments and trends in a timely manner.	Guideline	Health care providers and others with an interest in providing lighting for health care facilities	N/A	N/A	N/A	N/A
48	48	29 CFR §1910.1030: Bloodborne Pathogens. Occupational Safety and Health Administration. http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051 . Accessed December 9, 2015.		Reg							
49											

Guideline for Processing Flexible Endoscopes
Evidence Table

	A	C	D	E	F	I	J	K	L	M	N
	REFERENCE NUMBER	CITATION	PURPOSE	CONSENSUS SCORE	RESULTS AND CONCLUSIONS	EVIDENCE TYPE	POPULATION	INTERVENTIONS	COMPARISON	SAMPLE SIZE	OUTCOME MEASURE
1	49	Silva CV, Magalhaes VD, Pereira CR, Kawagoe JY, Ikura C, Ganc AJ. Pseudo-outbreak of <i>Pseudomonas aeruginosa</i> and <i>Serratia marcescens</i> related to bronchoscopes. Infect Control Hosp Epidemiol. 2003;24(3):195-197.	To investigate an apparent outbreak involving simultaneous isolation of <i>Pseudomonas aeruginosa</i> and <i>Serratia marcescens</i> from bronchoalveolar lavage samples.	VC	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.	Case report	Patients undergoing bronchoscopy between December 1994 and October 1996 from whom <i>P aeruginosa</i> and <i>S marcescens</i> were isolated	Chart review/Patient examination/Microbiological sampling/DNA fingerprinting	Before and after implementing improved disinfection methods	41	Negative cultures
50	50	NFPA 99: Health Care Facilities Code Handbook. Quincy, MA: National Fire Protection Association; 2015.	To provide minimum requirements for the installation, inspection, testing, maintenance, performance, and safe practices for facilities, material, equipment, and appliances, including other hazards associated with the primary hazards.	IVC	The code applies to all health care facilities.	Guideline	Health care providers and others with an interest in design of health care facilities	N/A	N/A	N/A	N/A
51	51	ANSI/ISA S7.0.01-1996 Quality Standard InstrumentAir. Research Triangle Park, NC: Instrument Society of America; 1996.	To define standards for instrument air.	IVC	Instrument air is filtered to 0.01 micron, free of liquids and hydrocarbon vapors, and dry to a dew point of -40° F (-40° C).	Guideline	Health care providers and others with an interest in design of health care facilities	N/A	N/A	N/A	N/A
52	52	29 CFR 1910.151: Medical and First Aid. Occupational Safety and Health Administration. https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9806 . Accessed December 9, 2015.		Reg							
53	53	American National Standards Institute/International Safety Equipment Association. American National Standard for Emergency Eyewash and Shower Equipment. Arlington, VA: International Safety Equipment Association; 2009.	This standard is intended to provide uniform minimum requirements for the performance, use, installation, test procedures, maintenance and training of emergency eyewash and shower equipment.	IVC	This standard establishes minimum performance and use requirements for eyewash and shower equipment for the emergency treatment of the eyes or body of a person who has been exposed to hazardous materials. It covers the following types of equipment: emergency showers, eyewashes, eye/face washes, and combination units.	Guideline	Health care providers and others with an interest in requirements for eyewash stations	N/A	N/A	N/A	N/A
54	54	Guideline for hand hygiene. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 2015:31-42.	To provide guidance for hand hygiene for surgical and other invasive procedures.	IVB	The term "hand hygiene" is used to describe all measures related to hand condition and decontamination. Decontamination of hands can be done by one or more methods: hand washing using soap and water, antiseptic and water, or antiseptic hand rub if visible soil is not present, or surgical hand scrub using water-aided brushless surgical antiseptics, waterless brushless surgical antiseptics, or traditional surgical hand scrub using a sponge.	Guideline	Perioperative RNs	N/A	N/A	N/A	N/A
55	55	Aumeran C, Poincloux L, Souweine B, et al. Multidrug-resistant <i>Klebsiella pneumoniae</i> outbreak after endoscopic retrograde cholangiopancreatography. Endoscopy. 2010;42(11):895-899.	To report an outbreak of severe nosocomial infection following endoscopic retrograde cholangiopancreatography, due to CTX-M-15 extended-spectrum beta-lactamase <i>Klebsiella pneumoniae</i> .	VA	Regular audits should be incorporated to ensure rigorous application of cleaning, high-level disinfection, and drying steps are crucial to avoid infection	Case report	Health care providers and others with an interest in preventing endoscopy-associated infection	N/A	N/A	N/A	N/A
56											

Guideline for Processing Flexible Endoscopes
Evidence Table

	A	C	D	E	F	I	J	K	L	M	N
	REFERENCE NUMBER	CITATION	PURPOSE	CONSENSUS SCORE	RESULTS AND CONCLUSIONS	EVIDENCE TYPE	POPULATION	INTERVENTIONS	COMPARISON	SAMPLE SIZE	OUTCOME MEASURE
1	56	Guideline for environmental cleaning. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 2015:9-30.	To provide guidance for environmental cleaning and disinfection in the perioperative practice setting	IVA	The literature describes a high risk of pathogen transmission in the perioperative setting due to multiple contacts among patients, perioperative team members, and environmental surfaces. Thus, thorough cleaning and disinfection of perioperative areas is essential to preventing the spread of potentially pathogenic microorganisms. Because surfaces that health care providers touch frequently may present a high risk for pathogen transmission to patients, routine cleaning of high-touch objects is an effective approach to limiting transmission of pathogens when implemented as part of a comprehensive environmental cleaning and disinfection program.	Guideline	Perioperative RNs	N/A	N/A	N/A	N/A
57	57	Guideline for surgical attire. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 2015:97-120.	To provide guidance for surgical attire including scrub attire, shoes, jewelry, head coverings, and masks worn in the semirestricted and restricted areas of the perioperative practice setting. This document also provides guidance for personal items such as stethoscopes, backpacks, briefcases, cell phones, and tablets.	IVA	The human body and inanimate surfaces inherent in the surgical environment are major sources of microbial contamination and transmission. Surgical attire and personal protective equipment are worn to provide a high level of cleanliness and hygiene within the perioperative environment and to promote patient and worker safety. Reducing the patient's exposure to microorganisms that are shed from the skin and hair of perioperative personnel may reduce the patient's risk for surgical site infection. Patient safety is the primary consideration for perioperative personnel.	Guideline	Perioperative RNs	N/A	N/A	N/A	N/A
58	58	Guideline for cleaning and care of surgical instruments. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 2015:615-650.	To provide guidance for cleaning surgical instruments, including point-of-use cleaning, selecting cleaning chemicals, and determining water quality.	IVA	Guidance is also provided for decontaminating, transporting, inspecting, and care of surgical instruments. Processing of laryngoscope blades and handles and ophthalmic instruments.	Guideline	Perioperative RNs	N/A	N/A	N/A	N/A
59	59	29 CFR 1910.133: Eye and Face Protection. Occupational Safety and Health Administration. https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9778 . Accessed December 9, 2015.		Reg							
60	60	ASGE Technology Committee; Pedrosa MC, Farraye FA, et al. Minimizing occupational hazards in endoscopy: personal protective equipment, radiation safety, and ergonomics. <i>Gastrointest Endosc.</i> 2010;72(2):227-235.	To discuss the current technology for minimizing occupational hazards in endoscopy, including personal protective equipment, radiation safety, and ergonomics.	VB	Basic ergonomic principles should be incorporated into the practice of endoscopy in an attempt to minimize the risk of musculoskeletal injury	Case report	Health care providers and others with an interest in preventing endoscopy-associated infection	N/A	N/A	N/A	N/A
61	61	Kaye MD. Herpetic conjunctivitis as an unusual occupational hazard (endoscopists' eye). <i>Gastrointest Endosc.</i> 1974;21(2):69-70.	To report herpetic conjunctivitis as an occupational hazard of endoscopy.	VB	There was a forceful ejection of fluid from the biopsy port of the esophagoscope into the endoscopist's face.	Case report	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
62											

Guideline for Processing Flexible Endoscopes
Evidence Table

	A	C	D	E	F	I	J	K	L	M	N
	REFERENCE NUMBER	CITATION	PURPOSE	CONSENSUS SCORE	RESULTS AND CONCLUSIONS	EVIDENCE TYPE	POPULATION	INTERVENTIONS	COMPARISON	SAMPLE SIZE	OUTCOME MEASURE
1	62	Guideline for product selection. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 2015:179-186.	To provide guidance for evaluating and purchasing medical devices and other products used in perioperative settings	IVB	Patient and worker safety, quality, and cost containment are primary concerns of perioperative RNs as they participate in evaluating and selecting medical devices and products for use in practice settings	Guideline	Health care providers and others with an interest in product selection	N/A	N/A	N/A	N/A
63	63	21 CFR Chapter 1. Subchapter H: Medical Devices. 2015. US Food and Drug Administration. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=820 . Accessed December 9, 2015.		Reg							
64	64	Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff. Silver Spring, MD: US Food and Drug Administration; 2015.		Reg							
65	65	Rudy SF, Adams J, Waddington C. Implementing the SOHN-endorsed AORN guidelines for reprocessing reusable upper airway endoscopes. ORL Head Neck Nurs. 2012;30(1):6-15.	To capture the rich audience discussion following the Adams and Waddington presentation for otorhinolaryngology nurses.	VB	Otorhinolaryngology nurses should remain immersed in the literature on relevant topics and actively engage in quality assurance and quality improvement activities in order to keep patients safe.	Expert opinion	Health care providers and others processing endoscopes	N/A	N/A	N/A	N/A
66	66	Weber DJ. Managing and preventing exposure events from inappropriately reprocessed endoscopes. Infect Control Hosp Epidemiol. 2012;33(7):657-660.	To discuss managing and preventing exposure events from incorrectly processed endoscopes.	VA	Multiple studies in many countries have documented a lack of compliance with established guidelines for disinfection and sterilization.	Expert opinion	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
67	67	Statham MM, Willging JP. Automated high-level disinfection of nonchanneled fiberoptic flexible endoscopes exposed to continuous use and automated reprocessing in a clinical practice. Laryngoscope. 2010;120(10):1946-1949.	To examine the durability of nonchanneled fiberoptic flexible endoscopes exposed to continuous use and automated reprocessing in a clinical practice.	IIIB	Automated reprocessing is an effective means to disinfect and process flexible endoscopes. Limiting the number of personnel processing the scopes may help reduce damage. Smaller scopes demonstrate a shortened time interval between repairs than larger scopes.	Nonexperimental	Nonchanneled flexible endoscopes	Review of repair	Smaller scopes compared with larger scopes	60	Reduced repairs and costs
68	68	Hutson P. Staffing the endoscopy department: what is the appropriate skill mix? Gastrointest Nurs. 2011;9(1):28-33.	To discuss the number of personnel needed to adequately and safely staff endoscopy units.	VB	The potential for a cheaper but efficient workforce should not over shadow the need for a skilled and regulated workforce that is legally accountable, capable of clinical decision-making, and can provide a comprehensive service including the preparation and administration of drugs.	Expert opinion	Health care providers and others processing endoscopes and accessories and caring for endoscopy patients	N/A	N/A	N/A	N/A
69	69	Choice Framework for local Policy and Procedures 01-06—Decontamination of flexible endoscopes: Operational management. 2013. UK Department of Health. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/148559/CFPP_01-06_Operational_mgmt_Final.pdf . Accessed December 9, 2015.	To provide a suite of evidence-based policy and guidance documents on the management and decontamination of reusable medical devices.	IVB	To set the policy context and discuss essential quality requirements for an endoscope decontamination service.	Guideline	Health care providers and others processing flexible endoscopes	N/A	N/A	N/A	N/A
70	70	Kolmos HJ, Lerche A, Kristoffersen K, Rosdahl VT. Pseudo-outbreak of Pseudomonas aeruginosa in HIV-infected patients undergoing fiberoptic bronchoscopy. Scand J Infect Dis. 1994;26(6):653-657.	To describe a pseudo-outbreak of respiratory tract infection due to <i>Pseudomonas aeruginosa</i> that originated from inadequate cleansing of the suction channels of bronchoscopes before chemical disinfection.	VC	The presence of <i>P aeruginosa</i> in lavage fluids should never be discounted and should be investigated as it may indicate faulty disinfection of bronchoscopy equipment and point to a risk of transmission of respiratory pathogens.	Case report	Bronchoalveolar lavage fluid from patients undergoing bronchoscopy	Serotyping of isolates/Inspection of cleaning and disinfection processes/Microbiological sampling	N/A	8	Negative cultures
71											

Guideline for Processing Flexible Endoscopes
Evidence Table

	A	C	D	E	F	I	J	K	L	M	N
	REFERENCE NUMBER	CITATION	PURPOSE	CONSENSUS SCORE	RESULTS AND CONCLUSIONS	EVIDENCE TYPE	POPULATION	INTERVENTIONS	COMPARISON	SAMPLE SIZE	OUTCOME MEASURE
1	71	McGill JJ, Schaeffer AJ, Gonzalez CM. Durability of flexible cystoscopes in the outpatient setting. <i>Urology</i> . 2013;81(5):932-937.	To ascertain cystoscope durability in relation to usage and cost in the outpatient setting.	IIIB	Outpatient flexible cystoscope durability seems directly related to optimization of handling and storage of cystoscopes. Costs related to mechanical failure were reduced with a rigorous reprocessing protocol.	Nonexperimental	Flexible cystoscopes	Retrospective review of repair and maintenance costs/Prospective data on mechanical failure and maintenance costs	Retrospective data compared with prospective data	6	Usage/Costs
72	72	Sooriakumaran P, Kaba R, Andrews HO, Buchholz NP. Evaluation of the mechanisms of damage to flexible ureteroscopes and suggestions for ureteroscope preservation. <i>Asian J Androl</i> . 2005;7(4):433-438.	To elucidate the nature of damages to the instruments and propose measures to avoid these during operation and storage.	IIIB	Thorough adherence to handling procedures, and courses for theater staff and surgeons on handling flexible ureteroscopes may help to reduce damages and prove a cost-saving investment.	Nonexperimental	Flexible ureteroscopes sent for repair	Analysis of repair figures and causes	N/A	35	Reduced repairs and costs
73	73	Semins MJ, George S, Allaf ME, Matlaga BR. Ureteroscope cleaning and sterilization by the urology operating room team: The effect on repair costs. <i>Journal of Endourology</i> . 2009;23(6):903-905.	To define the effect of having the urology nursing staff process and sterilize all ureteroscopes, rather than the central processing staff, the total repair cost and cost per use were analyzed.	VB	Training the nursing staff to clean and sterilize ureteroscopes is a reasonable means to reduce processing-related damages.	Organizational experience: financial	Ureteroscopes	Prospective data collection and analysis	Before and after training the nursing staff to clean and sterilize the ureteroscopes	11	Reduced repairs and costs
74	74	McDougall EM, Alberts G, Deal KJ, Nagy JM, 3rd. Does the cleaning technique influence the durability of the <9F flexible ureteroscope?. <i>Journal of Endourology</i> . 2001;15(6):615-618.	To determine whether the technique used to clean the flexible ureteroscope or the number of persons handling the instrument during the cleaning process influenced endoscope breakage or deterioration during regular use.	IIC	The technique and number of personnel involved in the maintenance and cleaning of the flexible ureteroscope does not have a significant effect on the durability and function of these instruments. It is the arduous demands of the procedure that influences the durability of the fragile endoscopes.	Quasi-experimental	7.5 flexible ureteroscope	Cleaning by surgeon	Cleaning by standard method	2	Repairs required
75	75	Smith F. <i>Pseudomonas</i> infection. <i>Nurs Times</i> . 1994;90(46):55-56.	To discuss two cases in which the source of infection was traced to syringes used to rinse instruments after disinfection	VB	The <i>Pseudomonas aeruginosa</i> was introduced into the patient's biliary tract on endoscopy instruments, contaminated after disinfection by the syringes used in rinsing.	Case report	Patients developing septicemia detected by routine surveillance of hospital isolates by the infection control team	Review of reprocessing procedures	N/A	2	Negative cultures
76	76	Machida H, Seki M, Yoshioka N, et al. Correlation between outbreaks of multidrug-resistant <i>Pseudomonas aeruginosa</i> infection and use of bronchoscopes suggested by epidemiological analysis. <i>Biol Pharm Bull</i> . 2014;37(1):26-30.	To verify the primary hypothesis of a relationship between infections and bronchoscopes, to identify other potential risk factors for infection, and to implement infection control measures to terminate the outbreak.	IIIB	The outbreak was suspended by renewing the former process of disinfection of bronchoscopes and related devices.	Case control	Patients who developed multidrug-resistant <i>Pseudomonas aeruginosa</i> after bronchoscopy	Microbiological studies	Patients from whom non-multidrug-resistant <i>Pseudomonas aeruginosa</i> was isolated	5	Negative cultures
77	77	ANSI/AAMI ST79: Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2013.	To provide guidelines for decontamination and steam sterilization processing in hospitals and other health care facilities.	IVC	The guidelines are intended to promote sterility assurance and to assist health care personnel in the correct use of processing equipment.	Guideline	Health care providers and others decontaminating and sterilizing items in hospitals and health care facilities	N/A	N/A	N/A	N/A
78	78	Centers for Disease Control and Prevention. Immediate Need for Healthcare Facilities to Review Procedures for Cleaning, Disinfecting, and Sterilizing Reusable Medical Devices. Health Alert Network. September 11, 2015. http://stacks.cdc.gov/view/cdc/34153 . Accessed December 9, 2015.	The CDC and FDA are alerting healthcare providers and facilities about the public health need to properly maintain, clean, and disinfect or sterilize reusable medical devices.	VB	Healthcare facilities (e.g., hospitals, ambulatory surgical centers, clinics, and doctors' offices) that utilize reusable medical devices are urged to immediately review current reprocessing practices at their facility to ensure they are complying with all steps as directed by the device manufacturers, and have appropriate policies and procedures in place that are consistent with current standards and guidelines.	Expert opinion	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
79											

Guideline for Processing Flexible Endoscopes
Evidence Table

	A	C	D	E	F	I	J	K	L	M	N
	REFERENCE NUMBER	CITATION	PURPOSE	CONSENSUS SCORE	RESULTS AND CONCLUSIONS	EVIDENCE TYPE	POPULATION	INTERVENTIONS	COMPARISON	SAMPLE SIZE	OUTCOME MEASURE
1	79	Bou R, Aguiar A, Perpian J, et al. Nosocomial outbreak of <i>Pseudomonas aeruginosa</i> infections related to a flexible bronchoscope. <i>J Hosp Infect.</i> 2006;64(2):129-135.	An outbreak of <i>Pseudomonas aeruginosa</i> infections affecting 17 patients was detected in the 27-bed intensive care unit of a community hospital.	IIIB	Multivariate analysis identified recent bronchoscopy and exposure to an infected patient as independent risk factors. A combined infection control strategy was implemented including strict isolation precautions and recommendations for cleaning and disinfecting bronchoscopes.	Case control	Patients identified with <i>Pseudomonas aeruginosa</i> infection	DNA characterization/Environmental investigation/Statistical analysis/Observation	Improvements in cleaning, disinfection, and maintenance of the bronchoscope	17	N/A
80	80	Srinivasan A, Wolfenden LL, Song X, Perl TM, Haponik EF. Bronchoscope reprocessing and infection prevention and control: bronchoscopy-specific guidelines are needed. <i>Chest.</i> 2004;125(1):307-314.	To assess how familiar bronchoscopists are with national guidelines and their local reprocessing and surveillance procedures.	IIIB	Many experience bronchoscopists are unfamiliar with national guidelines and local practices related to bronchoscope reprocessing. Publication of these guidelines in the pulmonary literature may help increase familiarity with the process.	Qualitative	Bronchoscopists	Survey	Knowledge of national guidelines	46	Compliance with national guidelines
81	81	Radford PD, Unadkat SN, Rollin M, Tolley NS. Disinfection of flexible fibre-optic endoscopes out-of-hours: confidential telephone survey of ENT units in England—10 years on. <i>J Laryngol Otol.</i> 2013;127(5):489-493.	To audit out-of-hours flexible endoscope disinfection practices in England and compare with a previously published audit.	IIIC	An overall moderate improvement in the safety of out-of-hours endoscopy in the past 10 years cannot obscure the urgent need for universal compliance with national guidelines.	Qualitative	ENT units	Telephone survey	Compliance with national guidelines	72	Compliance with national guidelines
82	82	Roberts CG. The role of biofilms in reprocessing medical devices. <i>Am J Infect Control.</i> 2013;41(5 Suppl):S77-S80.	To discuss the role of biofilm in reprocessing medical devices	VA	Reusable devices that are promptly cleaned and disinfected, rinsed, and dried pose little risk to patients.	Expert opinion	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
83	83	Joint AUA/SUNA white paper on reprocessing of flexible cystoscopes. <i>J Urol.</i> 2010;184(6):2241-2245.	Presents a brief overview of the current guidelines for reprocessing of flexible endoscopes and highlights particular aspects of instrument reprocessing that are unique to cystoscopy.	VC	Guidelines are provided for personnel and training, Spaulding system, sterilization, disinfection, processing of flexible and rigid cystoscopes, safety considerations, disposable sheaths, and reuse of single-use items.	Guideline	Cystoscope users	N/A	N/A	N/A	N/A
84	84	Cavaliere M, Iemma M. Guidelines for reprocessing nonlumened heat-sensitive ear/nose/throat endoscopes. <i>Laryngoscope.</i> 2012;122(8):1708-1718.	To standardize the correct way to carry out the disinfection procedure of heat-sensitive, nonlumened ear, nose, and throat endoscopes and discuss existing guidelines and new products.	VB	Ear, nose, and throat endoscopes differ from gastroscopes or bronchoscopes in the absence of the operating channel, their smaller size and construction, and their more frequent use. As a result, the guidelines used in digestive and respiratory endoscopy are not always functional in ear, nose, and throat departments.	Literature review	Health care providers and others with an interest in endoscopy processing	N/A	N/A	N/A	N/A
85	85	Lind N, Ninemeier JD, Bird BT; International Association of Healthcare Central Service Materiel Management. <i>Central Service Technical Manual.</i> Chicago, IL: International Association of Healthcare Central Service Materiel Management; 2007.	To discuss important considerations for handling and processing flexible endoscopes.	IVC	Serious infections can occur, and expensive equipment damaged if the correct reprocessing protocols are not consistently utilized.	Expert opinion	Health care providers and others with an interest in sterile processing	N/A	N/A	N/A	N/A
86	86	Merritt K, Hitchens VM, Brown SA. Safety and cleaning of medical materials and devices. <i>J Biomed Mater Res.</i> 2000;53(2):131-136.	To evaluate different procedures to safely remove microorganisms, protein, and mammalian cells from materials and provide a suitable method for cleaning and assessing effectiveness of cleaning medical devices for reuse.	IIB	Medical devices contaminated with microorganisms, protein, or mammalian cells, should not be allowed to dry before cleaning. A thorough cleaning procedure should precede sterilization or disinfection.	Quasi-experimental	Cleaning agents	Attempted removal of biofilm	No removal	14	Residual biofilm
87	87	Herrmann IF, Heeg P, Matteja B, et al. Silent risks and hidden dangers in endoscopy: what to do? <i>Acta Endoscopica.</i> 2008;38(5):493-502.	To demonstrate that the indentations, irregularities, and bifurcation inside endoscopes are weak points, where fresh patient material remains.	IIIC	The use of 10,000 pixel optics to check the channel system and to control the surface should be a requirement in daily practice.	Nonexperimental	Reprocessed endoscopes	Microscopic examination of the endoscope tip and entrances to channels	N/A	Not specified	Absence of microbes
88											

Guideline for Processing Flexible Endoscopes
Evidence Table

	A	C	D	E	F	I	J	K	L	M	N
	REFERENCE NUMBER	CITATION	PURPOSE	CONSENSUS SCORE	RESULTS AND CONCLUSIONS	EVIDENCE TYPE	POPULATION	INTERVENTIONS	COMPARISON	SAMPLE SIZE	OUTCOME MEASURE
1	88	Alfa MJ. Medical-device reprocessing. Infect Control Hosp Epidemiol. 2000;21(8):496-498.	To discuss processing of medical devices.	VA	The cleaning stage is critical regardless of what sterilization method is used and research into what cleaning methods will facilitate optimal killing by low-temperature sterilization methods is urgently needed.	Expert opinion	Health care providers and others with an interest in best methods for processing flexible endoscopes	N/A	N/A	N/A	N/A
89	89	Muscarella LF. Prevention of disease transmission during flexible laryngoscopy. Am J Infect Control. 2007;35(8):536-544.	To evaluate the risk of disease transmission and nosocomial infection associated with flexible laryngoscopes.	VA	A formal set of step-by-step guidelines is provided. Use of a disposable sheath to cover and protect the flexible laryngoscope from contamination during clinical use is discussed.	Literature review	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
90	90	TIR 30: A Compendium of Processes, Materials, Test Methods, and Acceptance Criteria for Cleaning Reusable Medical Devices. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2011.	To provide information regarding test protocols, materials, test soils, and acceptance criteria that can be used by medical device manufacturers to validate cleaning processes for reusable medical devices.	IVC	This report covers the validation of cleaning processes for medical devices that are intended and labeled by the manufacturer for reprocessing and reuse, and certain implant accessories that are provided as parts of sets and that are intended and labeled by the manufacturer for reprocessing if not used during a procedure.	Guideline	Manufacturers of medical devices	N/A	N/A	N/A	N/A
91	91	Johansen C, Falholt P, Gram L. Enzymatic removal and disinfection of bacterial biofilms. Appl Environ Microbiol. 1997;63(9):3724-3728.	To assess the applicability of commercially available enzymes for removal of bacterial biofilm and for their bactericidal activity against cells in biofilm.	IIIC	The use of enzymes for removal of bacterial biofilm is limited.	Nonexperimental	Bacterial biofilms	Fluorescence microscopy/Conductance test	Enzymatic compared with non-enzymatic detergents	8	Enzyme activity/Colony forming units
92	92	Pajkos A, Vickery K, Cossart Y. Is biofilm accumulation on endoscope tubing a contributor to the failure of cleaning and decontamination? J Hosp Infect. 2004;58(3):224-229.	To determine if biofilm is present on endoscopes used in routine clinical practice.	IIC	The physical conditions prevailing during endoscope use are suitable for bacterial biofilm formation and this may be the underlying reason for reported failures of disinfection/sterilization.	Quasi-experimental	Endoscope tubings	Scanning electron microscopy	New tubings	25	Presence of biofilm
93	93	Kovaleva J, Peters FT, van der Mei HC, Degener JE. Transmission of infection by flexible gastrointestinal endoscopy and bronchoscopy. Clin Microbiol Rev. 2013;26(2):231-254.	To present an overview of the infections and cross-contaminations related to flexible gastrointestinal endoscopes and bronchoscopes and to illustrate the impact of biofilm on endoscope reprocessing and postendoscopic infection.	VA	Process control of the cleaning and disinfection procedure does not guarantee prevention of biofilm formation during endoscopy. Implementation of microbiological surveillance of endoscope reprocessing is appropriate to detect early colonization and biofilm formation in the endoscope and to prevent contamination and infection in patients after endoscopic procedures.	Literature review	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
94	94	Costerton JW, Stewart PS, Greenberg EP. Bacterial biofilms: a common cause of persistent infections. Science. 1999;284(5418):1318-1322.	Formation of biofilm communities and their inherent resistance to antimicrobial agents are at the root of many persistent and chronic bacterial infections.	VB	Recent advances point to therapeutic agents that may provide a means for the control of biofilm infections.	Expert opinion	Health care providers and others interested in preventing endoscopy-associated infection	N/A	N/A	N/A	N/A
95	95	Ren W, Sheng X, Huang X, Zhi F, Cai W. Evaluation of detergents and contact time on biofilm removal from flexible endoscopes. Am J Infect Control. 2013;41(9):e89-e92.	To evaluate the effects of various detergents and different contact times on the removal of biofilm on flexible endoscopes based on an artificial biofilm model.	IB	Significantly more biofilm bacteria and biofilms were found in the enzymatic detergent groups compared with the nonenzymatic detergent group, whereas no significant difference was observed among the 3, 5, and 7 minute groups.	Randomized controlled trial	Teflon tubes designed to represent the inner surface of endoscopes	Exposure to cleaning solutions	Enzymatic compared with nonenzymatic detergents	60	Reduction in biofilm
96	96	Ren-Pei W, Hui-Jun X, Ke Q, Dong W, Xing N, Zhao-Shen L. Correlation between the growth of bacterial biofilm in flexible endoscopes and endoscope reprocessing methods. Am J Infect Control. 2014;42(11):1203-1206.	To investigate bacterial biofilm formed on endoscopes and to explore the possible correlation between endoscope reprocessing procedures and bacterial biofilm growth on endoscope channels.	IIIB	The formation of endoscopic biofilm may be related to reuse of detergent, manual cleaning, and incomplete drying.	Nonexperimental/Qualitative	Endoscope suction and biopsy channels	Scanning electron microscopy/Survey	Scopes with and without biofilm	66+13	Practices associated with increase d biofilm
97	97										

	A	C	D	E	F	I	J	K	L	M	N
	REFERENCE NUMBER	CITATION	PURPOSE	CONSENSUS SCORE	RESULTS AND CONCLUSIONS	EVIDENCE TYPE	POPULATION	INTERVENTIONS	COMPARISON	SAMPLE SIZE	OUTCOME MEASURE
1	97	Naas T, Cuzon G, Babics A, et al. Endoscopy-associated transmission of carbapenem-resistant <i>Klebsiella pneumoniae</i> producing Kpc-2 beta-lactamase. <i>J Antimicrob Chemother.</i> 2010;65(6):1305-1306.	To report an outbreak of carbapenem-resistant <i>Klebsiella pneumoniae</i> producing Kpc-2 B-lactamase in France, with regional inter-hospital dissemination mediated by a contaminated duodenoscope.	VB	The pre-wash of the endoscope was delayed 24 hours, resulting in drying of the device, after the peracetic wash, the drying procedure was not long enough, and the endoscope was not sufficiently dried.	Case report	Health care providers and others with an interest in preventing endoscopy-related infection	Screening of patients for multidrug-resistant bacteria/Antibiogram/Retrospective analysis of patients that had gastroscopy with the same endoscope	N/A	N/A	N/A
98	98	Hutchisson B, LeBlanc C. The truth and consequences of enzymatic detergents. <i>Gastroenterol Nurs.</i> 2005;28(5):372-376.	To report the results of two experiments designed to look at types of enzymatic detergents and the effect of cleaning conditions on the amount of orthophalaldehyde and the presence of stainable proteinaceous material recovered after high-level disinfection of colonoscopes.	II B	These findings emphasize the importance of diluting and using enzymatic detergents exactly as directed by the manufacturer to reduce bioburden and residual amounts of high-level disinfectant on flexible endoscopes.	Quasi-experimental	Endoscope segments/Colonoscopes	Manual cleaning under varying conditions	Cleaning conditions	5-Dec	OPA residuals
99	99	Alfa MJ. Can biofilm prevent high level disinfection? <i>J GENCA.</i> 2006;16(1):23-24.	To discuss whether biofilm forms inside channels of flexible endoscopes, and if so, whether organisms within the biofilm can survive HLD.	VA	Ensure cleaning is optimal as any residual debris contributes organic material that can be used by microbes to facilitate replication and protect them from high-level disinfection. Do not soak scopes in enzymatic cleaner overnight. Store endoscopes dry. Glutaraldehyde is not effective if build-up or traditional biofilm is allowed to form.	Expert opinion	Health care providers and others with an interest in processing flexible endoscopes	N/A	N/A	N/A	N/A
100	100	Shimono N, Takuma T, Tsuchimochi N, et al. An outbreak of <i>Pseudomonas aeruginosa</i> infections following thoracic surgeries occurring via the contamination of bronchoscopes and an automatic endoscope reprocessor. <i>J Infect Chemother.</i> 2008;14(6):418-423.	To report an outbreak of <i>Pseudomonas aeruginosa</i> infections following thoracic surgeries occurring via the contamination of bronchoscopes and an automatic endoscope reprocessor.	VB	The outbreak had two causes, a flaw in the automatic endoscope reprocessor, and inappropriate disinfection measures.	Case report	Patients undergoing thoracic surgeries with <i>P aeruginosa</i> strains in sputum	Chart review/Patient examination/Microbiological sampling/DNA fingerprinting	N/A	7	Negative cultures
101	101	Bultitude MF, Dasgupta P, Tiptaft RC, Glass JM. Prolonging the life of the flexible ureterorenoscope. <i>Int J Clin Pract.</i> 2004;58(8):756-757.	To analyze data for the number of procedures and repairs required for each new ureteroscope purchased.	VB	Precautions taken during use and storage help to maximize the lifespan of the ureteroscope.	Clinician experience	Health care providers and others using ureteroscopes	Analysis of number of procedures and repairs for each new ureteroscope	N/A	N/A	N/A
102	102	Thomas LA. Transporting the endoscope. <i>Gastroenterol Nurs.</i> 2005;28(2):145-146.	To provide guidance for transporting the endoscope.	VB	Three areas of attention are required: the location of the scope's metal components, configuration of the soft tubing, and support for the heavy parts.	Expert opinion	Health care providers and others processing flexible endoscopes	N/A	N/A	N/A	N/A
103	103	Collins JW, Keeley FX Jr, Timoney A. Cost analysis of flexible ureterorenoscopy. <i>BJU Int.</i> 2004;93(7):1023-1026.	To determine the indications for flexible ureterorenoscopy, use of laser probes, disposable instrumentation, and the cost and timing of ureteroscope repair.	IIIC	The costs of ancillary equipment exceeded the purchase and maintenance of the ureteroscope. The ureteroscope was repaired after the 29th and 88th cases. The advent of more durable ureteroscopes may reduce the frequency of costly repairs.	Nonexperimental	Ureteroscope/Ureteroscopic procedures	Prospective data collection and analysis	N/A	1 scope/100 procedures	Rate and cost of repair
104	104	Alfa MJ, Howie R. Modeling microbial survival in buildup biofilm for complex medical devices. <i>BMC Infect Dis.</i> 2009;9:56.	To investigate whether buildup biofilm represents a greater challenge to disinfectant efficacy and microbial eradication than traditional biofilm, which forms when a surface is constantly bathed in fluid.	II B	A wide range of microorganisms does occur in buildup biofilm and is most pronounced when a cross-linking disinfectant such as glutaraldehyde is used compared to accelerated hydrogen peroxide, an oxidizing agent. The data suggest that the assurance of high level disinfection may decrease if buildup biofilm develops within the channels.	Quasi-experimental	Buildup biofilm/Traditional biofilm	Repeated cycles of drying, disinfectant exposure, and re-exposure to the test organisms	Glutaraldehyde compared with accelerated hydrogen peroxide	96	Colony forming units
105											

Guideline for Processing Flexible Endoscopes
Evidence Table

	A	C	D	E	F	I	J	K	L	M	N
	REFERENCE NUMBER	CITATION	PURPOSE	CONSENSUS SCORE	RESULTS AND CONCLUSIONS	EVIDENCE TYPE	POPULATION	INTERVENTIONS	COMPARISON	SAMPLE SIZE	OUTCOME MEASURE
1	105	Yanaihara H, Hamasuna R, Takahashi S, et al. Current controversial issues in the decontamination process for urological endoscopes. <i>Int J Urol.</i> 2012;19(1):5-6.	To describe some controversial issues relative to the decontamination process for urological endoscope reprocessing.	VB	Current guidelines are based on gastrointestinal guidelines and lack the evidence of urological societies.	Expert opinion	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
106	106	Endoscope inspections fraught with challenges. <i>Healthc Purchasing News.</i> 2013;37(11):16-18.	To discuss important considerations for inspecting flexible endoscopes.	VB	The author provides suggestions to help processing personnel accurately evaluate flexible and rigid endoscopes before they are put into storage.	Expert opinion	Health care providers and others using and processing flexible endoscopes	N/A	N/A	N/A	N/A
107	107	Thomas LA. Essentials for endoscopic equipment. Leak testing. <i>Gastroenterol Nurs.</i> 2005;28(5):430-432.	To provide guidance for leak testing.	VB	Failure to leak test after every procedure greatly increases repair costs and decreases efficiency.	Expert opinion	Health care providers and others processing flexible endoscopes	N/A	N/A	N/A	N/A
108	108	Khan F, Mukhtar S, Marsh H, et al. Evaluation of the pressure leak test in increasing the lifespan of flexible ureteroscopes. <i>Int J Clin Pract.</i> 2013;67(10):1040-1043.	To examine the outcome of the pressure leak test on the condition of flexible ureteroscopes after every use and analyzing the damage and costs of maintenance.	IIIB	Pressure leak testing following flexible ureterorenoscopy helped to significantly control costs of maintenance and repair.	Quasi-experimental	Ureteroscopes	Leak testing after every procedure	Not leak testing	193	Damage and cost of repairs
109	109	Ramsey AH, Oemig TV, Davis JP, Massey JP, Torok TJ. An outbreak of bronchoscopy-related <i>Mycobacterium tuberculosis</i> infections due to lack of bronchoscope leak testing. <i>Chest.</i> 2002;121(3):976-981.	To describe an outbreak in which <i>Mycobacterium tuberculosis</i> was transmitted from a patient with active tuberculosis to at least two more patients via a contaminated bronchoscope.	VC	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.	Case control	Patients with an <i>M tuberculosis</i> positive culture from specimens obtained during bronchoscopy	Review of records/Observation of processing/Microbiological sampling/DNA fingerprinting	N/A	10	Negative cultures from bronchial washings
110	110	Cetre JC, Nicolle MC, Salord H, et al. Outbreaks of contaminated broncho-alveolar lavage related to intrinsically defective bronchoscopes. <i>J Hosp Infect.</i> 2005;61(1):39-45.	To summarize three consecutive outbreaks of broncho-alveolar lavage contamination related to a design defect in two bronchoscopes.	IIIB	No further cases occurred after removal of the implicated bronchoscopes. No deficiencies in disinfection procedures were detected and the source of contamination was found to be a loose port of the biopsy channel of the bronchoscope. The findings underscore the urgent need to test bronchoscopic samples regularly and to improve the design and structure of the scopes.	Case control	Patients undergoing bronchoscopic examination	Review of specimens connected to the outbreak/Detection of new patients with contaminated broncho-alveolar lavage specimens/Review of disinfection procedures	N/A	111	Contamination results of broncho-alveolar lavage samples
111	111	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. <i>Ann Otol Rhinol Laryngol.</i> 2010;119(3):150-154.	To detail the clinical course of two patients who suffered acute glutaraldehyde exposure during office injection procedures.	VB	Glutaraldehyde was retained in the endoscope because of a damaged channel.	Case report	Health care providers and others processing flexible endoscopes	Record review	N/A	2	Recovery from injury
112	112	Chu NS, Favero M. The microbial flora of the gastrointestinal tract and the cleaning of flexible endoscopes. <i>Gastrointest Endosc Clin N Am.</i> 2000;10(2):233-244.	To discuss the challenges of cleaning flexible endoscopes after exposure to microbial contamination.	VA	All of the evidence gathered to date has shown that endoscope cleaning controls the success of the processing procedure.	Expert opinion	Health care providers and others with an interest in endoscope processing	N/A	N/A	N/A	N/A
113	113	Chu NS, McAlister D, Antonoplos PA. Natural bioburden levels detected on flexible gastrointestinal endoscopes after clinical use and manual cleaning. <i>Gastrointest Endosc.</i> 1998;48(2):137-142.	To determine levels of bioburden of colonoscope insertion tube surfaces and suction channels after use and after manual cleaning	IC	After cleaning of in-use colonoscopes, fewer than 10 ⁶ vegetative bacteria could be recovered. Microflora from the colonoscopes indicated that the cleaning process introduced waterborne and enteric microorganisms, which highlights the importance of sanitation in the device processing area.	Randomized controlled trial	Colonoscopes	Measuring contamination levels	After use and after manual cleaning	20	Log reduction of colony forming units
114											

Guideline for Processing Flexible Endoscopes
Evidence Table

	A	C	D	E	F	I	J	K	L	M	N
	REFERENCE NUMBER	CITATION	PURPOSE	CONSENSUS SCORE	RESULTS AND CONCLUSIONS	EVIDENCE TYPE	POPULATION	INTERVENTIONS	COMPARISON	SAMPLE SIZE	OUTCOME MEASURE
1	114	Kampf G, Fliss PM, Martiny H. Is peracetic acid suitable for the cleaning step of reprocessing flexible endoscopes? World J Gastrointest Endosc. 2014;6(9):390-406.	To review the evidence and clarify the suitability of peracetic acid-based formulations for cleaning flexible endoscopes.	VA	Based on the review, peracetic acid-based formulations should not be used for cleaning flexible endoscopes	Literature review	Health care providers and others reprocessing endoscopes	N/A	N/A	N/A	N/A
115	115	Alfa MJ, Sitter DL. In-hospital evaluation of orthophthalaldehyde as a high level disinfectant for flexible endoscopes. J Hosp Infect. 1994;26(1):15-26.	To determine if a high-level disinfectant is an effective disinfectant for bronchoscopes, colonoscopes, and gastroscopes.	IIB	Othophthalaldehyde is an effective high-level disinfectant for flexible endoscopes.	Quasi-experimental	Bronchoscopes/Colonoscopes/Gastroscopes	Sampling	After use compared with after disinfection	100	Colony forming units
116	116	Weber DJ, Rutala WA. Lessons from outbreaks associated with bronchoscopy. Infect Control Hosp Epidemiol. 2001;22(7):403-408.	To discuss lessons learned from outbreaks associated with endoscopy.	VA	Nosocomial outbreaks have not been reported when recommendations were followed scrupulously.	Literature review	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
117	117	Spaulding EH, Lawrence CA, Block SS, Reddish GF. Chemical disinfection of medical and surgical materials. In: Lawrence CA, Block SS, Reddish GF, eds. Disinfection, Sterilization, and Preservation. Philadelphia, PA: Lea & Febiger; 1968:517-531.	To discuss chemical disinfection of medical and surgical materials.	VA	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. Noncritical items should be clean or low-level disinfected.	Expert opinion	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
118	118	Bajolek 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.	To report an outbreak of multidrug-resistant Pseudomonas aeruginosa related to a contaminated gastroscope.	VA	Observations of endoscope processing identified deviations from correct processes	Case report	Health care providers and others with an interest in preventing endoscopy-associated infection	N/A	N/A	N/A	N/A
119	119	Technical Information Report 34: Water for the Reprocessing of Medical Devices. Atlanta, GA: Association for the Advancement of Medical Instrumentation; 2014.	To address the selection and maintenance of effective water quality suitable for reprocessing medical devices.	IVC	Guidance is provided for selecting the water quality necessary for the reprocessing categories of medical devices, water treatment equipment, water distribution and storage, strategies for bacterial control, and environmental and personnel considerations.	Guideline	Manufacturers of medical devices	N/A	N/A	N/A	N/A
120	120	Alfa MJ. Methodology of reprocessing reusable accessories. Gastrointest Endosc Clin N Am. 2000;10(2):361-378.	To discuss the methodology of reprocessing reusable endoscope accessories.	VA	Emphasis should be placed on education of personnel performing processing of reusable devices for endoscopic procedures and a quality assurance program.	Expert opinion	Health care providers and others with an interest in cleaning flexible endoscopes	N/A	N/A	N/A	N/A
121	121	Alfa MJ, Jackson M. A new hydrogen peroxidebased medical-device detergent with germicidal properties: comparison with enzymatic cleaners. Am J Infect Control. 2001;29(3):168-177.	To evaluate the efficacy of the cleaning and bacterial killing ability of a new non-enzyme-based formulation compared with commercially available enzymatic detergents.	IIB	The detergent killing solution has microbial-killing ability in 3 minutes exposure at room temperature and cleans as well as the existing enzymatic detergents that were tested.	Quasi-experimental	Test carriers	Inoculation with test soils	Killing detergent solutions compared with enzymatic detergents	120	Log reduction of colony forming units
122	122	Rey JF, Kruse A, Neumann C; ESGE (European Society of Gastrointestinal Endoscopy); ESGENA (European Society of Gastrointestinal Endoscopy Nurses and Associates). ESGE/ESGENA technical note on cleaning and disinfection. Endoscopy. 2003;35(10):869-877.	To provide clarity on the topic of cleaning and disinfection.	VB	Cleaning is the most critical step in the cleaning and disinfection process.	Expert opinion	Health care providers and others processing flexible endoscopes	N/A	N/A	N/A	N/A

Guideline for Processing Flexible Endoscopes
Evidence Table

	A	C	D	E	F	I	J	K	L	M	N
	REFERENCE NUMBER	CITATION	PURPOSE	CONSENSUS SCORE	RESULTS AND CONCLUSIONS	EVIDENCE TYPE	POPULATION	INTERVENTIONS	COMPARISON	SAMPLE SIZE	OUTCOME MEASURE
1	123	Henoun Loukili N, Zink E, Grandadam S, Bientz M, Meunier O. Effectiveness of detergent-disinfecting agents on <i>Escherichia coli</i> 54127 biofilm. <i>J Hosp Infect.</i> 2004;57(2):175-178.	To test detergent activity using a prepared biofilm.	IIC	The view that enzymatic cleaners are more effective than non-enzymatic cleaners should be regarded with caution.	Quasi-experimental	Enzymatic and non-enzymatic detergents	Exposure to <i>Escherichia coli</i> biofilm	Enzymatic compared with non-enzymatic detergents	15	Colony forming units
124	124	Fang Y, Shen Z, Li L, et al. A study of the efficacy of bacterial biofilm cleanup for gastrointestinal endoscopes. <i>World J Gastroenterol.</i> 2010;16(8):1019-1024.	To compare the influence and clearance effect of enzymatic and non-enzymatic detergents against <i>Escherichia coli</i> biofilm on the inner surface of gastroscopes.	IB	Non-enzymatic detergent has a better inhibition effect on biofilm formation at room temperature. High speed pre-lavage and detergents are very important in temporal formed biofilm elimination.	Randomized controlled trial	Teflon tubes designed to represent the inner surface of endoscopes	Inoculation with <i>Escherichia coli</i>	Enzymatic compared with non-enzymatic detergents	15	Log reduction of colony forming units
125	125	Vickery K, Pajkos A, Cossart Y. Removal of biofilm from endoscopes: evaluation of detergent efficiency. <i>Am J Infect Control.</i> 2004;32(3):170-176.	To compare the efficacy of detergents used for endoscope reprocessing.	IIB	The only cleaner containing no enzymes significantly reduced bacterial viability and residual bacterial biofilm.	Quasi-experimental	Enzymatic and non-enzymatic detergents	Washing biofilm tubing/Scanning electron microscopy	Enzymatic compared with non-enzymatic detergents	5	Reduction in biofilm
126	126	Sava A. Biofilm digestion: more confusion than answers. <i>Am J Infect Control.</i> 2005;33(10):614.	To address concerns in the Vickery study #2986	VB	Certain steps in the study methodology may be in question and need clarification.	Expert opinion	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
127	127	Marion K, Freney J, James G, Bergeron E, Renaud FN, Costerton JW. Using an efficient biofilm detaching agent: an essential step for the improvement of endoscope reprocessing protocols. <i>J Hosp Infect.</i> 2006;64(2):136-142.	To compare new anti-biofilm combinations of detachment promoting agents with a cleaning product currently in use.	IIB	The anti-biofilm products prevented buildup of biofilm and removed a mature biofilm, whereas protocols based on detergent-disinfectants containing quaternary ammonium compounds showed low efficacy as these protocols and products fixed the biofilm on the endoscope surfaces.	Quasi-experimental	Teflon® tubes designed to represent the inner surface of endoscopes	Biofilm inoculation	Various cleaning products	5	Presence of biofilm
128	128	Perret-Vivancos C, Marion K, Renaud FN, Freney J. Efficient removal of attached biofilm in a naturally contaminated colonoscope using detachment-promoting agents. <i>J Hosp Infect.</i> 2008;68(3):277-278.	To report a procedure during which a highly contaminated colonoscope was effectively treated using an anti-biofilm procedure.	VB	The procedure consists of the sequential action of two detachment-promoting products: a multienzymatic solution that digests the anchorage points of the microorganisms to the support, and an enriched detergent solution that detaches the biomass from the support.	Case report	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
129	129	Thomas LA. Essentials for endoscopic equipment. Manual cleaning. <i>Gastroenterol Nurs.</i> 2005;28(6):512-513.	To provide guidance for manual cleaning of flexible endoscopes.	VB	The cleaning process has three components that should be present: brushes, chemicals, and friction.	Expert opinion	Health care providers and others processing flexible endoscopes	N/A	N/A	N/A	N/A
130	130	Herve R, Keevil CW. Current limitations about the cleaning of luminal endoscopes. <i>J Hosp Infect.</i> 2013;83(1):22-29.	To evaluate potential protein deposition and removal in the channels of flexible endoscopes during a simple contamination/cleaning cycle.	IIC	Limited action of current decontamination procedures and the lack of applicable quality control methods to assess the cleanliness of channels between patients and contribute to increasing the risk of cross-infection of potentially harmful microorganisms and molecules during endoscopy procedures.	Quasi-experimental	Endoscopy forceps/Biopsy channels	Inoculation of test soil into lumens/Examination of contamination of biopsy forceps	After washing/After use	Not specified	Level of contamination
131	131	Alfa MJ, Olson N, Degagne P, Jackson M. A survey of reprocessing methods, residual viable bioburden, and soil levels in patient-ready endoscopic retrograde cholangiopancreatography duodenoscopes used in Canadian centers. <i>Infect Control Hosp Epidemiol.</i> 2002;23(4):198-206.	To obtain information about current processing practices and to obtain samples from the biopsy channel to quantitate soil levels and bioburden in patient-ready flexible duodenoscopes used for endoscopic retrograde cholangiopancreatography.	IIIA	Cleaning was generally well done. Areas for improvement included ensuring the availability of written processing protocols, immersion of scopes during manual cleaning, use of adequate fluid for rinsing, adequate drying of scopes prior to storage, and the separation of valves from scopes during storage.	Qualitative/Nonexperimental	Canadian centers using duodenoscopes for endoscopic retrograde cholangiopancreatography	Survey/Sampling from biopsy channels	Compliance with national guidelines/Mock Samples/Levels of protein, carbohydrate, endotoxin	37/119	N/A
132											

Guideline for Processing Flexible Endoscopes
Evidence Table

	A	C	D	E	F	I	J	K	L	M	N
	REFERENCE NUMBER	CITATION	PURPOSE	CONSENSUS SCORE	RESULTS AND CONCLUSIONS	EVIDENCE TYPE	POPULATION	INTERVENTIONS	COMPARISON	SAMPLE SIZE	OUTCOME MEASURE
1	132	Pineau L, De Philippe E. Evaluation of endoscope cleanliness after reprocessing: a clinical-use study. Zentralsterilisation. 2013;21(1):15-27.	To evaluate endoscope cleanliness after clinical use in terms of bacteria, protein, and total organic carbon loads at four stages in the reprocessing process, and to assess the validity of the benchmarks of cleanliness used to validate automatic cleaning claims.	IIIB	Total organic carbon appears to be a more sensitive and reliable measure than total protein to accurately measure cleanliness levels.	Nonexperimental	Endoscopes from four different hospitals in France	Microbiological sampling/Protein assays/Carbon testing	Levels at four stages of reprocessing	206	Below levels determined by Alfa et al
133	133	Dietze B, Kircheis U, Schwarz I, Martiny H. Freely accessible endoscope channels improve efficacy of cleaning. Endoscopy. 2001;33(6):523-528.	To investigate the influence of the design of medical devices on the efficacy of manual cleaning of endoscope channels.	IIIB	Contamination may remain in channels that are only flushed and not brushed. The design of the device has an important influence on the reprocessing of flexible endoscopes.	Quasi-experimental	Duodenoscopes/Gastroscopes	Microbiological sampling	Flushed versus unflushed channels	4	Log reduction of colony forming units
134	134	Ishino Y, Ido K, Koiwai H, Sugano K. Pitfalls in endoscope reprocessing: brushing of air and water channels is mandatory for high-level disinfection. Gastrointest Endosc. 2001;53(2):165-168.	To examine the air and water channels to clarify whether they need cleaning.	IIIB	The air and water channels can become contaminated. Brushing every channel is mandatory for high-level disinfection. A redesign of the fundamental structure of endoscopes is proposed.	Quasi-experimental	Endoscopes	Quantifying residual protein/Microbiological sampling	Brushed channels versus unbrushed channels	42	Residual protein/Positive cultures
135	135	Agerton T, Valway S, Gore B, et al. Transmission of a highly drug-resistant strain (strain W1) of Mycobacterium tuberculosis. Community outbreak and nosocomial transmission via a contaminated bronchoscope. JAMA. 1997;278(13):1073-1077.	To assess transmission of multidrug-resistant tuberculosis.	VA	Inadequate cleaning and disinfection can lead to iatrogenic transmission	Case report	Bronchoscope users	N/A	N/A	N/A	
136	136	Alrabaa SF, Nguyen P, Sanderson R, et al. Early identification and control of carbapenemase-producing Klebsiella pneumoniae, originating from contaminated endoscopic equipment. Am J Infect Control. 2013;41(6):562-564.	To report transmission of <i>Klebsiella</i> -producing carbapenemase by contaminated endoscopic instruments.	VA	Quick identification of source, personnel education, contact precautions, and emphasis on hand and environmental hygiene led to case control and prevention of outbreak.	Case report	Endoscope users	Identification of source, education, contact precautions, and hand and environmental hygiene	N/A	N/A	N/A
137	137	Wendorf KA, Kay M, Baliga C, et al. Endoscopic retrograde cholangiopancreatography-associated AmpC <i>Escherichia coli</i> outbreak. Infect Control Hosp Epidemiol. 2015;36(6):634-642.	To determine the extent and epidemiologic characteristics of the outbreak, identify potential sources of transmission, design and implement infection control measures, and determine the association between the CR <i>Escherichia coli</i> and AmpC <i>E coli</i> circulating at hospital A.	VA	Recommended reprocessing guidelines are not sufficient	Case Report	Health care providers and others with an interest in preventing endoscopy-related infection	Review of laboratory, medical, endoscopy reports, and reprocessing procedures/Cultures/DNA fingerprinting	N/A	9	Negative cultures
138	138	Supplemental measures to enhance duodenoscope reprocessing: FDA safety communication. US Food and Drug Administration. http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm454766.htm . Accessed December 9, 2015.	To provide some additional steps that hospitals and health care facilities that utilize duodenoscopes can, in addition to meticulously following manufacturer reprocessing instructions, take one or more of these additional steps to further reduce the risk of infection and increase the safety of these devices.	VA	The following measures may help reduce the risk of infection transmission associated with the use of duodenoscopes: 1) microbiological culturing, 2) ethylene oxide sterilization, 3) use of a liquid chemical sterilant processing system, or 4) repeat high-level disinfection.	Expert opinion	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
139	139	Edmiston CE Jr, Spencer M. Endoscope reprocessing in 2014: why is the margin of safety so small? AORN J. 2014;100(6):609-615.	To provide a perspective on infection prevention related to flexible endoscopes.	VA	There is never an excuse for lapses in reprocessing that place patients or personnel at risk for exposure to a health care-associated pathogen or any preventable injurious event after endoscopy.	Expert opinion	Health care providers and others interested in preventing endoscopy-associated infection	N/A	N/A	N/A	N/A
140											

Guideline for Processing Flexible Endoscopes
Evidence Table

	A	C	D	E	F	I	J	K	L	M	N
	REFERENCE NUMBER	CITATION	PURPOSE	CONSENSUS SCORE	RESULTS AND CONCLUSIONS	EVIDENCE TYPE	POPULATION	INTERVENTIONS	COMPARISON	SAMPLE SIZE	OUTCOME MEASURE
141	140	An outbreak of carbapenem-resistant <i>Klebsiella pneumoniae</i> infections associated with endoscopic retrograde cholangiopancreatography (ERCP) procedures at a hospital. <i>Am J Infect Control.</i> 2010;38(5):e141.	To discuss an outbreak of carbapenem-resistant <i>Klebsiella pneumoniae</i> infections associated with ERCP procedures	VB	Residual material was found under the elevator mechanism	Case report	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
142	141	Notes from the field: New Delhi metallo-β-lactamase–producing <i>Escherichia coli</i> associated with endoscopic retrograde cholangiopancreatography—Illinois, 2013. <i>Morb Mortal Weekly Rep.</i> 2014;62(51):1051.	Since January 2013, a total of 69 patients with New Delhi Metallo-β-Lactamase-Producing <i>Escherichia coli</i> producing carbapenem-resistant Enterobacteriaceae have been identified in the US; 44 patients were from northeastern Illinois.	VA	A change from automated high-level disinfection to gas sterilization with ethylene oxide has produced not new cases.	Case report	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	Potential for transmission of carbapenem-resistant Enterobacteriaceae following endoscopic retrograde cholangiopancreatography
143	142	Advocate Lutheran General Hospital. Report No. 8196. January 16, 2014. Association of Health Care Journalists. http://www.hospitalinspections.org/report/8196 . Accessed December 9, 2015.		Reg							
144	143	Muscarella LF. Risk of transmission of carbapenem-resistant Enterobacteriaceae and related “superbugs” during gastrointestinal endoscopy. <i>World J Gastrointest Endosc.</i> 2014;6(10):457-474.	To evaluate the risk of carbapenem-resistant <i>Enterobacteriaceae</i> and their related superbugs during gastrointestinal endoscopy.	VA	If performed correctly, current practices for reprocessing gastrointestinal endoscopes appear adequate to prevent disease transmission.	Literature review	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
145	144	Ross AS, Baliga C, Verma P, Duchin J, Gluck M. A quarantine process for the resolution of duodenoscope-associated transmission of multidrug-resistant <i>Escherichia coli</i> . <i>Gastrointest Endosc.</i> 2015;82(3):477-483.	To report the results of their investigation and describe the process improvements made following duodenoscope transmission of multidrug-resistant <i>Escherichia coli</i> .	VA	The existing recommendations for HLD are inadequate for duodenoscopes. In the interim to design change, a reliable method to ensure that bacterial pathogens are not present on endoscopes after HLD is needed.	Case Report	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
146	145	Meeting of the FDA Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee [transcript]. Annapolis, MD: Free State Reporting, Inc; May 14, 2015.	To discuss a surveillance culture initiative.	VA	Duodenoscopes are quarantined until cultures are negative.	Expert opinion	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
147	146	Kola A, Piening B, Pape UF, et al. An outbreak of carbapenem-resistant OXA-48-producing <i>Klebsiella pneumoniae</i> associated to duodenoscopy. <i>Antimicrob Resist Infect Control.</i> 2015;4:8-015-0049-4. eCollection 2015.	To report an outbreak of Carbapenem-resistant <i>Klebsiella pneumoniae</i> in a German university hospital that was in part associated with duodenoscopy.	VA	Stringent reprocessing of endoscopic instruments is extremely important, and is especially true for complex instruments such as the duodenoscope.	Case report	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
148	147	Verfaillie CJ, Bruno MJ, F Voor In 't Holt A, et al. Withdrawal of a novel-design duodenoscope ends outbreak of a VIM-2-producing <i>Pseudomonas aeruginosa</i> . <i>Endoscopy.</i> 2015;47(6):493-502.	To report on a large outbreak of VIM-2- <i>Pseudomonas aeruginosa</i> that was linked to the use of a recently introduced duodenoscope with a specific modified design.	VA	Duodenoscope design modifications may compromise microbiological safety as illustrated by this outbreak. Extensive pre-marketing validation of the reprocessability of any new duodenoscope design and stringent post-marketing surveillance are necessary.	Case Report	Health care providers and others with an interest in preventing endoscopy-related infections	N/A	N/A	N/A	N/A

Guideline for Processing Flexible Endoscopes
Evidence Table

	A	C	D	E	F	I	J	K	L	M	N
	REFERENCE NUMBER	CITATION	PURPOSE	CONSENSUS SCORE	RESULTS AND CONCLUSIONS	EVIDENCE TYPE	POPULATION	INTERVENTIONS	COMPARISON	SAMPLE SIZE	OUTCOME MEASURE
1	148	Behnia MM, Amurao K, Clemons V, Lantz G. Pseudo-outbreak of <i>Stenotrophomonas maltophilia</i> and <i>Acinetobacter baumannii</i> by a contaminated bronchoscope in an intensive care unit. <i>Tanaffos</i> . 2010;9(3):44-49.	To report a cluster of pneumonias caused by <i>Stenotrophomonas maltophilia</i> and <i>Acinetobacter baumannii</i> in an intensive care unit of a community hospital in a span of two months. The source was traced back to a contaminated bronchoscope.	VB	Inadequate disinfection of bronchoscopes and cross contamination between patients could be a potential cause of ventilator-associated pneumonia	Case report	Health care providers and others with an interest in preventing bronchoscopy-related infection	N/A	N/A	N/A	N/A
149	149	Charlton TS. A comparison of the efficacy of lumen-cleaning devices for flexible gastrointestinal endoscopes. <i>Aust Infect Control</i> . 2007;12(3):81.	To compare the cleaning efficacy of a new lumen cleaning device for endoscopes.	IIIC	The device was found to offer a consistently significant improvement in soil removal and was equally effective across both lumen sizes and for both new and used lumens.	Nonexperimental	Endoscopes	Simulated blood soil	Before and after cleaning	4	Visual inspection and weight of residue soil remaining in lumen
150	150	Charlton TS. A comparison of two devices for the manual cleaning of flexible gastrointestinal endoscopes in a clinical setting. <i>Aust Infect Control</i> . 2007;12(4):130-130, 132, 134, passim.	To compare the cleaning efficacy of a new lumen cleaning device for endoscopes with reusable brushes in a clinical setting.	IIIB	No significant difference was found between the cleaning protocols; however, the authors concluded that the cleaning efficacy of one pass of the new device was as effective as six passes with a reusable brush.	Nonexperimental	Endoscopes	N/A	Before and after cleaning	53	Log reduction of colony forming units
151	151	Final report: Comparative Brush Study of the Cygnus Medical Dragon Tail Cleaning Brush and the Olympus Single Use Combination Cleaning Brush Protein Analysis. Study No. 1504-244. Rochester, NY: Highpower Validation Testing & Lab Services; 2015.	To conduct a comparative study of the dragontail brush and a manufacturer's recommended brush.	IIB	The dragontail brush provided a 4-log reduction compared with the manufacturer's brush that provided a 1.2-log reduction.	Quasi-experimental	Endoscopes	Inoculation with protein soil followed by cleaning with two types of brushes	Dragontail brush compared with the manufacturer's brush	6	Log reduction of protein soil
152	152	Society of Gastroenterology Nurses and Associates. Reprocessing of endoscopic accessories and valves. <i>Gastroenterol Nurs</i> . 2013;36(4):291-292.	To provide a position on the reprocessing of endoscopic accessories and valves.	IVB	Accessories, valves, and tubings labeled as reusable should be processed according to the manufacturer's instructions. Accessories, valves, and tubings labeled as single-use should not be reprocessed or reused.	Position statement	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
153	153	Society of Gastroenterology Nurses and Associates. Position Statement on Reprocessing of Water Bottles Used During Endoscopy. Updated 2011. http://www.ascquality.org/Library/endoscopy/reprocessingtoolkit/SGNA%20Water%20Bottle%20Reprocessing.pdf . Accessed December 9, 2015.	To provide a statement regarding reprocessing of water bottles used during endoscopy	IVB	Water bottles should be manually cleaned and high-level disinfected or sterilized at least daily. Sterile water should be used in the water bottle for all endoscopic procedures.	Position statement	Health care providers and others using and processing flexible endoscopes	N/A	N/A	N/A	N/A
154	154	Parente DM. Could biopsy port valves be a source for potential flexible endoscope contamination? <i>Infect Control Today</i> . 2007;11(5).	To determine whether reprocessed biopsy port valves could be a potential source for flexible endoscope contamination.	IIIC	Eight of 15 reusable biopsy port valves from three different hospitals exhibited some form of debris or potential contamination.	Nonexperimental	Reprocessed, reusable biopsy port valves	Examination under magnification and spectroscopy	N/A	15	Freedom from debris or contamination
155	155	Liquid chemical sterilization. US Food and Drug Administration. http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/ucm208018.htm . Accessed December 9, 2015.		Reg							
156	156	Veterans Affairs Office of Inspector General. Use and Reprocessing of Flexible Fiberoptic Endoscopes at VA Medical Facilities. Report No. 09-01784-146. Washington, DC: Department of Veterans Affairs; 2009.	To describe pertinent events at the Veteran's Affairs medical centers where problems were reported, assess the Veteran's Health Affairs' response to the events, and conduct a system-wide evaluation of current reprocessing practices.	VA	Facilities have not complied with management directives to ensure compliance with reprocessing of endoscopes, resulting in a risk of infectious disease to veterans. The failure of medical facilities to comply on such a large scale with repeated alerts and directives suggests fundamental defects in organizational structure.	Case report	Health care providers and others with an interest in preventing endoscopy-related infection	Site visits	N/A	N/A	N/A
157	157										

Guideline for Processing Flexible Endoscopes
Evidence Table

	A	C	D	E	F	I	J	K	L	M	N
	REFERENCE NUMBER	CITATION	PURPOSE	CONSENSUS SCORE	RESULTS AND CONCLUSIONS	EVIDENCE TYPE	POPULATION	INTERVENTIONS	COMPARISON	SAMPLE SIZE	OUTCOME MEASURE
157	157	Muscarella LF. Disinfecting endoscopes immediately before the first patient of the day. AORN J. 2001;73(6):1159-1163.	To discuss the need for disinfecting endoscopes immediately before the first patient of the day.	VA	In general, disinfecting endoscopes in the morning before the first patient appears to be unnecessary.	Expert opinion	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
158	158	Puterbaugh M, Barde C, Van Enk R. Endoscopy water source: tap or sterile water? Gastroenterol Nurs. 1997;20(6):203-206.	To determine whether the endoscopic water source holds a potential for transmission of pathogens.	IIC	The use of tap water and clean water bottles was found to carry no greater risk than using sterile water and sterile water bottles.	Quasi-experimental	Water bottles	Microbiological sampling	Sterile water and bottles compared with clean bottles and tap water	206	Negative cultures
159	159	Wilcox CM, Waites K, Brookings ES. Use of sterile compared with tap water in gastrointestinal endoscopic procedures. Am J Infect Control. 1996;24(5):407-410.	To determine the need for sterile water rather than tap water in the water bottle.	IIC	Bacterial growth in the water bottle was infrequent, consisted mainly of nonpathogenic organisms, and was not associated with any clinical complications. The study suggests that the use of tap water compared with sterile water may be practical.	Quasi-experimental	Cultures of water bottles	Microbiological sampling	Bottles filled with tap water compared with bottles filled with sterile water	36	Negative cultures
160	160	Rockey DC. Endoscopy: dollars and sense. Gastroenterology. 1995;108(6):1957.	To question the use of sterile water in water bottles.	VB	Sterile water is much more costly than utility water. There is no reason to think that using tap water would cause an infection.	Expert opinion	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
161	161	Patton RF, Wilcox CM, Blakely J. Benefits of sterile water use in an endoscopic laboratory [4] (multiple letters). Am J Infect Control. 1998;26(3):366-367.	To discuss Wilcox et al #3035 suggestion for using tap water rather than sterile or deionized water	VC	By using sterile or deionized water the potential problem of infection risk to the patient and the costly repairs to the scope would be reduced.	Expert opinion	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
162	162	Guideline for electrosurgery. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 2015:121-138.	To provide guidance to perioperative nurses in the use and care of electrosurgical equipment, including high frequency, ultrasound, and argon beam modalities.	IVB	Correct care and handling of electrosurgical equipment are essential to patient and personnel safety.	Guideline	Health care providers and others with an interest in electrosurgery	N/A	N/A	N/A	N/A
163	163	Wilson SJ, Everts RJ, Kirkland KB, Sexton DJ. A pseudo-outbreak of <i>Aureobasidium</i> species lower respiratory tract infections caused by reuse of single-use stopcocks during bronchoscopy. Infect Control Hosp Epidemiol. 2000;21(7):470-472.	To investigate and control an apparent outbreak of lower respiratory tract infections due to <i>Aureobasidium</i> species.	VB	Reuse of medical equipment labeled for single-use is potentially hazardous, especially if no quality control system is in place to monitor sterility and function after reprocessing.	Case report	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
164	164	Rutala WA, Weber DJ. New developments in reprocessing semicritical items. Am J Infect Control. 2013;41(5 Suppl):S60-S66.	To discuss reprocessing of semicritical items.	VA	Strict adherence to current guidelines is required.	Expert opinion	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
165	165	Meeting of the FDA Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee [transcript]. Annapolis, MD: Free State Reporting, Inc; May 15, 2015.	To discuss a modification of the Spaulding classification system.	VA	Critical items that should be sterile should include items that directly or secondarily enter sterile tissue or the vascular system	Expert opinion	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
166	166										

Guideline for Processing Flexible Endoscopes
Evidence Table

	A	C	D	E	F	I	J	K	L	M	N
	REFERENCE NUMBER	CITATION	PURPOSE	CONSENSUS SCORE	RESULTS AND CONCLUSIONS	EVIDENCE TYPE	POPULATION	INTERVENTIONS	COMPARISON	SAMPLE SIZE	OUTCOME MEASURE
1	166	Rutala WA, Weber DJ. Gastrointestinal endoscopes: a need to shift from disinfection to sterilization? JAMA. 2014;312(14):1405-1406.	To discuss the need for sterilization of endoscopes.	VA	To ensure the safety of flexible endoscopes, it is necessary to enforce best practices including equipment maintenance and routine audits with at least annual competency testing of personnel who use the reprocessing equipment. Better approaches to assess the effectiveness of cleaning and high-level disinfection are needed. Adequate resources must be provided by the manufacturer of endoscopes, automated endoscope reprocessors, high-level disinfectants, and sterilization technologies. Studies must be designed to determine the risks posed by current processing with new processing methods developed. Finally, a shift to sterile diagnostic methodologies should be encouraged.	Expert opinion	Health care providers and others with an interest in endoscopy-associated infection	N/A	N/A	N/A	N/A
167	167	Puzey A. Managing the risks of prion disease transmission through flexible endoscopy. Gastrointest Nurs. 2010;8(2):18-25.	To review the most recent advice on how to reduce the risk of transmitting prions to patients undergoing flexible endoscopy.	VA	Consider patient assessment, level of tissue infectivity, and the risk of invasive procedures.	Expert opinion	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
168	168	Tschudin-Sutter S, Frei R, Kampf G, et al. Emergence of glutaraldehyde-resistant <i>Pseudomonas aeruginosa</i> . Infect Control Hosp Epidemiol. 2011;32(12):1173-1178.	To report the results of a pseudo-outbreak caused by <i>Pseudomonas aeruginosa</i> with reduced susceptibility to an aldehyde disinfectant.	VA	<i>Pseudomonas aeruginosa</i> was obtained from endoscopes, and was also found in the rinsing water and drain of the mechanical processors. The glutaraldehyde showed no activity against the <i>P aeruginosa</i> .	Case report	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
169	169	Fisher CW, Fiorello A, Shaffer D, Jackson M, McDonnell GE. Aldehyde-resistant mycobacteria bacteria associated with the use of endoscope reprocessing systems. Am J Infect Control. 2012;40(9):880-882.	To investigate the potential for development of resistance in automated endoscope reprocessors using aldehyde disinfectants. Bacterial survival was investigated after disinfection, and any isolates were examined for disinfectant sensitivity.	IIC	Bacterial contamination was found after disinfection in all automated endoscope reprocessors, and some mycobacteria isolates demonstrated significant resistance to glutaraldehyde and orthophalaldehyde disinfectants. Bacteria can survive aldehyde-based disinfection and may pose a cross-contamination risk to patients.	Quasi-experimental	Automatic endoscope reprocessors using aldehyde disinfectants	Microbiological sampling	Glutaraldehyde compared with orthophalaldehyde	3	Mycobacterium isolates
170	170	Epstein L, Hunter JC, Arwady MA, et al. New Delhi metallo-beta-lactamase-producing carbapenem-resistant <i>Escherichia coli</i> associated with exposure to duodenoscopes. JAMA. 2014;312(14):1447-1455.	To identify a source for, and interrupt transmission of New Delhi Metallo-B-Lactamase-producing Carbapenem-resistant <i>Escherichia coli</i> associated with exposure to duodenoscopes.	IIIA	After the hospital changed its processing procedure to sterilization via ethylene oxide, no additional cases were identified.	Case-control study	Patients with duodenoscope exposure in one hospital	Ethylene oxide sterilization	High-level disinfection	39	No additional cases identified after change to ethylene oxide sterilization
171	171	McCool S, Clarke L, Query A, et al. Carbapenem-resistant Enterobacteriaceae (CRE) <i>Klebsiella pneumoniae</i> (KP) Cluster Analysis Associated with GI Scopes with Elevator Channel [poster]. 2013. Infectious Diseases Society of America. https://idsa.confex.com/idsa/2013/webprogram/Handout/id1798/POSTER188_1619.pdf . Accessed December 9, 2015.	To investigate an increase of Carbapenem-resistant <i>Enterobacteriaceae Klebsiella pneumoniae</i> isolates in abdominal transplant patients.	VA	High level disinfection was not sufficient to eradicate gastrointestinal flora. Routine scope culturing should occur to ensure high-level disinfection.	Case Report	Patients located on 4 gastrointestinal transplant floors/Duodenoscopes	Peri-rectal swabs/Review of reprocessing/Microbiological cultures/DNA fingerprinting	N/A	68/31	Reduction or elimination of CRKP incidence
172											

Guideline for Processing Flexible Endoscopes
Evidence Table

	A	C	D	E	F	I	J	K	L	M	N
	REFERENCE NUMBER	CITATION	PURPOSE	CONSENSUS SCORE	RESULTS AND CONCLUSIONS	EVIDENCE TYPE	POPULATION	INTERVENTIONS	COMPARISON	SAMPLE SIZE	OUTCOME MEASURE
1	172	Campagnaro RL, Teichtahl H, Dwyer B. A pseudoepidemic of <i>Mycobacterium chelonae</i> : contamination of a bronchoscope and autocleaner. Aust New Zealand J Med. 1994;24(6):693-695.	To report a series of bronchial wash specimens contaminated with <i>Mycobacterium chelonae</i> .	VB	To avoid contamination of bronchoscopes, use of autocleaners should be discouraged and sterile water and containers used in cleaning procedures. If contamination occurs, the bronchoscope and dismantled valve mechanism should undergo ethylene oxide sterilization.	Case report	Health care providers and others interested in preventing endoscopy-associated infection	N/A	N/A	N/A	N/A
173	173	Chang CL, Su LH, Lu CM, Tai FT, Huang YC, Chang KK. Outbreak of ertapenem-resistant <i>Enterobacter cloacae</i> urinary tract infections due to a contaminated ureteroscope. J Hosp Infect. 2013;85(2):118-124.	To report an outbreak of urinary tract infections caused by ertapenem-resistant <i>Enterobacter cloacae</i> .	IIIB	The outbreak was caused by a contaminated ureteroscope and was terminated by the implementation of a revised disinfection protocol for ureteroscopes.	Case control	Patients who had undergone ureteroscopy before the infection	Observation of disinfection/Surveillance cultures	N/A	15	Results of cultures
174	174	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.	To discuss the need for improved guidance for processing flexible endoscopes.	VA	Until improved methods are identified, the gastroenterology community should be cognizant that a potential risk of contamination exists despite HLD, particularly in procedures where a duodenoscope is used.	Expert opinion	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
175	175	Müller S, Maguilnik I, Konkewicz LR, Barth AL, Kuchenbecker RS. Biofilm in duodenoscope: hospital infection by pan-resistant aeruginosa pseudomonas related to endoscopic retrograde cholangiopancreatography (ERCP). J GENCA. 2010;20(1):13-14.	To report two cases of infection with pan-resistant <i>Pseudomonas aeruginosa</i> following ERCP.	VC	The culture from the duodenoscope was positive for <i>P aeruginosa</i> following routine disinfection, extended disinfection, and sterilization by ethylene oxide. The scope was sent to the manufacturer and the internal channels were changed.	Case report	Patients with positive blood cultures for <i>P aeruginosa</i> following ERCP	Routine processing/Reprocessing with extended disinfection time/Sterilization by ethylene oxide/Repair by manufacturer	N/A	2	Negative culture
176	176	Alfa MJ, DeGagne P, Olson N, Puchalski T. Comparison of ion plasma, vaporized hydrogen peroxide, and 100% ethylene oxide sterilizers to the 12/88 ethylene oxide gas sterilizer. Infect Control Hosp Epidemiol. 1996;17(2):92-100.	To assess the ability of two 100% ethylene oxide sterilizers, two ion plasma sterilizers, and a vaporized hydrogen peroxide rigid scope sterilizer to effect a six-log ₁₀ reduction in bacterial numbers compared to the standard 12/88 ethylene oxide sterilizer.	IIIB	The margin of safety is less for the five sterilizers tested than for the 12/88 sterilizers. The inability of all sterilizers to kill organisms in narrow lumens reliably when serum and salt were present raises concern about the current practice of gas sterilization of flexible endoscopes.	Quasi-experimental	Test carriers	Inoculation with test soils	12/88 ethylene oxide sterilizer compared to 100% ethylene oxide, ion plasma, vaporized hydrogen peroxide	5	Log reduction of colony forming units
177	177	Boyer JL. Bile formation and secretion. Compr Physiol. 2013;3(3):1035-1078.	Bile formation is a unique function of the liver that is vital to the survival of the organisms.	VA	Bile salts are the major organic solutes in bile and normally function to emulsify dietary fats and facilitate their intestinal absorption.	Literature review	Health care providers and others with an interest in bile formation	N/A	N/A	N/A	N/A
178	178	Alfa MJ, DeGagne P, Olson N, Hizon R. Comparison of liquid chemical sterilization with peracetic acid and ethylene oxide sterilization for long narrow lumens. Am J Infect Control. 1998;26(5):469-477.	To determine how well peracetic acid liquid chemical sterilization killed test organisms in the presence of 10% fetal bovine serum and 0.65% salt challenge compared with a 100% ethylene oxide sterilizer and an ethylene oxide hydrochlorofluorocarbon sterilization method with long narrow flexible lumens as the test carrier.	IIIB	The data indicate that of the sterilization methods evaluated, liquid chemical sterilization was the most effective for sterilizing narrow flexible lumens in the presence of residual organic and inorganic soil.	Quasi-experimental	Long, narrow, flexible lumens	Inoculation with test soils	Liquid chemical sterilization compared to ethylene oxide	6	Log reduction of colony forming units
179	179	Alfa MJ, DeGagne P, Olson N. Validation of ATS as an appropriate test soil to assess cleaning and sterilization efficacy in narrow lumened medical devices such as flexible endoscopes. Zentralsterilisation. 2005;13(6):387-402.	To evaluate artificial test soils as an indicator of cleaning efficacy and to assess artificial test soil as a worst case organic challenge to the microbial killing efficacy of various sterilization methods.	IIIB	The artificial test soil closely mimics worst case soiling for patient-used flexible endoscopes providing a scientifically based challenge for simulated-use testing that ensures that differential removal of various organic soil components and bioburden reduction can be assessed.	Quasi-experimental	Flexible endoscopes/Test carriers	Inoculation and drying followed by cleaning/Inoculation with bacterial cultures	Optimal compared with suboptimal cleaning/Various sterilization processes/Baseline testing before soiling	192	Log reduction of colony forming units
180											

Guideline for Processing Flexible Endoscopes
Evidence Table

	A	C	D	E	F	I	J	K	L	M	N
	REFERENCE NUMBER	CITATION	PURPOSE	CONSENSUS SCORE	RESULTS AND CONCLUSIONS	EVIDENCE TYPE	POPULATION	INTERVENTIONS	COMPARISON	SAMPLE SIZE	OUTCOME MEASURE
180	180	Muscarella LF. Automatic flexible endoscope reprocessors. <i>Gastrointest Endosc Clin N Am.</i> 2000;10(2):245-257.	To discuss the benefits and limitations of automatic endoscope processors	VA	Automated endoscope processors offer several advantages to manual reprocessing.	Expert opinion	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
181	181	Ofstead CL, Wetzler HP, Snyder AK, Horton RA. Endoscope reprocessing methods: a prospective study on the impact of human factors and automation. <i>Gastroenterol Nurs.</i> 2010;33(4):304-311.	To evaluate processing practices, employee perceptions, and occupational health issues related to processing guidelines.	IIIA	Enhanced training and accountability, combined with increased automation, may ensure guideline adherence and patient safety.	Qualitative	Managers, site coordinators, processing personnel from settings using automated endoscope processing or manual cleaning	Observation/Survey	Compliance with endoscope processing guidelines	5	N/A
182	182	Ubhayawardana DL, Kottahachchi J, Weerasekera MM, Wanigasooriya IW, Fernando SS, De Silva M. Residual bioburden in reprocessed side-view endoscopes for endoscopic retrograde cholangiopancreatography (ERCP). <i>Endosc Int Open.</i> 2013;1(1):12-16.	To evaluate the outcome quality of manual reprocessing techniques for removal and inactivation of the bioburden from side-view endoscopes used for endoscopic retrograde cholangiopancreatography in a tertiary referral endotherapy unit in Sri Lanka.	IIIB	There was a high culture-positive rate after reprocessing of the side-view endoscopes using the manual reprocessing procedure, despite strict adherence to the protocol for reprocessing.	Nonexperimental	Samples from two different side-view endoscopes	Microbiological sampling	Before and after cleaning and reprocessing	102	Negative cultures
183	183	Kenters N, Huijskens EG, Meier C, Voss A. Infectious diseases linked to cross-contamination of flexible endoscopes. <i>Endosc Int Open.</i> 2015;3(4):E259-E265.	To present an overview of publications about case reports and outbreaks related to contamination of flexible endoscopes.	VA	Mandatory education and competency training are necessary to ensure the quality of processing. Early detection of contamination would be easier if standardized periodic microbiological surveillance testing were included in the guidelines. Mechanical processors should be included in the guidelines. Periodic maintenance should be performed per the manufacturer's IFU. Mandatory reporting of lapses would provide a broader perspective on the incidence of cross contamination.	Literature review	Health care providers and others with an interest in preventing endoscope-related infection	N/A	N/A	N/A	N/A
184	184	Vickery K, Ngo QD, Zou J, Cossart YE. The effect of multiple cycles of contamination, detergent washing, and disinfection on the development of biofilm in endoscope tubing. <i>Am J Infect Control.</i> 2009;37(6):470-475.	To analyze the effect of 20 wash/contamination cycles on biofilm formation.	IIIB	Washing endoscopes under high flow rates with some detergents removes established biofilm and retards biofilm generation, emphasizing the importance of cleaning before disinfection. Continued research into the physicochemical mechanisms of biofilm adherence and removal is needed to optimize detergents.	Quasi-experimental	Enzymatic and non-enzymatic detergents	Multiple automated washes/Scanning electron microscopy	Enzymatic compared with non-enzymatic detergents	2	Reduction in biofilm
185	185	Balsamo AC, Graziano KU, Schneider RP, Antunes Junior M, Lacerda RA. Removing biofilm from an endoscopic: evaluation of disinfection methods currently used. <i>Rev Esc Enferm USP.</i> 2012;46(Spec): 91-98.	To evaluate the effectiveness of high-level disinfection after previous brushing for biofilm removal in sample specimens that simulate flexible endoscope channels.	IIIB	None of the disinfection methods tested totally removed the biofilm. The most effective was 2% glutaraldehyde in automated equipment.	Quasi-experimental	Tubes simulating flexible endoscopes	Inoculation with simulated biofilm	Five dissection methods	210	Percentage of remaining biofilm
186	186	Farina A, Fieviet MH, Plassart F, Menet MC, Thuillier A. Residual glutaraldehyde levels in fiberoptic endoscopes: measurement and implications for patient toxicity. <i>J Hosp Infect.</i> 1999;43(4):293-297.	To determine the residual levels of glutaraldehyde in fiberoptic endoscopes after manual or automatic disinfection and to evaluate the extent of toxicity.	IIIC	Residual glutaraldehyde levels were higher and more variable after manual disinfection than after automatic disinfection.	Nonexperimental	Endoscopes	Measurement of residual glutaraldehyde	Manual compared with automated disinfection	92	Residual levels of glutaraldehyde
187	187										

Guideline for Processing Flexible Endoscopes
Evidence Table

	A	C	D	E	F	I	J	K	L	M	N
	REFERENCE NUMBER	CITATION	PURPOSE	CONSENSUS SCORE	RESULTS AND CONCLUSIONS	EVIDENCE TYPE	POPULATION	INTERVENTIONS	COMPARISON	SAMPLE SIZE	OUTCOME MEASURE
187	187	Dirlam Langlay AM, Ofstead CL, Mueller NJ, Tosh PK, Baron TH, Wetzler HP. Reported gastrointestinal endoscope reprocessing lapses: the tip of the iceberg. <i>Am J Infect Control.</i> 2013;41(12):1188-1194.	To evaluate the occurrence, features, and implications of reprocessing lapses to gauge the nature and breadth of the problem in the context of widely available and accepted practice guidelines.	VA	Reprocessing lapses are an ongoing and widespread problem despite the existence of guidelines.	Literature review	Health care providers and others with an interest in endoscope processing	N/A	N/A	N/A	N/A
188	188	Moses FM, Lee JS. Current GI endoscope disinfection and QA practices. <i>Dig Dis Sci.</i> 2004;49(11-12):1791-1797.	To determine current practice at regional endoscopy centers with regard to endoscope cleaning and high-level disinfection, maintenance, and quality assurance practices.	IIIB	There are wide variations in reprocessing technique, and substantial numbers of professional endoscopic units use suboptimal practice. The vast majority of endoscopic centers have not effective method of monitoring the quality of this critical process.	Qualitative	Regional endoscopy centers in Pennsylvania, Delaware, Virginia, Maryland, and District of Columbia	Survey	Compared with recognized guidelines	230	Compliance with recognized guidelines
189	189	Schaefer MK, Jhung M, Dahl M, et al. Infection control assessment of ambulatory surgical centers. <i>JAMA.</i> 2010;303(22):2273-2279.	To describe compliance with basic infection control practices and other safety standards and to determine whether use of the audit tool and patient tracer improved inspection effectiveness.	IIIA	Among a sample of US ambulatory surgery centers, lapses in infection control were common.	Nonexperimental	Ambulatory surgery centers	Assessment of infection control practices	Infection control audit tool	68	Compliance
190	190	Park JB, Yang JN, Lim YJ, et al. Survey of endoscope reprocessing in Korea. <i>Clin Endosc.</i> 2015;48(1):39-47.	To determine whether reprocessing guidelines have been correctly followed and to determine the precise current status of endoscope reprocessing.	IIIB	The majority of respondents had a high compliance rate compared with previous surveys.	Qualitative	Nurses and nursing auxiliary personnel in eight Korean hospitals	Questionnaire	Compliance with guidelines	100	Compliance with guidelines
191	191	Przytulski K, Regula J. Disinfection of endoscopes and sterilization of accessories for gastrointestinal endoscopy in Polish units—analysis of the questionnaire. <i>Gastroenterol Pol.</i> 2004;11(3):241-243.	To assess compliance with guidelines for disinfection and sterilization of flexible endoscopes in Poland.	IIIC	There is a need for improvement of methods used for disinfection and sterilization in Polish gastrointestinal endoscopy units.	Qualitative	Polish gastrointestinal units	Survey	Compliance with guidelines	55	Compliance with guidelines
192	192	Yamada G, Takahashi H, Abe S. A survey of bronchoscope reprocessing procedure in Japan [2]. <i>J Bronchol.</i> 2005;12(3):184-185.	To assess aspects of reprocessing of bronchoscopes in Japan.	IIIC	Reprocessing procedures are in consistent.	Qualitative	Participants present at Japanese Society for Bronchology	Survey	Compliance with guidelines	369	Compliance with guidelines
193	193	Zhang X, Kong J, Tang P, et al. Current status of cleaning and disinfection for gastrointestinal endoscopy in China: a survey of 122 endoscopy units. <i>Dig Liver Dis.</i> 2011;43(4):305-308.	To investigate cleaning and disinfection practices in China.	IIIB	There is still room for improvement in the practice of endoscopy reprocessing, especially in mid-size and small cities.	Qualitative	Endoscopy units in China	Questionnaire	Compliance with guidelines	122	Compliance with guidelines
194	194	Akamatsu T, Tabata K, Hirong M, Kawakami H, Uyeda M. Transmission of <i>Helicobacter pylori</i> infection via flexible fiberoptic endoscopy. <i>Am J Infect Control.</i> 1996;24(5):396-401.	To determine disinfection procedures and bactericidal activities of seven disinfectants against <i>Helicobacter pylori</i> .	IIIB	<i>Helicobacter pylori</i> is readily killed by many common disinfectants and antiseptics; however, practices for disinfection of flexible endoscopes were not appropriate.	Qualitative/Nonexperimental	Institutions where endoscopy is regularly performed	Survey/Bactericidal activity against <i>Helicobacter pylori</i>	Method of disinfection/Effectiveness of disinfectant or antiseptic	20	Compliance/Bactericidal activity of disinfectant or antiseptic
195	195	Ahuja V, Tandon RK. Survey of gastrointestinal endoscope disinfection and accessory reprocessing practices in the Asia-Pacific region. <i>J Gastroenterol Hepatol.</i> 2000;15(Suppl):G78-G81.	To characterize endoscopic disinfection and accessory processing practices in the Asia-Pacific region.	IIIB	One-third of respondents did not practice disinfection at the start of the day's session. 2.9% were not using an HLD, and 34.7% used a glutaraldehyde soak time of less than 10 minutes. At 40% of the centers, forced air or alcohol was not used to dry the endoscopes. Reuse of accessories meant for single use was widely practiced.	Qualitative	Endoscopy centers	Assessment of endoscope disinfection and accessory processing practices	Survey	138	Compliance
196	196	Barbosa JM, Souza AC, Tipple AF, Pimenta FC, Leao LS, Silva SR. Endoscope reprocessing using glutaraldehyde in endoscopy services of Goiania, Brazil: a realidade em servicos de endoscopia de Goiania, GO. <i>Arq Gastroenterol.</i> 2010;47(3):219-224.	To characterize the reprocessing of endoscopes using glutaraldehyde in endoscopy services.	IIIB	The study shows failure in many different reprocessing steps, all of which can compromise the quality of the disinfection.	Nonexperimental	Endoscopes	Observation of processing	Compliance with recommended guidelines	60	N/A
197	197										

Guideline for Processing Flexible Endoscopes
Evidence Table

	A	C	D	E	F	I	J	K	L	M	N
	REFERENCE NUMBER	CITATION	PURPOSE	CONSENSUS SCORE	RESULTS AND CONCLUSIONS	EVIDENCE TYPE	POPULATION	INTERVENTIONS	COMPARISON	SAMPLE SIZE	OUTCOME MEASURE
198	197	Fratila O, Tantau M. Cleaning and disinfection in gastrointestinal endoscopy: current status in Romania. J Gastrointest Liver Dis. 2006;15(1):89-93.	To assess the methods and the conditions in which endoscopic disinfection is achieved in Romania.	IIIC	In general, the disinfection and sterilization of endoscopes are carried out in good conditions.	Qualitative	Endoscopy centers in Romania	Survey	Recommended practices and conditions	29	Compliance with recommended practices and conditions
199	198	Heudorf U, Exner M. German guidelines for reprocessing endoscopes and endoscopic accessories: guideline compliance in Frankfurt/Main, Germany. J Hosp Infect. 2006;64(1):69-75.	To examine the current endoscope reprocessing practices in a German urban region, covering all hospitals and private practices in the area.	IIIC	Infection control advice and the control of public health regulations resulted in the correction of most processing faults between 2003 and 2004.	Qualitative	Hospitals/Private practices	Survey	N/A	14/20	Compliance with recommended practices and conditions
200	199	Honeybourne D, Neumann CS. An audit of bronchoscopy practice in the United Kingdom: a survey of adherence to national guidelines. Thorax. 1997;52(8):709-713.	To audit bronchoscopy procedures with reference to disinfection, patient monitoring, precautions to prevent unnecessary staff exposure to glutaraldehyde, or infection using published national guidelines for comparison.	IIIC	The audit shows that many facilities do not adhere to guidelines on disinfection procedures and patient monitoring.	Qualitative	Bronchoscopy units in the United Kingdom	Survey	National guidelines	159	Compliance
201	200	Lubbe DE, Fagan JJ. South African survey on disinfection techniques for the flexible nasopharyngoscope. J Laryngol Otol. 2003;117(10):811-814.	To determine the flexible nasopharyngoscope disinfection practice employed by South African otolaryngologists and to establish whether a breach in the disinfection process exists.	IIIC	Current guidelines are not being followed.	Nonexperimental	South African otolaryngologists	Survey	Current guidelines	45	Compliance with guidelines
202	201	Orsi GB, Filocamo A, Di Stefano L, Tittobello A. Italian National Survey of Digestive Endoscopy Disinfection Procedures. Endoscopy. 1997;29(8):732-738.	To investigate the disinfection procedures carried out in the Italian centers of digestive endoscopy	IIIC	The data collected show that, in general, there is compliance with the guidelines, but there are still some important exceptions.	Qualitative	Digestive endoscopy centers in Italy	Questionnaire	Compliance with national guidelines	386	Compliance with national guidelines
203	202	Soares JB, Goncalves R, Banhudo A, Pedrosa J. Reprocessing practice in digestive endoscopy units of district hospitals: results of a Portuguese National Survey. Eur J Gastroenterol Hepatol. 2011;23(11):1064-1068.	To assess reprocessing practice in the endoscopy units of Portuguese district general hospitals.	IIIB	The data collected show that, in general, there is compliance with the guidelines, but there are still some important exceptions.	Qualitative	Endoscopy units of Portuguese district general hospitals	Questionnaire	Compliance with recognized standards	25	Compliance with recommended practices and conditions
204	203	Spinzi G, Fasoli R, Centenaro R, Minoli G; SIED Lombardia Working Group. Reprocessing in digestive endoscopy units in Lombardy: results of a regional survey. Dig Liver Dis. 2008;40(11):890-896.	To assess cleaning and disinfection practice in gastrointestinal endoscopy units in public and private institutions in the Lombardy region.	IIIB	There is good compliance with standard guidelines. There is room for improvement in equipment, disinfection protocols, and traceability of instruments in order to improve safety for patients and staff.	Qualitative	Endoscopy centers in Lombardy, Italy.	Questionnaire	Compliance with standard guidelines	79	Compliance with standard guidelines
205	204	Ribeiro MM, de Oliveira AC, Ribeiro SM, Watanabe E, de Resende Stojanoff MA, Ferreira JA. Effectiveness of flexible gastrointestinal endoscope reprocessing. Infect Control Hosp Epidemiol. 2013;34(3):309-312.	To evaluate whether or not the air/water channels of gastrointestinal endoscopes represent a risk factor for the transmission of microorganisms in patients undergoing endoscopy procedures.	IIIB	The contamination of the air/water channels represents a risk for the transmission of microorganisms during gastrointestinal endoscopy, possibly related to the inadequate reprocessing of these channels.	Qualitative/Nonexperimental	Endoscopy services in Brazil	Questionnaire/Microbiological sampling	Compliance with instructions for use	37	Compliance/Negative cultures
206	205	Lakhani R, Smithard A, Bleach N. How clean is your scope? A completed audit cycle of the disinfection of nasendoscopes. Ann R Coll Surg Engl. 2010;92(7):587-590.	To audit disinfection of nasendoscopes.	IIIB	The introduction of a poster and training in the disinfection of nasendoscopes proved successful in improving compliance with published guidelines.	Quasi-experimental	ENT clinics	Pre-text/Post-test	Compliance with national guidelines	22 sessions/67 cleaning episodes	Compliance with national guidelines
207	206	Banfield GK, Hinton AE. A national survey of disinfection techniques for flexible nasendoscopes in UK ENT out-patient departments. J Laryngol Otol. 2000;114(3):202-204.	To establish the methods used for disinfection of flexible nasendoscopes within ear, nose, and throat outpatient departments.	IIIC	The results demonstrate a lack of standard practice that is wasteful of financial resources and may expose patients to unnecessary risk.	Qualitative	Ear, nose, and throat outpatient departments	Survey	Standardized practice	82	N/A

Guideline for Processing Flexible Endoscopes
Evidence Table

	A	C	D	E	F	I	J	K	L	M	N
	REFERENCE NUMBER	CITATION	PURPOSE	CONSENSUS SCORE	RESULTS AND CONCLUSIONS	EVIDENCE TYPE	POPULATION	INTERVENTIONS	COMPARISON	SAMPLE SIZE	OUTCOME MEASURE
1	207	Brake MK, Lee BS, Savoury L, et al. Survey of nasopharyngoscope decontamination methods in Canada. J Otolaryngol Head Neck Surg. 2010;39(6):714-722.	To compare flexible nasopharyngoscope decontamination practices across Canada. Various procedures are employed throughout Canada owing to a lack of standardization.	IIIB	Responses indicate the Canadian otolaryngologists would appreciate a national standard for cleaning of flexible nasopharyngoscopes, particularly for nonhospital practices.	Qualitative	Members of the Canadian society of Otolaryngology-Head and Neck Surgery	Survey	Decontamination practices	171	N/A
208	208	Kressel AB, Kidd F. Pseudo-outbreak of Mycobacterium chelonae and Methylobacterium mesophilicum caused by contamination of an automated endoscopy washer. Infect Control Hosp Epidemiol. 2001;22(7):414-418.	To evaluate an unusual number of rapidly growing acid-fast bacilli, later identified as <i>Mycobacterium chelonae</i> , and pink bacterial, later identified as <i>Methylobacterium mesophilicum</i> from fungal cultures obtained by bronchoscopy.	VB	The automated washers were contaminated with a biofilm that rendered them resistant to decontamination. The washers then contaminated the endoscopes and bronchoscopes they were used to disinfect. New endoscopes and peracetic acid system were purchased.	Case report	Patients undergoing bronchoscopy from July 21 to October 2, 1998	Microbiological sampling/DNA fingerprinting/Review of records	Positive versus negative cultures	22	Negative cultures
209	209	Schelenz S, French G. An outbreak of multidrug-resistant <i>Pseudomonas aeruginosa</i> infection associated with contamination of bronchoscopes and an endoscope washer-disinfector. J Hosp Infect. 2000;46(1):23-30.	To report an outbreak of multidrug-resistant <i>Pseudomonas aeruginosa</i> infection associated with contamination of bronchoscopes and an endoscope washer-disinfector	VB	The operation and maintenance of the washer-disinfectors had not been supervised.	Case report	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
210	210	Blanc DS, Parret T, Janin B, Raselli P, Francioli P. Nosocomial infections and pseudo-infections from contaminated bronchoscopes: two-year follow up using molecular markers. Infect Control Hosp Epidemiol. 1997;18(2):134-136. -136.	To report an investigation of an outbreak of <i>Pseudomonas aeruginosa</i> infections and pseudo-infections.	IIIB	The epidemic was due to contamination of bronchoscopes by washing machines.	Case control	Patients with <i>Pseudomonas aeruginosa</i> isolated from bronchial specimens	Ribotyping	Ribotypes 1 or 2	35	N/A
211	211	Maloney S, Welbel S, Daves B, et al. Mycobacterium abscessus pseudo-infection traced to an automated endoscope washer: utility of epidemiologic and laboratory investigation. J Infect Dis. 1994;169(5):1166-1169.	To describe an outbreak of <i>Mycobacterium abscessus</i> pseudo-infections associated with bronchoscopy.	IIIB	Use of the implicated automated washer was discontinued and the outbreak ended.	Case control	Patients with positive cultures for <i>Mycobacterium abscessus</i> without evidence of infection following endoscopy	Retrospective record review/Observation of reprocessing/Microbiological cultures/DNA fingerprinting	N/A	15	Negative cultures
212	212	Centers for Disease Control and Prevention (CDC). Bronchoscopy-related infections and pseudo-infections—New York, 1996 and 1998. MMWR Morb Mortal Wkly Rep. 1999;48(26):557-560.	To summarize the results of investigations of three clusters of culture-positive bronchoscopy specimens from patients.	VA	Most reported bronchoscopy-related outbreaks or pseudo-outbreaks have been associated with inadequate cleaning and disinfection procedures. The findings in this report identified additional problems related to using automated reprocessing systems. Personnel using automated reprocessing systems in these clusters did not receive adequate device-specific training, and the wrong set up or connector systems were used.	Case report	Culture positive bronchoscopy specimens	N/A	N/A	N/A	N/A
213	213	Chronoeu A, Zimmerman SK, Cook S, et al. Molecular typing of Mycobacterium chelonae isolates from a pseudo-outbreak involving an automated bronchoscope washer. Infect Control Hosp Epidemiol. 2008;29(11):1088-1090.	To describe a pseudo-outbreak of <i>Mycobacterium chelonae</i> infection in bronchoalveolar lavage fluid from 9 patients that was traced to contamination of an automated bronchoscope washer.	VC	Molecular typing using repetitive extragenic palindromic polymerase chain reaction was helpful in confirming epidemiological and clinical findings.	Case report	Health care providers and others interested in preventing endoscopy-associated infection	Molecular typing	N/A	N/A	Positive cultures
214	214	Gillespie TG, Hogg L, Budge E, Duncan A, Coia JE. Mycobacterium chelonae isolated from rinse water within an endoscope washer-disinfector. J Hosp Infect. 2000;45(4):332-334.	To report an experience of contaminated water in a washer-disinfector leading to pseudo-infection in two patients and the measures required to eliminate the problem.	VC	In addition to standard tests to determine the bacteriological quality of water, sampling for mycobacteria should also be carried out.	Case report	Health care providers and others with an interest in preventing endoscopy-related infection	Microbiological sampling/Using an alternative disinfectant	N/A	2	Negative cultures
215											

Guideline for Processing Flexible Endoscopes
Evidence Table

	A	C	D	E	F	I	J	K	L	M	N
	REFERENCE NUMBER	CITATION	PURPOSE	CONSENSUS SCORE	RESULTS AND CONCLUSIONS	EVIDENCE TYPE	POPULATION	INTERVENTIONS	COMPARISON	SAMPLE SIZE	OUTCOME MEASURE
1	215	Rosengarten D, Block C, Hidalgo-Grass C, et al. Cluster of pseudo-infections with <i>Burkholderia cepacia</i> associated with a contaminated washer-disinfector in a bronchoscopy unit. <i>Infect Control Hosp Epidemiol.</i> 2010;31(7):769-771.	To describe a cluster of pseudo-infections in patients in a bronchoscopy unit who had <i>Burkholderia cepacia</i> complex isolated from bronchoalveolar lavage fluid samples.	VA	The investigation led to the source of the organism and a successful intervention.	Case report	Patients who grew organisms defined as <i>B cepacia</i> complex on culture	Microbiological sampling/DNA fingerprinting	N/A	3	Negative cultures
216	216	Ramirez J, Ahmed Z, Gutierrez CN, Byrd RP Jr, Roy TM, Sarubbi FA. Impact of atypical mycobacterial contamination of bronchoscopy on patient care: report of an outbreak and review of the literature. <i>Infect Dis Clin Pract (Baltim Md).</i> 1998;7(6):281-285.	To report contamination of 13 bronchial washings by <i>Mycobacterium goodii</i> that occurred over a 12-month period.	VC	The automatic disinfection machine was the source for the atypical bacteria.	Case report	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
217	217	Zweigner J, Gastmeier P, Kola A, Klefisch F-R, Schweizer C, Hummel M. A carbapenem-resistant <i>Klebsiella pneumoniae</i> outbreak following bronchoscopy. <i>Am J Infect Control.</i> 2014;42(8):936-937.	To report an outbreak of carbapenem-resistant <i>Klebsiella pneumoniae</i> in an intensive care unit.	VB	Flushing solutions from the bronchoscope channels revealed growth of CRKP from one bronchoscope and high levels of bacteria from both scopes. The manufacturer observed defects in the internal channels of both bronchoscopes.	Case report	Patients with CRKP producing and oxacillinase carbapenemase identified between May 22, 2013 and June 30, 2013	Microbiological sampling/DNA fingerprinting	N/A	8	Negative cultures
218	218	Mean M, Mallaret MR, Richard P, Shum J, Zarski JP. Gastrointestinal endoscopes cleaned without detergent substance following an automated endoscope washer/disinfector dysfunction. <i>Gastroenterol Clin Biol.</i> 2006;30(5):665-668.	To analyze a series of 72 patients exposed to an endoscope reprocessed without detergent and to describe the crisis situation related to the risk of infectious disease transmission following the dysfunction of an automated processor in a gastrointestinal unit.	VC	No viral infection was transmitted during the dysfunction. After this incident, the monitoring of the endoscopic procedures and traceability of the cleaning process were both improved to prevent further incidents.	Case report	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
219	219	Larson JL, Lambert L, Stricof RL, Driscoll J, McGarry MA, Ridzon R. Potential nosocomial exposure to <i>Mycobacterium tuberculosis</i> from a bronchoscope. <i>Infect Control Hosp Epidemiol.</i> 2003;24(11):825-830.	To report the investigation of a possible outbreak of tuberculosis.	VA	One of the bronchoscopes was contaminated with <i>Mycobacterium tuberculosis</i> and inadequately cleaned and disinfected.	Case report	Patients with positive TB sputum cultures	Record review/Observation of processes/DNA fingerprinting	N/A	3	Negative cultures
220	220	Kara M, Turan I, Polat Z, Dogru T, Bagci S. Chemical colitis caused by peracetic acid or hydrogen peroxide: a challenging dilemma. <i>Endoscopy.</i> 2010;42(Suppl 2):E3-E4.	To report four cases of chemical colitis following use of a new automated disinfection device	VC	A programming error was discovered in the automated disinfection device, related to the rinsing of the air/water channels of the endoscopes.	Case report	Patients developing chemical colitis following endoscopy	N/A	N/A	N/A	N/A
221	221	Cammarota G, Cesaro P, Cazzato A, et al. Hydrogen peroxide-related colitis (previously known as "pseudolipomatosis"): a series of cases occurring in an epidemic pattern. <i>Endoscopy.</i> 2007;39(10):916-919.	To report several cases of hydrogen peroxide-related colitis that occurred in a gastrointestinal endoscopy center	VC	The colitis was caused by a technical failure in the rinsing of the air channel, leading to vaporization of residues of peroxide derivatives during insufflations or injecting of water. Cases stopped after the machine was serviced.	Case report	10 patients with a form of colitis showing snow white patterns	N/A	N/A	N/A	N/A
222	222	Gamble HP, Duckworth GJ, Ridgway GL. Endoscope decontamination incidents in England 2003-2004. <i>J Hosp Infect.</i> 2007;67(4):350-354.	To report on the results of the task force assigned to review endoscope decontamination incidents in England from 2003 to 2004 and the recommendations of the task force.	VB	The nature of the incidents suggested that there were problems associated with defining roles and responsibilities for endoscope decontamination, personnel training, and incompatibility between endoscopes and reprocessors.	Case report	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
223	223	Vanhems P, Gayet-Ageron A, Ponchon T, et al. Follow-up and management of patients exposed to a flawed automated endoscope washer-disinfector in a digestive diseases unit. <i>Infect Control Hosp Epidemiol.</i> 2006;27(1):89-92.	To describe and discuss the postevent management of a population potentially exposed to a flawed endoscopic washer-disinfector in a digestive diseases unit.	VB	This event created the conditions for improvement in safety procedures. See erratum #1526.	Case report	Patients undergoing endoscopic examination using an endoscope processed in a flawed washer-disinfector	Risk analysis/Clinical and biological screening	N/A	236	No cases of HIV, HCV, or HBV
224	224										

Guideline for Processing Flexible Endoscopes
Evidence Table

	A	C	D	E	F	I	J	K	L	M	N
	REFERENCE NUMBER	CITATION	PURPOSE	CONSENSUS SCORE	RESULTS AND CONCLUSIONS	EVIDENCE TYPE	POPULATION	INTERVENTIONS	COMPARISON	SAMPLE SIZE	OUTCOME MEASURE
1	224	Vanhems P, Gayet-Ageron A, Ponchon T, et al. Erratum: Follow-up and management of patients exposed to a flawed automated endoscope washer-disinfector in a digestive diseases unit (Infection Control and Hospital Epidemiology [January 2006] 27 [89-91]). Infect Control Hosp Epidemiol. 2006;27(4):431.		N/A	Erratum to #2976						
225	225	Alfa MJ, Olson N, DeGagne P. Automated washing with the Reliance Endoscope Processing System and its equivalence to optimal manual cleaning. Am J Infect Control. 2006;34(9):561-570.	To compare the efficacy of the automated washing phase in the Reliance EPS with that of optimal cleaning.	II B	The efficacy of the Reliance EPS washing phase was equivalent to optimal manual cleaning for all of the makes and models (bronchoscope, duodenoscope, colonoscope) tested.	Quasi-experimental	Flexible endoscopes	Artificial test soil	Manual cleaning compared with automated cleaning	30	Log reduction of colony forming units
226	226	Funk SE, Reaven NL. High-level endoscope disinfection processes in emerging economies: financial impact of manual process versus automated endoscope reprocessing. J Hosp Infect. 2014;86(4):250-254.	To compare the potential results of guideline-recommended automatic endoscope processors to manual disinfection along three dimensions: productivity, need for endoscope repair, and infection transmission risk in India, China, and Russia.	IIIC	Conversion from manual soak to use of automatic endoscope processors may generate costs and revenue offsets that could produce direct financial gains for some endoscopy units in Russia and China.	Nonexperimental	Endoscopy centers in Russia, China, and India	Financial modeling/Market research	Manual processing compared with automated processing	N/A	Productivity level/Amount of scope repair/Risk of infection transmission
227	227	Forte L, Shum C. Comparative cost-efficiency of the EVOTECH endoscope cleaner and reprocessor versus manual cleaning plus automated endoscope reprocessing in a real-world Canadian hospital endoscopy setting. BMC Gastroenterology. 2011;11:105.	To determine the cost-efficiency of an endoscope cleaner and reprocessor compared with manual cleaning and an automated endoscope reprocessor.	IIIB	The endoscope cleaner and reprocessor was more efficient and less costly to use than manual cleaning followed by automated reprocessing.	Nonexperimental	Colonoscopes/Gastrosopes/Bronchoscopes	Data analysis of cost and time	Endoscope cleaner reprocessor compared with manual cleaning and automated reprocessing	81	Time and cost
228	228	Alfa MJ, DeGagne P, Olson N, Fatima I. EVOTECH endoscope cleaner and reprocessor (ECR) simulated-use and clinical-use evaluation of cleaning efficacy. BMC Infect Dis. 2010;10:200.	To perform simulated and after use testing to assess the efficacy of an endoscope cleaner and reprocessor for cleaning flexible colonoscopes, duodenoscopes, gastroscopes, and bronchoscopes. The main aim was to determine if the cleaning achieved using the processor was at least equivalent to optimal manual cleaning.	IIA	The processor provides an effective automated approach that ensures surfaces and channels of the flexible endoscopes are adequately cleaned after having only a bedside flush and no manual cleaning.	Quasi-experimental	Bronchoscopes/Duodenoscopes/Colonoscopes	Samples	After actual and simulated use post cleaning	55	Amount and types of soil remaining on scopes
229	229	Bhatt JM, Peterson EM, Verma SP. Microbiological sampling of the forgotten components of a flexible fiberoptic laryngoscope: what lessons can we learn? Otolaryngol Head Neck Surg. 2014;150(2):235-236.	To evaluate the effectiveness of a glutaraldehyde-based decontamination protocol in cleaning various components of flexible laryngoscopes.	IIIC	The study demonstrates that potential contaminants may be present on eyepieces and light cables.	Nonexperimental	Portions of flexible laryngoscopes	Culturing before use	Culture result	17	N/A
230	230	Sorin M, Segal-Maurer S, Mariano N, Urban C, Combest A, Rahal JJ. Nosocomial transmission of imipenem-resistant <i>Pseudomonas aeruginosa</i> following bronchoscopy during August through October 1998	To assess transmission of imipenem-resistant <i>Pseudomonas aeruginosa</i> following bronchoscopy during August through October 1998	IIIB	The similarity of device connectors and limited training by the manufacturer regarding automatic endoscope processors for bronchoscopes were the two factors responsible for the outbreak.	Case control	Patients with IRPA bronchial wash isolates	Review of clinical data/Environmental cultures/Molecular analysis/Observation of disinfection	N/A	18	Negative cultures
231	231	Esteban J, Gadea I, Fernandez-Roblas R, et al. Pseudo-outbreak of <i>Aeromonas hydrophila</i> isolates related to endoscopy. J Hosp Infect. 1999;41(4):313-316.	To report a pseudo-outbreak of <i>Aeromonas hydrophila</i> in colonic biopsies.	VC	During the study period, endoscopic materials were disinfected with quaternary ammonia and glutaraldehyde phenate.	Case report	Colonic biopsies	Genetic typing/Observation of disinfectant processes	N/A	15	Negative cultures
232	232										

Guideline for Processing Flexible Endoscopes
Evidence Table

	A	C	D	E	F	I	J	K	L	M	N
	REFERENCE NUMBER	CITATION	PURPOSE	CONSENSUS SCORE	RESULTS AND CONCLUSIONS	EVIDENCE TYPE	POPULATION	INTERVENTIONS	COMPARISON	SAMPLE SIZE	OUTCOME MEASURE
1	232	West AB, Kuan SF, Bennick M, Lagarde S. Glutaraldehyde colitis following endoscopy: clinical and pathological features and investigation of an outbreak. <i>Gastroenterology</i> . 1995;108(4):1250-1255.	To describe the clinical features of glutaraldehyde-induced colitis and the pathology of the mucosal injury in four patients, in at least one of whom the disinfectant was not retained in the endoscope itself.	VC	The source of the glutaraldehyde was found to be the tubing connecting water bottles to the endoscopes which was disinfected rigorously but flushed inconsistently between cases.	Case report	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
233	233	Kim SJ, Baek IH. Colonic mucosal pseudolipomatosis: disinfectant colitis? <i>Gastroenterol Nurs</i> . 2012;35(3):208-213.	To highlight a series of 12 cases of colonic pseudolipomatosis in order to describe the endoscopic and pathological features and discuss the harmful effect of disinfectants as a possible cause of pseudolipomatosis.	IIIB	The endoscopic disinfectant was the probable cause of pseudolipomatosis. These cases highlight the importance of completing all steps of the reprocessing of endoscopes and following the manufacturer's instructions for use of automatic endoscope reprocessors.	Case control	Patients who developed colonic pseudolipomatosis following endoscopy	N/A	Specimens of patients with pseudolipomatosis with resected pig specimens	12	Chemical colitis
234	234	Rozen P, Somjen GJ, Baratz M, Kimel R, Arber N, Gilat T. Endoscope-induced colitis: description, probable cause by glutaraldehyde, and prevention. <i>Gastrointest Endosc</i> . 1994;40(5):547-553.	To report six cases of acute, self-limited colitis that occurred after screening flexible sigmoidoscopy probably caused by glutaraldehyde residues in an automatic disinfection machine.	VC	The colitis was caused by a combination of technical and human errors.	Case report	Health care providers and others with an interest in preventing endoscopy-related infection	Histologic examination//Evaluation of the automatic endoscope disinfectant/Estimation of disinfectant residues in rinse water	Normal tissue/IFUs	6 patients with colitis	No glutaraldehyde in endoscope or rinse water
235	235	Tsai MS, Chiu HH, Li JH. Education and imaging. <i>Gastrointestinal: glutaraldehyde proctocolitis</i> . <i>J Gastroenterol Hepatol</i> . 2008;23(9):1460.	To report a case of glutaraldehyde-induced colitis	VC	The colitis was caused by inadequate rinsing after immersion of the endoscope in a glutaraldehyde solution.	Case report	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
236	236	Yen HH, Chen YY. Glutaraldehyde colitis. <i>Endoscopy</i> . 2006;38(Suppl 2):E98.	To report a case of glutaraldehyde-induced colitis	VB	There was a defect in one of the endoscope cleaning machines that caused retention of the disinfectant in the endoscope channel.	Case report	Health care providers and others with an interest in preventing endoscopy-related infection.	N/A	N/A	N/A	N/A
237	237	Mohamad MZ, Koh KS, Chong VH. Glutaraldehyde-induced colitis: a rare cause of lower gastrointestinal bleeding. <i>Am J Emerg Med</i> . 2014;32(6):685.e1-685.e2.	To report a case of glutaraldehyde-induced colitis	VC	The mechanism of exposure to glutaraldehyde is through inadequate rinsing of endoscopic channels or contamination of the rinsing water with glutaraldehyde.	Case report	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
238	238	Mee AS, Bower M. Risk factors for pancreatitis [2]. <i>Gut</i> . 1997;40(2):289.	To propose the possibility that glutaraldehyde residues remaining after endoscope processing could be the cause of an increase in pancreatitis following ERCP.	VC	It became apparent that rinsing of the elevator wire channel was less than adequate after automatic disinfection with glutaraldehyde.	Expert opinion	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
239	239	Stein BL, Lamoureux E, Miller M, Vasilevsky CA, Julien L, Gordon PH. Glutaraldehyde-induced colitis. <i>Can J Surg</i> . 2001;44(2):113-116.	To describe the clinical course of acute colitis occurring after flexible endoscopy.	VC	The entity of glutaraldehyde-induced colitis should be recognized and special attention given during instrument cleansing to minimize the risk of its development.	Case report	Patients who sought assessment of potential colonic disease	Investigation of processes	N/A	8	Adequate rinsing to prevent colitis
240	240	Caprilli R, Viscido A, Frieri G, Latella G. Acute colitis following colonoscopy. <i>Endoscopy</i> . 1998;30(4):428-431.	To describe three cases of severe acute self-limited colitis.	VC	Careful cleaning and care of the endoscope after disinfection following a standard rinsing protocol is the principal means of preventing this complication.	Case report	3 patients with severe acute self-limited colitis following endoscopy	N/A	N/A	N/A	N/A
241											

Guideline for Processing Flexible Endoscopes
Evidence Table

	A	C	D	E	F	I	J	K	L	M	N
	REFERENCE NUMBER	CITATION	PURPOSE	CONSENSUS SCORE	RESULTS AND CONCLUSIONS	EVIDENCE TYPE	POPULATION	INTERVENTIONS	COMPARISON	SAMPLE SIZE	OUTCOME MEASURE
1	241	Bennett SN, Peterson DE, Johnson DR, Hall WN, Robinson-Dunn B, Dietrich S. Bronchoscopy-associated Mycobacterium xenopi pseudo-infections. Am J Respir Crit Care Med. 1994;150(1):245-250.	To investigate 60 mycobacterial isolates from a Michigan hospital identified as <i>Mycobacterium xenopi</i> .	IIIA	Adequate disinfection of contaminated bronchoscopes and careful collection of specimens to avoid contamination with contaminated water are essential, both for limiting diagnostic confusion caused by mycobacterial pseudo-infections and for reducing the risks of disease transmission.	Case control	Mycobacterial isolates identified as <i>Mycobacterium xenopi</i>	Procedural review/Laboratory investigation	Culture result	60	N/A
242	242	Wendelboe AM, Baumbach J, Blossom DB, Frank P, Srinivasan A, Sewell CM. Outbreak of cystoscopy related infections with <i>Pseudomonas aeruginosa</i> : New Mexico, 2007. J Urol. 2008;180(2):588-592.	To report an outbreak of <i>Pseudomonas aeruginosa</i> potentially associated with outpatient cystoscopy performed by a urologist between January 1 to April 22, 2007.	IIIB	A contaminated cystoscope was implicated as the likely source of the infections.	Case control	Patients with blood or during cultures positive for <i>P aeruginosa</i> during the study period	Review of processing processes/Review of records	Control patients with blood or during cultures ordered through the same laboratory	23	Negative cultures
243	243	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.	To quantitatively assess the current status of contamination for routinely used duodenoscopes and to determine the effect of drying on bacterial load.	IIIA	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.	Nonexperimental	Duodenoscopes	Microbiological sampling/Increased drying time	N/A	42	Negative cultures
244	244	Muscarella LF. Inconsistencies in endoscopereprocessing and infection-control guidelines: the importance of endoscope drying. Am J Gastroenterol. 2006;101(9):2147-2154.	To evaluate the importance of endoscope drying to the prevention of disease transmission.	VA	Endoscope drying is as important to the prevention of infection as cleaning and high-level disinfection (or liquid sterilization).	Literature review	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
245	245	Wang HC, Liaw YS, Yang PC, Kuo SH, Luh KT. A pseudoepidemic of <i>Mycobacterium chelonae</i> infection caused by contamination of a fiberoptic bronchoscope suction channel. Eur Respir J. 1995;8(8):1259-1262.	To report a pseudoepidemic involving <i>Mycobacterium chelonae</i> .	IIIC	The channel of the bronchoscope was contaminated.	Case control	Patients whose bronchial washing specimens yielded <i>M chelonae</i> .	Review of processing processes/Review of records	Patients who had bronchial washing specimens sent for culture that did not yield <i>M chelonae</i>	48	Negative cultures
246	246	Gavalda L, Olmo AR, Hernandez R, et al. Microbiological monitoring of flexible bronchoscopes after highlevel disinfection and flushing channels with alcohol: results and costs. Respir Med. 2015;109(8):1079-1085.	To assess whether bronchoscope processing methods achieved acceptable decontamination and whether manual flushing with alcohol reduced the risk of contamination.	IIIB	The results of the study suggest that the alcohol flush improves processing. The authors also concluded that microbiologic culturing is expensive and time consuming.	Quasi-experimental	Bronchoscopes used during a four year period	Alcohol flush/Cost analysis	N/A	620	Negative cultures
247	247	Muscarella LF. Application of environmental sampling to flexible endoscope reprocessing: the importance of monitoring the rinse water. Infect Control Hosp Epidemiol. 2002;23(5):285-289.	To determine the need for sampling of the rinse water used during endoscope reprocessing.	VA	The author recommends routine microbiologic sampling of the rinse water used during endoscope reprocessing.	Literature review	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
248	248	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.	To study the effects of peracetic-acid based disinfectant with and without additional drying on various microbes isolated from contaminated flexible endoscopes in single- and dual-species biofilms.	IIIB	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.	Nonexperimental	Single- and dual-species biofilm	Treatment with disinfectant	Moist environment compared with dry environment	4 single species/2 dual species	Colony forming units
249	249	Hagan ME, Klotz SA, Bartholomew W, Potter L, Nelson M. A pseudoepidemic of <i>Rhodotorula rubra</i> : a marker for microbial contamination of the bronchoscope. Infect Control Hosp Epidemiol. 1995;16(12):727-728.	To describe a pseudoepidemic of <i>Rhodotorula rubra</i> related to a contaminated bronchoscope.	VC	Disinfection control methods included gas sterilization of the bronchoscope and the institution of an alcohol and air flush through the suction channel to allow complete drying of the scope between each patient use. Since these measures were implemented there have been no further isolates.	Case report	Patients from whom <i>Rhodotorula rubra</i> was isolated from bronchial specimens	Review of cases/Evaluation of bronchoscopy equipment	N/A	11	Negative cultures
250											

Guideline for Processing Flexible Endoscopes
Evidence Table

	A	C	D	E	F	I	J	K	L	M	N
	REFERENCE NUMBER	CITATION	PURPOSE	CONSENSUS SCORE	RESULTS AND CONCLUSIONS	EVIDENCE TYPE	POPULATION	INTERVENTIONS	COMPARISON	SAMPLE SIZE	OUTCOME MEASURE
1	250	Carbonne A, Thiolet JM, Fournier S, et al. Control of a multi-hospital outbreak of KPC-producing <i>Klebsiella pneumoniae</i> type 2 in France, September to October 2009. Euro Surveill. 2010;15(48):pii:19734.	To describe a multi-hospital outbreak of <i>Klebsiella pneumoniae</i> carbapenemas-producing <i>Klebsiella pneumoniae</i> type 2, which occurred in a suburb south of Paris, France, in September and October 2009.	VA	The outbreak described in this report highlights the risk of transmitting multi-drug resistant bacteria through endoscopy and reinforces the need for adequate drying after each reprocessing cycle. The outbreak also demonstrates the usefulness of a coordinated healthcare-associated infection response system.	Case report	Cases of <i>Klebsiella pneumoniae</i> carbapenemas-producing <i>Klebsiella pneumoniae</i> type 2	Epidemiological investigation/Microbiological investigation/Evaluation of duodenoscope disinfection practices	Hospital infection control procedures/Absence of additional cases	N/A	N/A
251	251	Rutala WA, Weber DJ. ERCP scopes: what can we do to prevent infections? Infect Control Hosp Epidemiol. 2015;36(6):643-648.	To briefly discuss the outbreak described by Wendorf et al; to discuss what alternative exist today that might improve the safety margin associated with duodenoscope reprocessing; and to discuss how to prevent future outbreaks associated with flexible endoscopes.	VA	No single, immediately available strategy will eliminate this problem. However, the immediate risks can be minimized by a multicomponent strategy (eg, compliance with endoscope reprocessing guideline, high-level disinfection followed by ethylene oxide sterilization, and periodic microbiologic sampling).	Expert opinion	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
252	252	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.	To determine the type and amount of soil found on various types of flexible endoscopes after routine patient use both before and after cleaning.	IIA	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.	Quasi-experimental	Bronchoscopes/Duodenoscopes/Colonoscopes	Samples	Before and after cleaning	61	Amount and types of soil remaining on scopes
253	253	Foliente RL, Kovacs BJ, Apreco RM, Bains HJ, Kettering JD, Chen YK. Efficacy of high-level disinfectants for reprocessing GI endoscopes in simulated-use testing. Gastrointest Endosc. 2001;53(4):456-462.	To determine the efficacy of selected disinfection agents.	IIC	Commercially available high-level disinfectants are equally efficacious for reprocessing flexible endoscopes when used in conjunction with cleaning and in accordance with recommended guidelines.	Quasi-experimental	Colonoscopes/Duodenoscopes	Inoculation with <i>Mycobacterium chelonae</i>	Selected disinfection agents	10	Log reduction of colony forming units
254	254	Rutala WA, Weber DJ. FDA labeling requirements for disinfection of endoscopes: a counterpoint. Infect Control Hosp Epidemiol. 1995;16(4):231-235.	To discuss FDA labeling requirements for disinfection of endoscopes.	VB	To prevent the spread of infection, all endoscopes should undergo thorough cleaning and high-level disinfection following each use.	Expert opinion	Health care providers and others with an interest in endoscope processing	N/A	N/A	N/A	N/A
255	255	Guideline for selection and use of packaging systems for sterilization. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 2015:651-664.	To provide guidance to perioperative personnel for evaluating, selecting, and using packaging systems and for packaging the items to be sterilized and subsequently used in the perioperative setting.	IVA	Packaging systems should permit sterilization of the contents within the package, protect the integrity of the sterilized contents, prevent contamination of the contents until the package is opened for use, and permit the aseptic delivery of the contents to the sterile field.	Guideline	Perioperative RNs	N/A	N/A	N/A	N/A
256	256	Guideline for sterilization. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 2015:665-692.	To provide guidance for sterilizing items to be used in the perioperative setting.	IVA	These recommended practices include recommendations for high-temperature sterilization (ie, sterilization by steam), low-temperature sterilization (ie, ethylene oxide, low-temperature hydrogen peroxide gas plasma, low-temperature hydrogen peroxide vapor, dry heat, ozone), and processing using a liquid chemical sterilant system using peracetic acid.	Guideline	Perioperative RNs	N/A	N/A	N/A	N/A
257	257	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.	To provide guidance for disinfection and sterilization of prion-contaminated medical instruments.	IVA	Prion-contaminated medical devices that are impossible to clean or fully expose to steam and other sterilants should be discarded.	Guideline	Health care providers and others processing endoscopes	N/A	N/A	N/A	N/A
258	258										

Guideline for Processing Flexible Endoscopes
Evidence Table

	A	C	D	E	F	I	J	K	L	M	N
	REFERENCE NUMBER	CITATION	PURPOSE	CONSENSUS SCORE	RESULTS AND CONCLUSIONS	EVIDENCE TYPE	POPULATION	INTERVENTIONS	COMPARISON	SAMPLE SIZE	OUTCOME MEASURE
1	258	Widmer A. Prions and endoscopy: an unresolved problem. Zentralsterilisation. 2004;12(Suppl 1):70-77.	To discuss prions and the disinfection of flexible endoscopes.	VB	If risk patients are identified, cleaning improved, subsequent disinfection optimized, and the entire process documented and monitored, the risk of transmission can be reduced.	Expert opinion	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
259	259	Cooke RP, Goddard SV. Endoscopes and protective sheaths. J Hosp Infect. 2002;52(2):153-154.	To discuss endoscopes and protective sheaths.	VC	A clear statement from endoscope manufacturers on the efficacy and appropriateness of using protective sheaths followed by alcohol wipes for endoscope decontamination is clearly needed. This should include validation data subject to peer review before the standard of high-level disinfection is lowered.	Expert opinion	Health care providers and other using and processing flexible endoscopes	N/A	N/A	N/A	N/A
260	260	Lawrentschuk N, Chamberlain M. Sterile disposable sheath system for flexible cystoscopes. Urology. 2005;66(6):1310-1313.	To document experience using a flexible cystoscope with a disposable sheath in a urologic setting.	VC	Endoscopes with disposable sheaths are safe to use and comply with standard precautions in the prevention of cross contamination. Sheaths may provide protection against prions. They are an attractive alternative to current instrumentation and sterilization.	Case report	Consecutive patients undergoing flexible cystoureteroscopy performed in an office setting	Disposable sheaths	Cost of procedure using disposable sheath versus standard cystoscope	200	Infection/Patient experience/Cost
261	261	Baker KH, Chaput MP, Clavet CR, Varney GW, To TM, Lytle CD. Evaluation of endoscope sheaths as viral barriers. Laryngoscope. 1999;109(4):636-639.	To evaluate ear, nose, and throat endoscope sheaths as barriers to virus passage.	IIIC	Use of a sheath combined with intermediate level disinfection should provide a safe instrument of ear, nose, and throat endoscopy.	Nonexperimental	Ear, nose, and throat endoscope sheaths	Virus challenge	Number of virus particles	20	N/A
262	262	Elackattu A, Zoccoli M, Spiegel JH, Grundfast KM. A comparison of two methods for preventing cross-contamination when using flexible fiberoptic endoscopes in an otolaryngology clinic: disposable sterile sheaths versus immersion in germicidal liquid. Laryngoscope. 2010;120(12):2410-2416.	To assess the efficacy of using a sterile sheath to prevent cross-contamination when using a fiberoptic nasopharyngolaryngoscope in an otolaryngology clinic.	IIIB	Using an individually packaged disposable sterile sheath on a nasopharyngolaryngoscope prevents microbes from adhering to the shaft of the scope, thus providing a reasonably safe method of avoiding the transmission of infection to the next when using the scope successively on multiple patients.	Quasi-experimental	Nasopharyngolaryngoscopes	Microbiological cultures	Sheath versus high-level disinfection	100	Colony forming units
263	263	Mayinger B, Strenkert M, Hochberger J, Martus P, Kunz B, Hahn EG. Disposable-sheath, flexible gastroscope system versus standard gastroscopes: a prospective, randomized trial. Gastrointest Endosc. 1999;50(4):461-467.	To investigate the function, reprocessing, and hygienic status of the sheathed endoscope system in comparison with standard systems.	IB	Procedure time was slightly longer with the sheathed system. Set up and reprocessing times were significantly shorter. No post-procedure sheath leakage or rupture was seen.	Randomized controlled trial	Endoscopic procedures	Sheathed endoscope	Sheath versus standard	100	Procedure duration/Set up and reprocessing time/Preference/Rupture
264	264	Alvarado CJ, Anderson AG, Maki DG. Microbiologic assessment of disposable sterile endoscopic sheaths to replace high-level disinfection in reprocessing: a prospective clinical trial with nasopharyngoscopes. Am J Infect Control. 2009;37(5):408-413.	To report a prospective clinical trial with rigorous microbiologic assessment of a disposable, sterile, polyurethane sheath that can be easily and snugly applied to a nasopharyngoscope before performing the endoscopic procedure, with enzymatic cleansing and disinfection of the instrument with 70% ethanol following the procedure to determine whether the use of the sheath can provide reliable protection against bacterial contamination and obviate the need for routine high-level disinfection.	IA	Use of a high-quality, snugly fitting, sterile, disposable polyurethane sheath on a nasopharyngoscope during a clinical examination, combined with enzymatic detergent cleaning and disinfection with 70% ethanol, can provide a reliable decontaminated, patient-ready instrument, eliminating the need for high-level disinfection of endoscopes.	Randomized controlled trial	Patients undergoing examinations of the larynx and nasopharynx	Using a sheath on nasopharyngoscopes	Baseline and unused sheaths	100	Colony forming units
265	265										

Guideline for Processing Flexible Endoscopes
Evidence Table

	A	C	D	E	F	I	J	K	L	M	N
	REFERENCE NUMBER	CITATION	PURPOSE	CONSENSUS SCORE	RESULTS AND CONCLUSIONS	EVIDENCE TYPE	POPULATION	INTERVENTIONS	COMPARISON	SAMPLE SIZE	OUTCOME MEASURE
1	265	Colt HG, Beamis JJ, Harrell JH, Mathur PM. Novel flexible bronchoscope and single-use disposable-sheath endoscope system. A preliminary technology evaluation. Chest. 2000;118(1):183-187.	To measure image clarity, ease of use, and handling performance of a flexible fiberoptic bronchoscope and sterile, single-use disposable sheath endoscope system.	VB	The flexible fiberoptic bronchoscope with the sterile, single-use disposable sheath endoscope system has the potential to reduce scope downtime by eliminating the need for high-level disinfection between procedures. Illumination, image clarity, and ease of insertion are very good, justifying future prospective studies comparing this device to conventional flexible fiberoptic bronchoscopes.	Case report	Patients undergoing bronchoscopy	Use of a flexible fiberoptic bronchoscope and disposable sheath endoscope system	N/A	24	Satisfactory performance
266	266	Street I, Hamann J, Harries M. Audit of nasendoscope disinfection practice. Surgeon. 2006;4(1):11-13.	To audit the use of disposable sheaths over a six month period.	VC	Chlorine dioxide wipes were a satisfactory method of disinfection. There were no advantages to sheath use.	Organizational experience: financial	Nasoendoscopy procedures performed during a six month period	Audit of sheath use	Sheath use compared with automated processing and chlorine dioxide wipes	209	Reduced costs and ease of use
267	267	Jorgensen PH, Slotsbjerg T, Westh H, Buitenhuis V, Hermann GG. A microbiological evaluation of level of disinfection for flexible cystoscopes protected by disposable endosheaths. BMC Urol. 2013;13:46.	To make a microbiological post disinfection efficacy assessment of flexible cystoscopes using disposable sterile endosheaths.	IIIB	All 100 endosheaths passed the leak test. All samples showed a clean endoscope and low numbers of CFU.	Nonexperimental	Patients who underwent flexible cystoscopy	Microbiological sampling/Visual inspection	Traditional disinfection compared with endosheaths	100	Colony forming units/Contamination with body fluids
268	268	Guidance for manufacturers seeking marketing clearance of ear, nose, and throat endoscope sheaths used as protective barriers: guidance for industry. US Food and Drug Administration. http://www.fda.gov/RegulatoryInformation/Guidances/ucm073746.htm . Accessed December 9, 2015.		Reg							
269	269	FDA-cleared sterilants and high level disinfectants with general claims for processing reusable medical and dental devices—March 2015. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofReusableMedicalDevices/ucm437347.htm . Accessed December 9, 2015.		Reg							
270	270	Javed F, Sood S, Banfield G. Decontamination methods for flexible nasal endoscopes. Br J Nurs. 2014;23(15):850-852.	To investigate the current UK practices for decontaminating flexible nasal endoscopes.	IIIB	Decontamination with chlorine dioxide wipes was the most favored method, used in 58% of hospitals that participated in the study. Automated machines were also used in many places. Only a few used flexible sheaths.	Qualitative	Ear, nose and throat outpatient departments in the UK	Survey	N/A	121	Most common practices
271	271	Bhattacharyya N, Kepnes LJ. The effectiveness of immersion disinfection for flexible fiberoptic laryngoscopes. Otolaryngol Head Neck Surg. 2004;130(6):681-685.	To determine whether high-level disinfection renders fiberoptic laryngoscopes free of infectious microorganisms.	IIB	High-level disinfection provides a reasonably effective method of reducing bacterial and fungal contamination of flexible laryngoscopes.	Quasi-experimental	Flexible laryngoscopes	Culturing before use, mid-day, and at the end of the day	Control laryngoscopes contaminated with saliva	48	Positive cultures
272	272	Chang D, Florea A, Rowe M, Seiberling KA. Disinfection of flexible fiberoptic laryngoscopes after in vitro contamination with <i>Staphylococcus aureus</i> and <i>Candida albicans</i> . Arch Otolaryngol Head Neck Surg. 2012;138(2):119-121.	To determine the efficacy of various cleaning and disinfective methods in reducing bacterial and fungal load on flexible fiberoptic laryngoscopes.	IIB	Various different cleaning methods appeared to disinfect flexible laryngoscopes after experimental contamination with <i>Staphylococcus aureus</i> and <i>Candida albicans</i> in an in vitro model.	Quasi-experimental	Flexible laryngoscopes contaminated with <i>Staphylococcus aureus</i> and <i>Candida albicans</i>	Multiple cleaning methods	Results of cultures	100	N/A
273											

Guideline for Processing Flexible Endoscopes
Evidence Table

	A	C	D	E	F	I	J	K	L	M	N
	REFERENCE NUMBER	CITATION	PURPOSE	CONSENSUS SCORE	RESULTS AND CONCLUSIONS	EVIDENCE TYPE	POPULATION	INTERVENTIONS	COMPARISON	SAMPLE SIZE	OUTCOME MEASURE
1	273	Tzanidakis K, Choudhury N, Bhat S, Weerasinghe A, Marais J. Evaluation of disinfection of flexible nasendoscopes using Tristel wipes: a prospective single blind study. <i>Ann R Coll Surg Engl.</i> 2012;94(3):185-188.	To evaluate the in use efficacy of chlorine dioxide wipes in decontaminating nasendoscopes and to identify significant contamination between cleaning and usage.	IIIB	In use efficacy was 100%. Attention to hand hygiene and use of gloves should be considered when handling the cleaned scopes to minimize the risk of contamination between cleaning and application to patients.	Nonexperimental	Nasendoscope cleaning episodes	Microbiological sampling	After use compared with before use	31	Negative cultures
274	274	Liming B, Funnell I, Jones A, Demons S, Marshall K, Harsha W. An evaluation of varying protocols for highlevel disinfection of flexible fiberoptic laryngoscopes. <i>Laryngoscope.</i> 2014;124(11):2498-2501.	To evaluate and compare the efficacy of varying techniques of high-level disinfection of flexible fiberoptic laryngoscopes.	IIB	Quicker and more cost-effective practices are equally efficacious to more time-consuming and expensive techniques with regard to bacterial contamination of flexible fiberoptic laryngoscopes.	Quasi-experimental	Flexible fiberoptic laryngoscopes used for routine examinations on adult patients	Various disinfection protocols	Disinfection protocols compared with no decontamination and a 30 minute run in a mechanical processor	100	Negative bacterial growth
275	275	Phua CQ, Mahalingappa Y, Karagama Y. Sequential cohort study comparing chlorine dioxide wipes with automated washing for decontamination of flexible nasendoscopes. <i>J Laryngol Otol.</i> 2012;126(8):809-814.	To compare the efficacy and cost-effectiveness of chlorine dioxide wipes versus an automated washer and to calculate costs.	IIB	Chlorine dioxide wipes were more efficacious compared with the automated washer; however, the automated washer is cheaper to use in the long run.	Quasi-experimental	Flexible nasendoscopes	Microbiological sampling	Cleaning and disinfection with chlorine dioxide wipes compared with cleaning and disinfection in automated washer	3	Negative cultures
276	276	Foxcroft L, Monaghan W, Faoagali J. Controlled study of the Lancer FD8 drying/storage cabinet for endoscopes. <i>J GENCA.</i> 2008;18(2):5-11.	To determine whether the high efficiency particulate air drying cycle of the FD8 cabinet reduced the bacterial regrowth compared with the standard storage method and to review the time savings associated with a 72 hour hold time.	IIB	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.	Quasi-experimental	Endoscopes	Microbiological sampling	Endoscopes stored in the FD8 drying cabinet compared with endoscopes stored in open cabinets	32	Colony forming units
277	277	Pineau L, Villard E, Duc DL, Marchetti B. Endoscope drying/storage cabinet: interest and efficacy. <i>J Hosp Infect.</i> 2008;68(1):59-65.	To determine the efficacy of an endoscope drying and storage cabinet.	IIC	The results of this study confirm the inherent risk in maintaining a potentially contaminated, wet endoscope in a non-controlled environment.	Quasi-experimental	Endoscopes	Microbiological sampling after various periods of storage in a controlled drying cabinet	Comparison with storage in a non-controlled environment	3	Negative cultures
278	278	Wardle B. Endoscope storage cabinets. <i>J GENCA.</i> 2007;17(3):5.	To determine the effectiveness of a storage cabinet to store flexible endoscopes for up to 72 hours before reprocessing.	IIC	The results of the study suggest that flexible endoscopes may be stored for up to 72 hours in the cabinet without reprocessing before use.	Quasi-experimental	Colonoscopes/Gastrosopes	Microbiological sampling	Length of time stored in cabinet	8	Negative cultures
279	279	Rejchrt S, Cermak P, Pavlatova L, McKova E, Bures J. Bacteriologic testing of endoscopes after high-level disinfection. <i>Gastrointest Endosc.</i> 2004;60(1):76-78.	To evaluate the durability of high-level disinfection of endoscopes stored in a dust-proof cabinet for 5 days.	IIC	When endoscope reprocessing guidelines are strictly observed and the endoscopes are stored in a dust proof cabinet, they may be stored for up to 5 days without reprocessing.	Quasi-experimental	Endoscopes	Microbiological sampling	Immediately after HLD compared with after storage for 5 days	10	Negative cultures
280	280	Vergis AS, Thomson D, Pieroni P, Dhalla S. Reprocessing flexible gastrointestinal endoscopes after a period of disuse: is it necessary? <i>Endoscopy.</i> 2007;39(8):737-739.	To assess the microbiological stability of gastrointestinal endoscopes after high level disinfection.	IIB	With correct disinfection and storage, endoscopes may be store for up to 7 days to 2 weeks before reprocessing.	Quasi-experimental	Colonoscopes/Duodenoscopes	Microbiological sampling	Storage after 24 hours and 1 week	7	Negative cultures
281	281	Marino M, Grieco G, Moscato U, et al. Is reprocessing after disuse a safety procedure for bronchoscopy?: a cross-sectional study in a teaching hospital in Rome. <i>Gastroenterol Nurs.</i> 2012;35(5):324-330.	To determine whether reprocessing removes microbiological contamination and whether the instruments could be used safely after extended storage without repeating the disinfection before bronchoscopy.	IIB	Findings support the suggestion that reprocessing after storage can be avoided in the safe usage of the instrument if earlier decontaminations are performed correctly.	Quasi-experimental	Bronchoscopes	Microbiological cultures	Pre-processing compared with post-processing	264	Negative cultures
282	282	Ingram J, Gaines P, Kite R, Morgan M, Spurling S, Winsett RP. Evaluation of medically significant bacteria in colonoscopes after 8 weeks of shelf life in open air storage. <i>Gastroenterol Nurs.</i> 2013;36(2):106-111. <i>Nursing.</i> 2013;36(2):106-111.	To examine bacterial growth in colonoscopes in a series of graduated shelf times.	IIB	No medically significant growth was detected any of the culture points. Further evidence to assess fungal or viral growth is needed to make suggestions for colonoscope shelf life.	Quasi-experimental	Colonoscopes	Microbiological sampling	After cleaning and disinfection	4	Positive cultures
283											

Guideline for Processing Flexible Endoscopes
Evidence Table

	A	C	D	E	F	I	J	K	L	M	N
	REFERENCE NUMBER	CITATION	PURPOSE	CONSENSUS SCORE	RESULTS AND CONCLUSIONS	EVIDENCE TYPE	POPULATION	INTERVENTIONS	COMPARISON	SAMPLE SIZE	OUTCOME MEASURE
1	283	Grandval P, Hautefeuille G, Marchetti B, Pineau L, Laugier R. Evaluation of a storage cabinet for heatsensitive endoscopes in a clinical setting. J Hosp Infect. 2013;84(1):71-76.	To evaluate the efficiency of a storage cabinet for heat-sensitive endoscopes in a clinical setting.	IIIB	Use of the cabinet helped maintain the microbiological quality of endoscopes.	Nonexperimental	Endoscopes	Microbiological sampling	Heat sensitive storage cabinet/Regular storage cabinet/Regular cabinet plus disinfection	25	Colony forming units
284	284	Osborne S, Reynolds S, George N, Lindemayer F, Gill A, Chalmers M. Challenging endoscopy reprocessing guidelines: a prospective study investigating the safe shelf life of flexible endoscopes in a tertiary gastroenterology unit. Endoscopy. 2007;39(9):825-830.	To estimate a safe shelf life for flexible endoscopes in a high-turnover gastroenterology unit.	IIIB	When processed according to established guidelines, flexible endoscopes remain free from pathogenic organisms between last case and next day first case use.	Nonexperimental	Endoscopes in active use during a three week period in a high turnover gastroenterology unit	Microbiological sampling	N/A	200	Negative cultures
285	285	Alfa MJ, Sepehri S, Olson N, Wald A. Establishing a clinically relevant bioburden benchmark: a quality indicator for adequate reprocessing and storage of flexible gastrointestinal endoscopes. Am J Infect Control. 2012;40(3):233-236.	To assess the bioburden in routinely processed flexible gastrointestinal endoscopes stored over the weekend for 48 hours and to define a realistic benchmark for residual microbial levels.	IIIB	The researchers recommend 100 CFU/mL as a reliable and routinely achievable cutoff for bioburden residuals in processed endoscope channels.	Nonexperimental	Gastrointestinal endoscopes	Sampling all channels for bacteria and fungi	Colony forming unit/mL	141	N/A
286	286	Brock AS, Steed LL, Freeman J, Garry B, Malpas P, Cotton P. Endoscope storage time: assessment of microbial colonization up to 21 days after reprocessing. Gastrointest Endosc. 2015;81(5):1150-1154.	To demonstrate whether flexible endoscopes may be stored for as long as 21 days after reprocessing without colonization by pathogenic microbes.	IIIB	Endoscopes can be stored for as long as 21 days after standard reprocessing with a low risk of pathogenic microbial colonization. Extension of reprocessing protocols for 21 days could effect significant cost savings.	Nonexperimental	Duodenoscopes/Colonoscopes/Gastroscopes	Microbial sampling	N/A	96	Negative cultures
287	287	Riley R, Beanland C, Bos H. Establishing the shelf life of flexible colonoscopes. Gastroenterol Nurs. 2002;25(3):114-119.	To determine the shelf life of flexible colonoscopes and to validate the adequacy of cleaning procedures for flexible endoscopes.	IIIB	The findings suggest that colonoscopes may be left for up to 1 week before needing to be reprocessed before use.	Nonexperimental	Colonoscope	Cleaning validation/Microbiological sampling	Storage after 24 hours and 1 week	1	Negative cultures
288	288	Thomas LA. Essentials for endoscopic equipment. Recommended care and handling of flexible endoscopes: endoscope storage. Gastroenterol Nurs. 2005;28(1):45-46.	To provide guidance for storage of flexible endoscopes.	VB	Storage of flexible endoscopes revolves around three basic safeguarding principles: ownership, device safety, and infection control.	Expert opinion	Health care providers and others processing and storing flexible endoscopes	N/A	N/A	N/A	N/A
289	289	Nomides N, Sweeney J, Sturm L, et al. Ready for patient use? Implementing a visual cue for high level disinfected endoscopes. Am J Infect Control. 2014;42:S40-S41.	To address a gap in the process of endoscope reprocessing that could affect patient safety.	VA	Use of a distinct visual cue is an effective way to identify reprocessed endoscopes and improve patient safety.	Organizational experience: quality improvement	Large academic health system where endoscopes are utilized in numerous procedural areas	Use of a visual cue to confirm processing of endoscope	N/A	N/A	Address gap in practice to define reprocessed from unprocessed endoscopes
290	290	Muscarella LF. The study of a contaminated colonoscope. Clin Gastroenterol Hepatol. 2010;8(7):577-580.e1.	To report on the study of a contaminated colonoscope	VA	The periodic monitoring of a GI endoscope may be performed to evaluate the effectiveness of an endoscope processing procedure or to determine the cause of an identified infection.	Case report	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
291	291	Saliou P, Baron R. Method for assessing the microbial contamination of GI endoscopes. Gastrointest Endosc. 2015;82(3):582.	To respond to Brock's proposed 21 day storage	VA	The culture medium may have affected their results. See Brock #4954	Expert opinion	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
292											

Guideline for Processing Flexible Endoscopes
Evidence Table

	A	C	D	E	F	I	J	K	L	M	N
	REFERENCE NUMBER	CITATION	PURPOSE	CONSENSUS SCORE	RESULTS AND CONCLUSIONS	EVIDENCE TYPE	POPULATION	INTERVENTIONS	COMPARISON	SAMPLE SIZE	OUTCOME MEASURE
1	292	Schmelzer M, Daniels G, Hough H. Safe storage time for reprocessed flexible endoscopes: a systematic review. JBI Database System Rev Implement Rep. 2015;13(9):187-243.	To systematically review the evidence related to endoscope storage time	IIIC	7 days. Length of storage depends on effective processing, thorough drying, storage conditions, surveillance.	Systematic review	Articles related to endoscope storage	Search and analysis	N/A	11	Length of acceptable storage
293	293	Guideline for health care information management. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 2015:491-512.	These recommended practices provide guidance to assist perioperative nurses in documenting and managing patient care information within the perioperative practice setting.	IVB	Documentation includes related information about the patient's current and past health status, nursing diagnoses and interventions, expected patient outcomes, and evaluation of the patient's response to perioperative nursing care.	Guideline	Perioperative RNs	N/A	N/A	N/A	N/A
294	294	State Operations Manual Appendix A—Survey Protocol, Regulations and Interpretive Guidelines for Hospitals. Rev. 105. Washington, DC: Department of Health and Human Services, Centers for Medicare & Medicaid Services. 2014.		Reg							
295	295	State Operations Manual Appendix L—Guidance for Surveyors: Ambulatory Surgical Centers. Rev. 99. Washington, DC: Department of Health and Human Services, Centers for Medicare & Medicaid Services. 2014.		Reg							
296	296	42 CFR 482. Conditions of participation for hospitals. 2013. US Government Publishing Office. https://www.gpo.gov/fdsys/granule/CFR-2011-title42-vol5/CFR-2011-title42-vol5-part482/content-detail.html . Accessed December 10, 2015.		Reg							
297	297	42 CFR 416: Ambulatory surgical services. 2013. US Government Publishing Office. https://www.gpo.gov/fdsys/granule/CFR-2011-title42-vol3/CFR-2011-title42-vol3-part416 . Accessed December 10, 2015.		Reg							
298	298	RC.01.01.01: The hospital maintains complete and accurate medical records for each individual patient. In: Hospital Accreditation Standards. 2014 ed. Oakbrook Terrace, IL: Joint Commission Resources; 2014.		Acc							
299	299	MS.16 Medical record maintenance. In: NIAHO Interpretive Guidelines and Surveyor Guidance. 10.1 ed. Milford, OH: DNV Healthcare Inc; 2012:29.		Acc							
300	300	RC.01.01.01: The organization maintains complete and accurate clinical records. In: Standards for Ambulatory Care 2014: Standards, Elements of Performance, Scoring, Accreditation Policies. Oakbrook Terrace, IL: Joint Commission Resources; 2014.		Acc							
301	301	Clinical records and health information. In: 2014 Accreditation Handbook for Ambulatory Health Care. Skokie, IL: Accreditation Association for Ambulatory Health Care; 2014:37-39.		Acc							
302											

Guideline for Processing Flexible Endoscopes
Evidence Table

	A	C	D	E	F	I	J	K	L	M	N
	REFERENCE NUMBER	CITATION	PURPOSE	CONSENSUS SCORE	RESULTS AND CONCLUSIONS	EVIDENCE TYPE	POPULATION	INTERVENTIONS	COMPARISON	SAMPLE SIZE	OUTCOME MEASURE
1	302	Medical records: pre-operative medical record. In: Regular Standards and Checklist for Accreditation of Ambulatory Surgery Facilities. Version 14 ed. Gurnee, IL: American Association for Accreditation of Ambulatory Surgery Facilities; 2014:59-60.		Acc							
303	303	Medical records: operating room records. In: Regular Standards and Checklist for Accreditation of Ambulatory Surgery Facilities. Version 14 ed. Gurnee, IL: American Association for Accreditation of Ambulatory Surgery Facilities; 2014:62-64.		Acc							
304	304	Medical records: general. In: Regular Standards and Checklist for Accreditation of Ambulatory Surgery Facilities. Version 14 ed. Gurnee, IL: American Association for Accreditation of Ambulatory Surgery Facilities; 2014:58-59.		Acc							
305	305	Medical records: general. In: Procedural Standards and Checklist for Accreditation of Ambulatory Surgery Facilities. Version 3 ed. Gurnee, IL: American Association for Accreditation of Ambulatory Surgery Facilities; 2011:60-61.		Acc							
306	306	Medical records: procedure room records. In: Procedural Standards and Checklist for Accreditation of Ambulatory Surgery Facilities. Version 3 ed. Gurnee, IL: American Association for Accreditation of Ambulatory Surgery Facilities; 2011:64-66.		Acc							
307	307	Standards of perioperative nursing practice. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 2015:693-708.	The standards of perioperative nursing provide a mechanism to delineate the responsibilities of RNs engaged in practice in the perioperative setting. These standards serve as the basis for quality monitoring and evaluation systems; databases; regulatory systems; the development and evaluation of nursing service delivery systems and organizational structures; certification activities; job descriptions and performance appraisals; agency policies, procedures, and protocols; and educational offerings. The standards of perioperative nursing are generic and apply to all RNs engaged in perioperative practice, regardless of clinical setting, practice setting, or educational preparation.	IVB	It is the perioperative RN's responsibility to meet these standards, assuming that adequate environmental working conditions and necessary resources are available to support and facilitate the nurse's attainment of these standards.	Guideline	Perioperative RNs	N/A	N/A	N/A	N/A
308											

Guideline for Processing Flexible Endoscopes
Evidence Table

	A	C	D	E	F	I	J	K	L	M	N
	REFERENCE NUMBER	CITATION	PURPOSE	CONSENSUS SCORE	RESULTS AND CONCLUSIONS	EVIDENCE TYPE	POPULATION	INTERVENTIONS	COMPARISON	SAMPLE SIZE	OUTCOME MEASURE
1	308	Jordan C, Thomas MB, Evans ML, Green A. Public policy on competency: how will nursing address this complex issue? J Contin Educ Nurs. 2008;39(2):86-91.	To provide an overview of international, national, and state perspectives and approaches in addressing the issue of assuring competency from a public policy perspective, including one state's experience to date.	VA	The primary responsibility for maintaining ongoing competency remains with the individual licensee.	Expert opinion	Nurses and members of the public	N/A	N/A	N/A	N/A
309											
310	309	HR.01.05.03: Staff participate in ongoing education and training. In: Comprehensive Accreditation Manual: CAMH for Hospitals. 2014 ed. Oakbrook Terrace, IL: Joint Commission Resources; 2014.		Acc							
311											
312	310	MS.10 Continuing education. In: NIAHO Interpretive Guidelines and Surveyor Guidance. 10.1 ed. Milford, OH: DNV Healthcare Inc; 2012:24.		Acc							
313											
314	311	HR.01.05.03: Staff participate in ongoing education and training. In: Comprehensive Accreditation Manual: CAMAC for Ambulatory Care. 2014 ed. Oakbrook Terrace, IL: Joint Commission Resources; 2014.		Acc							
315											
316	312	Governance. In: 2014 Accreditation Handbook for Ambulatory Health Care. Skokie, IL: Accreditation Association for Ambulatory Health Care; 2014:19-26.		Acc							
317											
318	313	Personnel: personnel records; individual personnel files. In: Regular Standards and Checklist for Accreditation of Ambulatory Surgery Facilities. Version 14 ed. Gurnee, IL: American Association for Accreditation of Ambulatory Surgery Facilities; 2014:75-76.		Acc							
319											
320	314	Personnel: knowledge, skill & CME training. In: Regular Standards and Checklist for Accreditation of Ambulatory Surgery Facilities. Version 14 ed. Gurnee, IL: American Association for Accreditation of Ambulatory Surgery Facilities; 2014:77-78.		Acc							
321											
322	315	Personnel: personnel safety. In: Procedural Standards and Checklist for Accreditation of Ambulatory Surgery Facilities. Version 3 ed. Gurnee, IL: American Association for Accreditation of Ambulatory Surgery Facilities; 2011:79-80.		Acc							
323											
324	316	Personnel: knowledge, skill & CME training. In: Procedural Standards and Checklist for Accreditation of Ambulatory Surgery Facilities. Version 3 ed. Gurnee, IL: American Association for Accreditation of Ambulatory Surgery Facilities; 2011:79.		Acc							
325											

Guideline for Processing Flexible Endoscopes
Evidence Table

	A	C	D	E	F	I	J	K	L	M	N
	REFERENCE NUMBER	CITATION	PURPOSE	CONSENSUS SCORE	RESULTS AND CONCLUSIONS	EVIDENCE TYPE	POPULATION	INTERVENTIONS	COMPARISON	SAMPLE SIZE	OUTCOME MEASURE
1	317	Jackson FW, Ball MD. Correction of deficiencies in flexible fiberoptic sigmoidoscope cleaning and disinfection technique in family practice and internal medicine offices. Arch Fam Med. 1997;6(6):578-582.	To assess whether deficiencies exist in the processing of contaminated flexible sigmoidoscopes in family practice and internal medicine offices and whether training of office personnel results in a correction of identified deficiencies.	IIC	Personnel responsible for processing flexible endoscopes in family practice and internal medicine offices are insufficiently trained for this function. After training, these persons maintain their equipment close to, or according to standards.	Quasi-experimental	Processing personnel from family practice and internal medicine offices	Pre-text/Post-test	Compliance with recognized standards	14 family practice/5 internal medicine	Improved compliance with recognized standards
318	318	Lunn W, Garland R, Gryniuk L, Smith L, Feller-Kopman D, Ernst A. Reducing maintenance and repair costs in an interventional pulmonology program. Chest. 2005;127(4):1382-1387.	To report their experience with repairs to equipment before and after starting an interventional pulmonary program, and the effect of an educational program on reducing these costs.	VB	An educational program was effective in dramatically decreasing the costs of equipment repair after initiating an interventional pulmonary program.	Organizational experience: financial	Bronchoscopes used during an eight year period	Retrospective chart review/Cost analysis/Educational program	Repair costs before and after introduction of an IP program and the educational program	N/A	Reduced repairs and costs
319	319	LD.04.01.07: The hospital has policies and procedures that guide and support patient care, treatment, and services. In: Hospital Accreditation Standards. 2014 ed. Oakbrook Terrace, IL: Joint Commission Resources; 2014.		Acc							
320	320	SS.1: Organization. In: NIAHO Interpretive Guidelines and Surveyor Guidance. 10.1 ed. Milford, OH: DNV Healthcare Inc; 2012:70-71.		Acc							
321	321	LD.04.01.07: The organization has policies and procedures that guide and support patient care, treatment, or services. In: Standards for Ambulatory Care 2014: Standards, Elements of performance, Scoring, Accreditation policies. Oakbrook Terrace, IL: Joint Commission Resources; 2014.		Acc							
322	322	Personnel: personnel safety. In: Regular Standards and Checklist for Accreditation of Ambulatory Surgery Facilities. Version 14 ed. Gurnee, IL: American Association for Accreditation of Ambulatory Surgery Facilities; 2014:79.		Acc							
323	323	Personnel: personnel records. In: Procedural Standards and Checklist for Accreditation of Ambulatory Surgery Facilities. Version 3 ed. Gurnee, IL: American Association for Accreditation of Ambulatory Surgery Facilities; 2011:77-79.		Acc							
324	324	200.35: High Level Disinfection of Endoscopes. In: Regular Standards and Checklist for Accreditation of Ambulatory Surgery Facilities. Gurnee, IL: American Association for Accreditation of Ambulatory Surgery Facilities; 2014:28.		Acc							
325	325	200.40: Instrument Processing. In: Regular Standards and Checklist for Accreditation of Ambulatory Surgery Facilities. Gurnee, IL: American Association for Accreditation of Ambulatory Surgery Facilities; 2014:28.		Acc							
326											

Guideline for Processing Flexible Endoscopes
Evidence Table

	A	C	D	E	F	I	J	K	L	M	N
	REFERENCE NUMBER	CITATION	PURPOSE	CONSENSUS SCORE	RESULTS AND CONCLUSIONS	EVIDENCE TYPE	POPULATION	INTERVENTIONS	COMPARISON	SAMPLE SIZE	OUTCOME MEASURE
1	326	200.30: Procedures—Sterilization. In: Procedural Standards and Checklist for Accreditation of Ambulatory Surgery Facilities. Gurnee, IL: American Association for Accreditation of Ambulatory Surgery Facilities; 2011:34-36.		Acc							
327	327	PI.03.01.01: The hospital improves performance on an ongoing basis. In: Hospital Accreditation Standards. 2014 ed. Oakbrook Terrace, IL: Joint Commission Resources; 2014.		Acc							
328	328	IC.02.01.01: The hospital implements its infection prevention and control plan. In: Comprehensive Accreditation Manual for Hospitals e-dition. Washington, DC: The Joint Commission; August 2014.		Acc							
329	329	IC.02.02.01: The hospital reduces the risk of infections associated with medical equipment, devices, and supplies. In: Comprehensive Accreditation Manual for Hospitals e-dition. Washington, DC: The Joint Commission; August 2014.		Acc							
330	330	IC.03.01.01: The hospital evaluates the effectiveness of its infection prevention and control plan. In: Comprehensive Accreditation Manual for Hospitals e-dition. Washington, DC: The Joint Commission; August 2014.		Acc							
331	331	EC.02.04.03: The hospital inspects, tests, and maintains medical equipment. In: Hospital Accreditation Standards. 2015 ed. Oakbrook Terrace, IL: Joint Commission Resources; 2015.		Acc							
332	332	Quality management system. In: NIAHO Interpretive Guidelines and Surveyor Guidance. 10.1 ed. Milford, OH: DNV Healthcare Inc; 2012:10-16.		Acc							
333	333	Infection prevention and control. In: NIAHO Accreditation Requirements Interpretive Guidelines & Surveyor Guidance. 10.1 ed. Milford, OH: DNV Healthcare; 2012.		Acc							
334	334	Physical environment. PE.1 Facility. In: NIAHO Accreditation Requirements Interpretive Guidelines & Surveyor Guidance Revision. 10.1 ed. Milford, OH: DNV Healthcare; 2012.		Acc							
335	335	PI.03.01.01: The organization improves performance. In: Standards for Ambulatory Care 2014: Standards, Elements of Performance, Scoring, Accreditation Policies. Oakbrook Terrace, IL: Joint Commission Resources; 2014.		Acc							
336											

Guideline for Processing Flexible Endoscopes
Evidence Table

	A	C	D	E	F	I	J	K	L	M	N
	REFERENCE NUMBER	CITATION	PURPOSE	CONSENSUS SCORE	RESULTS AND CONCLUSIONS	EVIDENCE TYPE	POPULATION	INTERVENTIONS	COMPARISON	SAMPLE SIZE	OUTCOME MEASURE
1	336	IC.02.01.01: The organization implements infection prevention and control activities. In: Comprehensive Accreditation Manual for Ambulatory Care e-dition. Washington, DC: The Joint Commission; August 2014.		Acc							
337	337	IC.02.02.01: The organization reduces the risk of infections associated with medical equipment, devices, and supplies. In: Comprehensive Accreditation Manual for Ambulatory Care e-dition. Washington, DC: The Joint Commission; August 2014.		Acc							
338	338	IC.03.01.01: The organization evaluates the effectiveness of its infection prevention and control activities. In: Comprehensive Accreditation Manual for Ambulatory Care e-dition. Washington, DC: The Joint Commission; August 2014.		Acc							
339	339	EC.02.04.03: The organization inspects, tests, and maintains medical equipment. In: Ambulatory Accreditation Standards. 2015 ed. Oakbrook Terrace, IL: Joint Commission Resources; 2015.		Acc							
340	340	Quality management and improvement. In: Accreditation Handbook for Ambulatory Health Care. Skokie, IL: Accreditation Association for Ambulatory Health Care; 2014:32-36.		Acc							
341	341	Infection prevention and control and safety. In: Accreditation Handbook for Ambulatory Health Care. Skokie, IL: Accreditation Association for Ambulatory Health Care; 2014:40-43.		Acc							
342	342	Facilities and environment. In: Accreditation Handbook for Ambulatory Health Care. Skokie, IL: Accreditation Association for Ambulatory Health Care; 2014:44-45.		Acc							
343	343	Quality assessment/quality improvement: quality improvement. In: Regular Standards and Checklist for Accreditation of Ambulatory Surgery Facilities. Version 14 ed. Gurnee, IL: American Association for Accreditation of Ambulatory Surgery Facilities; 2014:65.		Acc							
344	344	Quality assessment/quality improvement: unanticipated operative sequelae. In: Regular Standards and Checklist for Accreditation of Ambulatory Surgery Facilities. Version 14 ed. Gurnee, IL: American Association for Accreditation of Ambulatory Surgery Facilities; 2014:68-70.		Acc							
345											

Guideline for Processing Flexible Endoscopes
Evidence Table

	A	C	D	E	F	I	J	K	L	M	N
	REFERENCE NUMBER	CITATION	PURPOSE	CONSENSUS SCORE	RESULTS AND CONCLUSIONS	EVIDENCE TYPE	POPULATION	INTERVENTIONS	COMPARISON	SAMPLE SIZE	OUTCOME MEASURE
346	345	Operating room policy, environment, and procedures: equipment. In: Regular Standards and Checklist for Accreditation of Ambulatory Surgery Facilities. Version 14 ed. Gurnee, IL: American Association for Accreditation of Ambulatory Surgery Facilities; 2014:45.		Acc							
347	346	Evans P. Cystoscope reprocessing safety: one practice's experience. AAACN Viewpoint. 2014;36(2):10-11.	To describe how an organization worked to improve cystoscopy reprocessing to enhance patient safety.	VB	The team members report improved confidence in their ability to reprocess the equipment and feel that they are taking steps to ensure patient safety.	Organizational experience: quality improvement	Urology office	Literature review/Review of current processes/Gap analysis/Education/Process improvement monitor	Before and after quality improvement interventions	N/A	Compliance
348	347	Angtuaco TL, Oprescu FG, Lal SK, et al. Universal precautions guideline: self-reported compliance by gastroenterologists and gastrointestinal endoscopy nurses—a decade's lack of progress. Am J Gastroenterol. 2003;98(11):2420-2423.	To assess and compare universal precaution practices of gastroenterologists and gastrointestinal endoscopy nurses.	IIIC	Nurses adhered to universal precaution better than gastroenterologists. Nonetheless, for both groups, compliance with hand washing and use of gloves, face shields, and gowns was very poor.	Qualitative	Gastroenterologists and GI endoscopy nurses	Questionnaire	Gastroenterologists and GI endoscopy nurses	77/157	Compliance with universal precautions
349	348	Baudet JS, Martín JM, Sánchez del Río A, Aguirre-Jaime A. Occupational risk prevention in endoscopy units: a pending issue. Rev Esp Enferm Dig. 2011;103(2):83-88.	To assess compliance with occupational risk prevention measures in gastrointestinal endoscopy units.	IIIB	Compliance is inadequate and should be improved. Public hospitals comply with fewer occupational risk prevention measures than private facilities.	Qualitative	Gastrointestinal endoscopy units	Survey	Compliance with occupational risk prevention measures	198	N/A
350	349	Joint Working Group of the Hospital Infection Society (HIS) and the Public Health Laboratory Service (PHLS). Rinse water for heat labile endoscopy equipment. J Hosp Infect. 2002;51(1):7-16.	The problems relating to the prevention of contamination of rinse water and its monitoring procedures have not been addressed previously.	IVA	Problems are identified and guidance provided on the monitoring and provision of high-quality rinse water.	Clinical practice guideline	Health care providers and other processing flexible endoscopes	N/A	N/A	N/A	N/A
351	350	Kovaleva J, Degener JE, van der Mei HC. Methylobacterium and its role in health care-associated infection. J Clin Microbiol. 2014;52(5):1317-1321.	To present an overview of documented infections and cross-contaminations with Methylobacterium related to endoscopic procedures and to illustrate the health care associated relevance of this slow-growing bacterium.	VA	Due to its slow growth, the bacterium can be easily missed during surveillance of endoscope reprocessing. The ability to form biofilms and to exhibit tolerance to cleaning and disinfecting agents and to high temperatures and is probably the cause of their prevalence in hospital environments, particularly in tap water and endoscope channels.	Literature review	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
352	351	Phillips G, McEwan H, Butler J. Quality of water in washer-disinfectors. J Hosp Infect. 1995;31(2):152-154.	To discuss a project conducted to determine the effectiveness of filters supplied with a new washer disinfectant in producing bacteria free water.	VC	There was a wide variation in the microbiological colony counts depending partly on where the samples were taken in relation to decontamination of the filters.	Quality improvement: organizational improvement	Health care providers and others processing endoscopes	Microbiological sampling of water from various locations	N/A	N/A	Negative cultures
353	352	Marek A, Smith A, Peat M, et al. Endoscopy supply water and final rinse testing: five years of experience. J Hosp Infect. 2014;88(4):207-212.	To report experience gained over five years of testing, reporting and managing the quality of final rinse water for endoscopic devices.	VA	Quality control principles coupled with appropriate thermal and chemical disinfection of endoscope washer disinfectors resulted in the achievement of microbiological standards for final rinse water.	Organizational experience: quality improvement	Endoscopic reprocessing units	Rigorous methods for testing, reporting and managing quality of final rinse water	N/A	3	Compliance with national levels
354	353	Cooke RP. Hazards of water. J Hosp Infect. 2004;57(4):290-293.	To discuss the hazards of water relative to endoscope processing.	VB	The microbiological quality of rinse water is of critical importance in endoscopy procedures. Rinse water not only removes toxic chemical residues after endoscopic disinfections, but also acts as a valuable biological indicator.	Expert opinion	Health care providers and others using and processing flexible endoscopes	N/A	N/A	N/A	N/A

Guideline for Processing Flexible Endoscopes
Evidence Table

	A	C	D	E	F	I	J	K	L	M	N
	REFERENCE NUMBER	CITATION	PURPOSE	CONSENSUS SCORE	RESULTS AND CONCLUSIONS	EVIDENCE TYPE	POPULATION	INTERVENTIONS	COMPARISON	SAMPLE SIZE	OUTCOME MEASURE
1	354	Cooke RP, Whyment-Morris A, Umasankar RS, Goddard SV. Bacteria-free water for automatic washer-disinfectors: an impossible dream? J Hosp Infect. 1998;39(1):63-65.	To examine the ability of new automatic washer-disinfectors systems with a water filtration system to provide bacteria-free water for flexible bronchoscopes.	IIIC	Although mycobacterial contamination of bronchoscopes was not evident, the water filtration system was unable to reliably provide sterile rinse water.	Nonexperimental	Washer-disinfectors	Water samples/Bronchoalveolar samples	Positive versus negative cultures	53 water samples/60 Bronchoalveolar samples	Culture results
355	355	Curtis B, Cooke RPD, Whyment-Morris A, Umasankar RS, Goddard SV. Testing water quality for automatic washer-disinfectors (multiple letters) [5]. J Hosp Infect. 1999;42(1):74-76.	To respond to the report by Cooke (Ref ID #1997)	VB	Bacteria free water is possible, but a rigorous protocol is required.	Expert opinion	Health care providers and others processing endoscopes	N/A	N/A	N/A	N/A
356	356	Falkinham JO 3rd. Hospital water filters as a source of Mycobacterium avium complex. J Med Microbiol. 2010;59(Pt 10):1198-1202.	To collect samples from the hospital water system and bronchoscopy-processing laboratory, test them for the presence of Mycobacteria, and, if recovered, compare the DNA fingerprints of the patient and environmental isolates.	VC	Bronchoscopes and the filters used for washing them were found to yield high numbers of Mycobacteria sharing the same fingerprint as Mycobacterium recovered from patient samples collected by bronchoscopy. Improved cleaning, drying and storage procedures, combined with new filters have resolved the problem.	Case report	Health care providers and others with an interest in preventing endoscopy-related infection	Microbial sampling/Observation of processing	Before and after changing filters and remediating processes	51	Negative cultures
357	357	Rossetti R, Lencioni P, Innocenti F, Tortoli E. Pseudoepidemic from Mycobacterium gordonae due to a contaminated automatic bronchoscope washing machine. Am J Infect Control. 2002;30(3):196-197.	To report on the repeated isolation of Mycobacterium gordonae from outpatients undergoing bronchoscopy	VB	The organism was isolated from samples of tap water feeding the washing machine and from the filtering unit.	Case report	Bronchial aspirate cultures with isolates of acid fast bacilli	Microbiological sampling	N/A	16	Negative cultures
358	358	Khalsa K, Smith A, Morrison P, et al. Contamination of a purified water system by Aspergillus fumigatus in a new endoscopy reprocessing unit. Am J Infect Control. 2014;42(12):1337-1339.	To describe the detection and management of Aspergillus fumigatus contamination of a new reverse osmosis unit supplying 10 automated endoscope reprocessors basins.	VB	These findings support the use of purified water for final rinsing of endoscopes, but systems must still be accompanied by appropriate quality monitoring of the purified water.	Case report	Reverse osmosis unit supplying automated endoscope reprocessors	Microbiological surveillance	N/A	N/A	N/A
359	359	Mitchell DH, Hicks LJ, Chiew R, Montanaro JC, Chen SC. Pseudoepidemic of Legionella pneumophila serogroup 6 associated with contaminated bronchoscopes. J Hosp Infect. 1997;37(1):19-23.	To report a pseudoepidemic involving Legionella pneumophila .	VB	This report demonstrates that the environment is a potential source of endoscope decontamination, and that this may occur despite adequate precleaning and disinfection procedures if non-sterile rinse water is used.	Case report	Patients with Legionella pneumophila isolated from bronchial aspirate specimens	Observation of processes/DNA fingerprinting	Comparison of DNA fingerprints from isolates	3 + 2	Negative cultures
360	360	Kiely JL, Sheehan S, Cryan B, Bredin CP. Isolation of Mycobacterium chelonae in a bronchoscopy unit and its subsequent eradication. Tuber Lung Dis. 1995;76(2):163-167.	To identify and assess the importance of factors thought to be relevant in the etiology of these contamination events and by removing these factors, to eradicate the problem of continuing Mycobacterium chelonae contamination.	VC	Insertion of bacterial filters into the water supply, with the addition of a more sophisticated semi-automatic cleaning machine involving an ultrasound cycle in addition to conventional cleaning methods currently used, will help reduce or eradicate contamination events with M chelonae in bronchoscopy units.	Case report	Patients undergoing bronchoscopic examination	Insertion of bacterial filters/Installation of a new semi-automatic cleaning machine	Before and after changes	7	Negative cultures
361	361	Phillips L. Identification and resolution of contamination causes found in flexible endoscopes. Gastroenterol Nurs. 1997;20(1):9-11.	To discuss the identification and resolution of contamination causes found in flexible endoscopes	VC	Tap water was eventually determined to be the source of the contamination problem	Quality improvement: organizational improvement	Health care providers and others processing endoscopes	Microbiological sampling of water from various locations	N/A	N/A	Negative cultures
362	362	Hubner NO, Assadian O, Poldrack R, et al. Endowashers: an overlooked risk for possible postendoscopic infections. GMS Krankenhhyg Interdiszip. 2011;6(1):o13.	To investigate the potential for endowashers to act as a possible source of infection.	IIB	Endowashers can be a potential source of infection. They are not routinely sampled microbiologically.	Quasi-experimental	Endowashers	Microbiological sampling	N/A	44	Colony forming units
363	363	Robertson P, Smith A, Mead A, et al. Risk-assessment-based approach to patients exposed to endoscopes contaminated with Pseudomonas spp. J Hosp Infect. 2015;90(1):66-69.	To describe a two-phase risk assessment following pseudomonal contamination of a family of 75 endoscopes, detected through routine surveillance and attributed to one endoscope washer-disinfectant.	VB	No patients developed complications due to infection.	Case Report	Patients assessed as higher risk of infection	Two-phase risk assessment	N/A	9	Absence of infection
364											

Guideline for Processing Flexible Endoscopes
Evidence Table

	A	C	D	E	F	I	J	K	L	M	N
	REFERENCE NUMBER	CITATION	PURPOSE	CONSENSUS SCORE	RESULTS AND CONCLUSIONS	EVIDENCE TYPE	POPULATION	INTERVENTIONS	COMPARISON	SAMPLE SIZE	OUTCOME MEASURE
1	364	Phillips G, McEwan H, McKay I, Crowe G, McBeath J. Black pigmented fungi in the water pipe-work supplying endoscope washer disinfectors. <i>J Hosp Infect.</i> 1998;40(3):250-251.	To report an experience in finding biofilm on the water pipe-work supplying an automated washer disinfectant used for decontaminating flexible endoscopes	VC	Specific fungal cultures have been added to the routine monitoring of the rinse water.	Quality improvement: organizational improvement	Health care providers and others processing endoscopes	Microbiological sampling of water from various locations	N/A	N/A	Negative cultures
365	365	Imbert G, Seccia Y, La Scola B. <i>Methylobacterium</i> sp. bacteraemia due to a contaminated endoscope. <i>J Hosp Infect.</i> 2005;61(3):268-270.	To report on the case of a patient who developed bacteraemia due to <i>Methylobacterium mesophilicum</i> following ERCP.	VC	The infection was linked to a contaminated endoscope.	Case report	Patient who underwent ERCP and developed bacteraemia	Microbiological sampling of water from various locations	N/A	1	Positive cultures
366	366	Choice Framework for local Policy and Procedures 01-06—Decontamination of flexible endoscopes: Validation and verification. 2013. UK Department of Health. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/148562/CFPP_01-06_Validation_Final.pdf . Accessed December 10, 2015.	To provide a suite of evidence-based policy and guidance documents on the management and decontamination of reusable medical devices.	IVB	To highlight the type of tests and maintenance procedures that are needed to ensure that decontamination has been achieved.	Guideline	Health care providers and others processing flexible endoscopes	N/A	N/A	N/A	N/A
367	367	Chiu KW, Fong TV, Wu KL, et al. Surveillance culture of endoscope to monitor the quality of high-level disinfection of gastrointestinal reprocessing. <i>Hepatogastroenterology.</i> 2010;57(99-100):531-534.	To utilize microbiological cultures of endoscopes to assess the adequacy of standard reprocessing procedures.	IIC	Endoscopy culturing is a useful method to assess the effectiveness of standard reprocessing procedures. Servicing of automated endoscope washer regularly is mandatory to minimize cross infection and quality assurance.	Quasi-experimental	Health care providers and others using and processing endoscopes	Microbiological culturing	N/A	49	Positive cultures
368	368	Corne P, Godreuil S, Jean-Pierre H, et al. Unusual implication of biopsy forceps in outbreaks of <i>Pseudomonas aeruginosa</i> infections and pseudo-infections related to bronchoscopy. <i>J Hosp Infect.</i> 2005;61(1):20-26.	To describe the epidemiological investigations undertaken to prove that this increase was associated with the spread of <i>Pseudomonas aeruginosa</i> clones and to search for the common source of infection.	VB	Contamination of the endoscopes was controlled after replacing the inner channels and establishing the use of disposable biopsy forceps despite their cost. These outbreaks emphasize the need for surveillance procedures for detecting contamination of bronchoscopes, and the importance of recording each endoscopic procedures to facilitate epidemiological investigations in case of suspected outbreaks.	Case report	Bronchoscopes used during the period of increased positive respiratory tract specimens for <i>Pseudomonas aeruginosa</i>	Bacterial strain profiles/Pulsed-field gel electrophoresis/Review of clinical data and outcomes/Observation of bronchoscope cleaning procedures	N/A	N/A	N/A
369	369	Qiu L, Zhou Z, Liu Q, Ni Y, Zhao F, Cheng H. Investigating the failure of repeated standard cleaning and disinfection of a <i>Pseudomonas aeruginosa</i> -infected pancreatic and biliary endoscope. <i>Am J Infect Control.</i> 2015;43(8):e43-e46.	To discuss cases related to a contaminated pancreatic and biliary endoscope that was cleaned and disinfected multiple times after surgery, but still tested positive for <i>Pseudomonas aeruginosa</i> .	VB	The repair center replaced the internal tubes of the endoscope. It is recommended to perform immediate culture after endoscopic operation on a patient with suspected bile duct infection.	Case report	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
370	370	Hunter J, Epstein L. Epi-Aid trip report: cluster of plasmid-mediated AmpC-producing carbapenem-resistant Enterobacteriaceae (CRE)—Washington, 2014. Atlanta, GA: Department of Health and Human Services, Centers for Disease Control and Prevention; 2014.	To investigate a duodenoscope-associated cluster of carbapenem-resistant Enterobacteriaceae in which no breaches in processing or device defects were identified to explain transmission.	VA	The findings from this investigation add evidence to previous concerns that the complex design of duodenoscopes makes them challenging to consistently process and raise additional questions about the frequency with this duodenoscopes should be examined by the manufacturer.	Case report	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
371	371	DiazGranados CA, Jones MY, Kongphet-Tran T, et al. Outbreak of <i>Pseudomonas aeruginosa</i> infection associated with contamination of a flexible bronchoscope. <i>Infect Control Hosp Epidemiol.</i> 2009;30(6):550-555.	To report an outbreak or pseudo-outbreak of <i>Pseudomonas aeruginosa</i> infection that resulted from contamination of a damaged flexible endoscope.	IIIA	Maintenance inspections may be required to prevent the occurrence of such events. Surveillance cultures may be considered.	Case control	Patients with respiratory cultures positive for <i>Pseudomonas aeruginosa</i> with a unique antibiogram during June and July 2007 at a 1000 bed teaching hospital	Microbiological culture/Pulsed-field gel electrophoresis/Data analysis	N/A	12	Positive cultures matching the unique antibiogram
372	372										

Guideline for Processing Flexible Endoscopes
Evidence Table

	A	C	D	E	F	I	J	K	L	M	N
	REFERENCE NUMBER	CITATION	PURPOSE	CONSENSUS SCORE	RESULTS AND CONCLUSIONS	EVIDENCE TYPE	POPULATION	INTERVENTIONS	COMPARISON	SAMPLE SIZE	OUTCOME MEASURE
1	372	Lee DH, Kim DB, Kim HY, et al. Increasing potential risks of contamination from repetitive use of endoscope. Am J Infect Control. 2015;43(5):e13-e17.	To compare differences in surface alterations between not-aged and accelerated aging samples. The samples were exposed to potential contaminants and treated with the same cleaning conditions. Then the residual contaminants were analyzed and adhesion characteristics were investigated.	II B	The results suggest the necessity of limiting the duration of time that reusable medical devices may be used.	Nonexperimental	Endoscope material	Surface observation using scanning electron microscopy/Evaluation of binding affinities of protein, carbohydrate, hemoglobin and lipid	Not aged samples compared with accelerated aging samples	2 groups	Surface alterations/bacterial adhesion
373	373	ASGE Technology Committee; Komanduri S, Abu Dayyeh BK, et al. Technologies for monitoring the quality of endoscope reprocessing. Gastrointest Endosc. 2014;80(3):369-373.	To discuss the current technology for monitoring the efficacy of flexible endoscope reprocessing.	VB	Further research is warranted to determine whether surveillance strategies can effectively identify failures of cleaning, disinfection, or storage that are not detected by process monitoring and that create a risk of iatrogenic transmission	Case report	Health care providers and others with an interest in preventing endoscopy-associated infection	N/A	N/A	N/A	N/A
374	374	Obee PC, Griffith CJ, Cooper RA, Cooke RP, Bennion NE, Lewis M. Real-time monitoring in managing the decontamination of flexible gastrointestinal endoscopes. Am J Infect Control. 2005;33(4):202-206.	To evaluate the overall efficacy of standard gastrointestinal endoscope processing in two endoscopy units and to evaluate ATP as a means to assist in the management of the decontamination process.	IIIB	ATP provided a rapid means of assessing the efficacy of cleaning steps before terminal disinfection.	Nonexperimental	Endoscopes used in two different endoscopy units	Microbiological sampling/ATP	Microbiological culturing compared with ATP testing	63	Negative cultures/ATP results
375	375	Visrodia KH, Ofstead CL, Yellin HL, Wetzler HP, Tosh PK, Baron TH. The use of rapid indicators for the detection of organic residues on clinically used gastrointestinal endoscopes with and without visually apparent debris. Infect Control Hosp Epidemiol. 2014;35(8):987-994.	To evaluate contamination of clinically used endoscopes, using visual inspection and rapid indicator tests before and after manual cleaning. A second objective was to determine which rapid indicator instruments and methods could be used for quality improvement initiatives in endoscope reprocessing.	II B	Relying solely on visual inspection of endoscopes before high-level disinfection is insufficient to ensure reprocessing effectiveness. Tests of different endoscope components using more than 1 indicator may be necessary. Additional research is warranted.	Quasi-experimental	Endoscopes	Visual inspection/Rapid indicator testing	Before and after manual cleaning	12	Negative indication of protein, blood, and ATP
376	376	Petersen BT. Monitoring of endoscope reprocessing: accumulating data but best practices remain undefined. Infect Control Hosp Epidemiol. 2014;35(8):995-997.	To discuss best practices for monitoring of endoscope reprocessing.	VA	Best practices remain undefined. Further research is warranted.	Expert opinion	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
377	377	Alfa MJ. Monitoring and improving the effectiveness of cleaning medical and surgical devices. Am J Infect Control. 2013;41(5 Suppl):S56-S59.	To discuss and summarize the key issues related to monitoring and improving the effectiveness of medical and surgical devices.	VA	Monitoring of manual and automated cleaning is necessary to ensure that inadequately cleaned devices are re-cleaned before disinfection or sterilization.	Expert opinion	Health care providers and others with an interest in cleaning flexible endoscopes	N/A	N/A	N/A	N/A
378	378	Alfa MJ, Fatima I, Olson N. The adenosine triphosphate test is a rapid and reliable audit tool to assess manual cleaning adequacy of flexible endoscope channels. Am J Infect Control. 2013;41(3):249-253.	To verify that the ATP benchmark of <200 relative light units was achievable in a busy endoscopy clinic that followed the manufacturer's manual cleaning instructions.	IIA	By following the endoscope manufacturer's manual cleaning recommendations 96% of channels in gastrointestinal endoscopes would have <200 relative light units for the ATP test kit evaluation and would meet the accepted clean benchmarks for protein and bioburden.	Quasi-experimental	Channels from patient used colonoscopes and duodenoscopes	ATP testing	Benchmark levels	120	Residual ATP, protein, and bioburden
379	379	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.	To determine whether colonoscope and gastroscope contamination caused by clinical use persists despite reprocessing in accordance with current guidelines by performing microbiological cultures and rapid indicator tests for adenosine triphosphate, protein, hemoglobin, and carbohydrate residue.	II B	Despite reprocessing in accordance with US guidelines, viable microbes and biologic debris persisted on clinically used gastrointestinal endoscopes, suggesting current reprocessing guidelines are not sufficient to ensure successful decontamination.	Quasi-experimental	Colonoscopes/Esophagogastroduodenoscopes (without elevator channel)	ATP/Protein/Hemoglobin/Carbohydrate testing/Microbiological cultures	New endoscopes compared with used endoscopes	13 scopes/60 encounters	Negative cultures/Rapid indicator results
380	380										

Guideline for Processing Flexible Endoscopes
Evidence Table

	A	C	D	E	F	I	J	K	L	M	N
	REFERENCE NUMBER	CITATION	PURPOSE	CONSENSUS SCORE	RESULTS AND CONCLUSIONS	EVIDENCE TYPE	POPULATION	INTERVENTIONS	COMPARISON	SAMPLE SIZE	OUTCOME MEASURE
1	380	Hansen D, Benner D, Hilgenhoner M, Leisebein T, Brauksiepe A, Popp W. ATP measurement as method to monitor the quality of reprocessing flexible endoscopes. <i>Ger Med Sci.</i> 2004;2:o04.	To compare ATP bioluminescence for hygiene checking of reprocessing with routine microbiological cultures.	IIIB	ATP luminescence does not replace routine microbiologic methods but it can indicate the need of immediate check of reprocessing.	Nonexperimental	Endoscopes	ATP testing/Microbiological sampling	ATP testing compared with microbiological sampling	108	Relative light units/Colony forming units
381	381	Alfa MJ, Olson N, Degagne P, Simmer PJ. Development and validation of rapid use scope test strips to determine the efficacy of manual cleaning for flexible endoscope channels. <i>Am J Infect Control.</i> 2012;40(9):860-865.	To validate the sample collection protocol and the Rapid Use Scope Test and then assess its usefulness in clinical use.	IIIA	The validated test provides users with a rapid audit tool for manual cleaning that can be integrated into the quality program in endoscopy.	Nonexperimental	Duodenoscopes, colonoscopes, gastroscopes/Endoscopy clinics	Test strips	Predetermined benchmark levels	30/1489	Negative measurement on test strip
382	382	Fernando G, Collignon P, Beckingham W. ATP bioluminescence to validate the decontamination process of gastrointestinal endoscopes. <i>Healthc Infect.</i> 2014;19(2):59-64.	To evaluate adenosine triphosphate bioluminescence, measured as relative light units to validate the decontamination processing of endoscopes.	IIA	Adenosine triphosphate bioluminescence has the potential to play an important role in the validation process.	Quasi-experimental	Endoscopes	Microbiological cultures/ATP testing	Microbiological culturing compared with ATP testing	120	Log reduction of colony forming units/Relative light units
383	383	Fushimi R, Takashina M, Yoshikawa H, et al. Comparison of adenosine triphosphate, microbiological load, and residual protein as indicators for assessing the cleanliness of flexible gastrointestinal endoscopes. <i>Am J Infect Control.</i> 2013;41(2):161-164.	To evaluate 3 potential indicators of gastrointestinal endoscope cleanliness: ATP, microbiological load, and protein.	IIIB	ATP measurement can provide a reliable, rapid and practical assessment of endoscope cleanliness for routine monitoring in the clinical setting.	Nonexperimental	Endoscopes	ATP testing/Microbiological sampling/Protein sampling	ATP testing compared with microbiological sampling and protein sampling	39	Relative light units/Colony forming units/Micrograms per sample
384	384	Sciortino CV Jr, Xia EL, Moze A. Assessment of a novel approach to evaluate the outcome of endoscope reprocessing. <i>Infect Control Hosp Epidemiol.</i> 2004;25(4):284-290.	To investigate and evaluate the use of a portable luminometer system for detecting contamination following the reprocessing and high-level disinfection of flexible endoscopes.	IIC	The system provided a rapid microbiological outcome monitor for the cleaning and disinfection process. The system was easy to use and relatively accurate.	Quasi-experimental	Flexible endoscopes	Portable luminometer system testing	ATP testing compared with microbiological sampling	31+63+15	Negative results for contamination
385	385	Whiteley GS, Derry C, Glasbey T. Sampling plans for use of rapid adenosine triphosphate (ATP) monitoring must overcome variability or suffer statistical invalidity. <i>Infect Control Hosp Epidemiol.</i> 2015;36(2):236-237.	To reply to Visrodia #2990.	VA	Sampling plans for use of ATP monitoring must overcome variability or suffer statistical invalidity.	Expert opinion	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
386	386	Visrodia KH, Ofstead CL, Wetzler HP, Tosh PK, Baron TH. Reply to Whiteley et al. <i>Infect Control Hosp Epidemiol.</i> 2015;36(2):237-238.	Visrodia et al respond to Whiteley #4969.	VA	Additional research is necessary to better define the role of ATP testing; however, ATP levels were very high and provide a user-friendly method to validate manual cleaning.	Expert opinion	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
387	387	Alfa MJ, Fatima I, Olson N. Validation of adenosine triphosphate to audit manual cleaning of flexible endoscope channels. <i>Am J Infect Control.</i> 2013;41(3):245-248.	To validate ATP water test method for monitoring manual cleaning of flexible endoscopes.	IIB	Flexible endoscopes that have complete manual cleaning will have <200 relative light units using the ATP test.	Quasi-experimental	Flexible endoscope channels	ATP testing	Uncleaned and partially cleaned scope compared with fully cleaned scope	1	Residual ATP, protein, hemoglobin, and bioburden
388	388	Whiteley GS, Derry C, Glasbey T, Fahey P. The perennial problem of variability in adenosine triphosphate (ATP) tests for hygiene monitoring within healthcare settings. <i>Infect Control Hosp Epidemiol.</i> 2015;36(6):658-663.	To investigate the reliability of commercial ATP bioluminometers and to document precision and variability measurements using known and quantified standard materials.	IIIA	The variability of commercial ATP bioluminometers and their consumables is unacceptably high with the current technical configuration. The advantage of speed of response is undermined by instrument imprecision expressed in the numerical scale of relative light units.	Nonexperimental	ATP bioluminometers	Quantitated ATP/Microbiological testing	ATP compared with microbiological samples	4	Consistent and precise measurements
389	389										

Guideline for Processing Flexible Endoscopes
Evidence Table

	A	C	D	E	F	I	J	K	L	M	N
	REFERENCE NUMBER	CITATION	PURPOSE	CONSENSUS SCORE	RESULTS AND CONCLUSIONS	EVIDENCE TYPE	POPULATION	INTERVENTIONS	COMPARISON	SAMPLE SIZE	OUTCOME MEASURE
1	389	Alfa MJ, Olson N, Murray BL. Comparison of clinically relevant benchmarks and channel sampling methods used to assess manual cleaning compliance for flexible gastrointestinal endoscopes. <i>Am J Infect Control.</i> 2014;42(1):e1-e5.	To recommend sample collection methods based on relative soiling in patient-used gastrointestinal endoscopes and determine whether the published benchmarks for protein, bioburden, and adenosine triphosphate remain relevant for pump-assisted manual cleaning.	IIA	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.	Quasi-experimental	Flexible gastrointestinal endoscopes	Microbiological sampling	Before and after manual cleaning	60	Validity of benchmark levels of protein, bioburden and ATP
390	390	Bommarito M, Thornhill GA, Morse DJ. A multi-site field study evaluating the effectiveness of manual cleaning of flexible endoscopes with an ATP detection system. <i>Am J Infect Control.</i> 2013;41(6 Suppl):S24.	To monitor the cleanliness of flexible endoscopes after manual cleaning for five hospitals across the US.	IIIC	Considerably higher levels of ATP contamination after the manual cleaning of duodenoscopes and gastroscopes compared to colonoscopes. More attention should be placed on manual cleaning of upper GI endoscopes.	Nonexperimental	Three types of flexible endoscopes from five different hospitals	ATP testing	Duodenoscopes, gastroscopes, colonoscopes	245	Relative light units
391	391	Beilenhoff U, Neumann CS, Rey JF, et al. ESGEESGENA guideline for quality assurance in reprocessing: microbiological surveillance testing in endoscopy. <i>Endoscopy.</i> 2007;39(2):175-181.	To address the necessity for microbiological surveillance in endoscopy and provide information about testing the quality of the microbiological outcomes of manual and automated reprocessing procedures used in endoscopy.	IVC	Microbial surveillance is an important means for evaluating the outcome quality of reprocessing procedures and is an instrument of quality control in endoscopy. It is an instrument for detecting and redressing weaknesses and mistakes in the processing procedure and for preventing the transmission of infectious agents through endoscopy.	Guideline	Health care providers and others reprocessing gastrointestinal endoscopes	N/A	N/A	N/A	N/A
392	392	Chiu KW, Tsai MC, Wu KL, Chiu YC, Lin MT, Hu TH. Surveillance cultures of samples obtained from biopsy channels and automated endoscope reprocessors after high-level disinfection of gastrointestinal endoscopes. <i>BMC Gastroenterol.</i> 2012;12:120.	To assess the effectiveness of decontamination using reprocessors after high-level disinfection by comparing the cultured samples obtained from biopsy channels of gastrointestinal endoscopes and the internal surfaces of automated endoscope reprocessors.	IIA	Culturing rinse samples obtained from biopsy channels provides a better indication of the effectiveness of the decontamination of gastrointestinal endoscopes after high-level disinfection than culturing swab samples obtained from the inner surfaces of the automated endoscope reprocessors as the swab samples only indicate whether the reprocessors are free from microbial contamination or not.	Quasi-experimental	Endoscopes/Automated endoscope reprocessors	Surveillance cultures	Biopsy channels of endoscopes versus internal surfaces of automated endoscope reprocessors	840	Positive cultures
393	393	Saviuc P, Picot-Gueraud R, Shum Cheong Sing J, et al. Evaluation of the quality of reprocessing of gastrointestinal endoscopes. <i>Infect Control Hosp Epidemiol.</i> 2015;36(9):1017-1023.	To discuss the advantages of microbiological surveillance testing of endoscopes.	IIIA	Microbiological surveillance is indispensable to monitor processing, reinforce good practices, and detect endoscopes requiring maintenance	Nonexperimental	Microbiological samples	Retrospective analysis	N/A	846	Parameters influencing compliance
394	394	Tunuguntla A, Sullivan MJ. Monitoring quality of flexible endoscope disinfection by microbiologic surveillance cultures. <i>Tenn Med.</i> 2004;97(10):453-456.	To assess the adequacy of currently approved high-level disinfection for flexible endoscopes by reviewing retrospectively the results of cultures on ready to use endoscopes.	VB	Using cultures for monitoring effectiveness of reprocessing activities is valuable to identifying the source of possible contamination and rectifying protocols.	Organizational experience: quality improvement	Endoscopy unit	Routine microbiological surveillance	N/A	N/A	Negative culture results
395	395	Merighi A, Contato E, Scagliarini R, et al. Quality improvement in gastrointestinal endoscopy: microbiologic surveillance of disinfection. <i>Gastrointest Endosc.</i> 1996;43(5):457-462.	To assess and improve the quality of cleaning and disinfection in gastrointestinal endoscopy through a microbiological surveillance protocol.	VC	The microbiological surveillance pointed out the main weak points that could be improved by the adoption of corrective interventions.	Organizational experience: quality improvement	Health care facilities and others who reprocess endoscopes	Microbiological surveillance	Before and after initiating microbiological surveillance	109	Reduced numbers of bacteria on endoscopes
396	396	Moses FM, Lee J. Surveillance cultures to monitor quality of gastrointestinal endoscope reprocessing. <i>Am J Gastroenterol.</i> 2003;98(1):77-81.	To review retrospectively the results of environmental cultures of flexible endoscopes and to analyze the pattern of results.	VA	Surveillance culture results can be used to identify patterns of poor technique, to reinforce correct procedures, and to modify clinical practice.	Organizational experience: quality improvement	Surveillance cultures from endoscopes from Walter Reed Army Medical Center	Microbiological cultures/Retrospective review and analysis of data	N/A	312	Negative cultures
397											

Guideline for Processing Flexible Endoscopes
Evidence Table

	A	C	D	E	F	I	J	K	L	M	N
	REFERENCE NUMBER	CITATION	PURPOSE	CONSENSUS SCORE	RESULTS AND CONCLUSIONS	EVIDENCE TYPE	POPULATION	INTERVENTIONS	COMPARISON	SAMPLE SIZE	OUTCOME MEASURE
1	397	Brethauer M, Jorgensen A, Kristiansen BE, Hofstad B, Hoff G. Quality control in colorectal cancer screening: systematic microbiological investigation of endoscopes used in the NORCCAP (Norwegian Colorectal Cancer Prevention) trial. <i>BMC Gastroenterol.</i> 2003;3:15.	To investigate the quality of cleaning of endoscopes used in colorectal cancer screening.	IIIA	Growth of bacteria occurred in a clinically significant number of samples from ready to use endoscopes. Pathogenic bacteria were found in only one sample. Microbiological surveillance of endoscopes is recommended.	Nonexperimental	Endoscopes used for colorectal cancer screening	Cultures	Results of cultures	178	N/A
398	398	Buss AJ, Been MH, Borgers RP, et al. Endoscope disinfection and its pitfalls—requirement for retrograde surveillance cultures. <i>Endoscopy.</i> 2008;40(4):327-332.	To discuss the design of a microbiological surveillance system to evaluate the efficacy of cleaning and disinfection and to trace disinfection problems to individual endoscopes or washer-disinfectors.	VA	The protocol was able to detect a structural problem in the endoscope disinfection process. Retrograde sampling was crucial for this purpose because it has much higher sensitivity than anterograde sampling. Endoscopes with damaged working channels are probably the source of the contamination problem with <i>Candida</i> species.	Quality improvement	Health care providers and others interested in preventing endoscopy-associated infection	Microbial surveillance using antero- and retrograde sampling/Decision algorithm	Culture result	N/A	N/A
399	399	Hong KH, Lim YJ. Recent update of gastrointestinal endoscope reprocessing. <i>Clin Endosc.</i> 2013;46(3):267-273.	To discuss the current state of endoscope processing.	VA	Correct processing is imperative to prevent transmission of infections during gastrointestinal endoscopy.	Literature review	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
400	400	Kovaleva J, Meessen NE, Peters FT, et al. Is bacteriologic surveillance in endoscope reprocessing stringent enough? <i>Endoscopy.</i> 2009;41(10):913-916.	To report an investigation of an outbreak of multidrug-resistant <i>Pseudomonas aeruginosa</i> sepsis affecting three patients after ERCP and describe the importance of the surveillance procedure for microbiological safety.	VA	Though the current surveillance system did not prevent the infections, the microbiological surveillance protocol was helpful in detecting the source of contamination and probably avoided cross-contamination in other patients who underwent ERCP procedures.	Case report	Patients with multidrug-resistant <i>P aeruginosa</i> after ERCP	Molecular typing/Ethylene oxide sterilization/Channel replacement	Isolates from affected patients	3	Negative cultures
401	401	Chiu KW, Lu LS, Wu KL, et al. Surveillance culture monitoring of double-balloon enteroscopy reprocessing with high-level disinfection. <i>Eur J Clin Invest.</i> 2012;42(4):427-431.	To use microbiological surveillance culture monitoring to assess the adequacy of high-level disinfection with standard reprocessing procedures of double-balloon enteroscopes	IIIC	Surveillance culture monitoring is a useful method to assess the effectiveness of high-level disinfection reprocessing of double-balloon endoscopes. Machine washing may not achieve complete disinfection. Additional procedures are necessary due to the longer and anal route of double-balloon endoscopy.	Nonexperimental	Double-balloon endoscopes	Microbiological culturing	N/A	57	Positive cultures
402	402	Bisset L, Cossart YE, Selby W, et al. A prospective study of the efficacy of routine decontamination for gastrointestinal endoscopes and the risk factors for failure. <i>Am J Infect Control.</i> 2006;34(5):274-280.	To determine the efficacy of decontamination procedures in a busy endoscopy center.	IIIA	Recommended decontamination procedures do not entirely eliminate persistence of low numbers of organisms on endoscopes, but this is unlikely to cause serious consequences in patients. Bacterial biofilm is difficult to remove and may explain this low-level persistence.	Nonexperimental	Gastrosopes and colonoscopes	Aerobic and anaerobic cultures and polymerase chain reaction	Results of cultures	1376/987	N/A
403	403	Infection Control Devices Branch Division of General and Restorative Devices Office of Device Evaluation Center for Devices and Radiological Health Food and Drug Administration. Guidance on Premarket Notification [510(k)] Submissions for Sterilizers Intended for Use in Health Care Facilities. March 1993. US Food and Drug Administration. http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm081341.pdf . Accessed December 10, 2015.		Reg							
404	404										

Guideline for Processing Flexible Endoscopes
Evidence Table

	A	C	D	E	F	I	J	K	L	M	N
	REFERENCE NUMBER	CITATION	PURPOSE	CONSENSUS SCORE	RESULTS AND CONCLUSIONS	EVIDENCE TYPE	POPULATION	INTERVENTIONS	COMPARISON	SAMPLE SIZE	OUTCOME MEASURE
1	404	Addendum to: Guidance on Premarket Notification [510(k)] Submissions for Sterilizers Intended for Use in Health Care Facilities. September 19, 1995. US Food and Drug Administration. http://www.fda.gov/RegulatoryInformation/Guidances/ucm080300.htm . Accessed December 10, 2015.		Reg							
405	405	Fraser TG, Reiner S, Malczynski M, Yarnold PR, Warren J, Noskin GA. Multidrug-resistant <i>Pseudomonas aeruginosa</i> cholangitis after endoscopic retrograde cholangiopancreatography: failure of routine endoscope cultures to prevent an outbreak. <i>Infect Control Hosp Epidemiol</i> . 2004;25(10):856-859.	To describe an outbreak of multidrug-resistant <i>Pseudomonas aeruginosa</i> after endoscopic retrograde cholangiopancreatography.	IIIC	Infectious morbidity can occur after endoscopy despite a negative surveillance culture of the implicated endoscope one month earlier.	Case control	Patients with <i>Pseudomonas aeruginosa</i> isolated from cultures after undergoing ERCP	Epidemiologic investigation	Patients with positive cultures compared with patients with negative cultures	5	Use of a contaminated endoscope
406	406	Nelson DB. Recent advances in epidemiology and prevention of gastrointestinal endoscopy related infections. <i>Curr Opin Infect Dis</i> . 2005;18(4):326-330.	To review publications relevant to endoscope processing and the potential for transmission of infection during gastrointestinal endoscopy.	VB	Increased compliance with existing guidelines and new initiatives to enhance endoscope reprocessing are increasingly important.	Literature review	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
407	407	Gillespie EE, Kotsanas D, Stuart RL. Microbiological monitoring of endoscopes: 5-year review. <i>J Gastroenterol Hepatol</i> . 2008;23(7 Pt 1):1069-1074.	To review microbiological testing of pathology and endoscopy records during a five year period.	IIIB	Microbiological testing should be performed on commissioning, annually, and following repair.	Nonexperimental	Records of microbiological testing	Review and analysis	N/A	2374	Colony forming units
408	408	Lu LS, Wu KL, Chiu YC, Lin MT, Hu TH, Chiu KW. Swab culture monitoring of automated endoscope processors after high-level disinfection. <i>World J Gastroenterol</i> . 2012;18(14):1660-1663.	To conduct a bacterial culture study for monitoring decontamination of automated endoscope processors after high-level disinfection.	IIIA	Swab culturing is a useful method for monitoring automatic endoscope processor decontamination after each processing cycle.	Nonexperimental	Processors from a single facility	Random swab culturing	N/A	7	Positive cultures
409	409	Muscarella LF. Investigation and prevention of infectious outbreaks during endoscopic retrograde cholangiopancreatography. <i>Endoscopy</i> . 2010;42(11):957-959.	To discuss investigation and prevention of infectious outbreaks during ERCP	VA	The author discusses ERCP-related infections, endoscope drying, environmental versus patient related sources of infection, and endoscope sampling.	Expert opinion	Health care providers and others with an interest in endoscopy-associated infection	N/A	N/A	N/A	N/A
410	410	Interim duodenoscope surveillance protocol. Centers for Disease Control and Prevention. http://www.cdc.gov/hai/organisms/cre/cre-duodenoscope-surveillanceprotocol.html . Accessed December 10, 2015.	To provide an interim protocol for healthcare facilities regarding surveillance for bacterial contamination of duodenoscopes after reprocessing.	VA	These considerations are intended for facilities that perform procedures using duodenoscopes to assess the adequacy of reprocessing. These measures can also be implemented for other flexible endoscopes. This document is intended to supplement and not replace or modify manufacturer's recommendations.	Expert opinion	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
411	411	H0245 01: ECRI institute Recommends Culturing Duodenoscopes as a Key Step to Reducing CRE Infections [Hazard Report]. Plymouth Meeting, PA: ECRI Institute. March 3, 2015.	To provide an alert recommending culturing duodenoscopes as a key step in reducing CRE infections.	VA	This hazard required immediate action. ERCP procedures are vital. Duodenoscopes should be cultured after each use or at least weekly.	Expert opinion	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
412											

Guideline for Processing Flexible Endoscopes
Evidence Table

	A	C	D	E	F	I	J	K	L	M	N
	REFERENCE NUMBER	CITATION	PURPOSE	CONSENSUS SCORE	RESULTS AND CONCLUSIONS	EVIDENCE TYPE	POPULATION	INTERVENTIONS	COMPARISON	SAMPLE SIZE	OUTCOME MEASURE
413	412	Interim duodenoscope sampling method. Centers for Disease Control and Prevention. http://www.cdc.gov/hai/settings/lab/lab-duodenoscope-sampling.html . Accessed December 10, 2015.	To provide an interim sampling method for the duodenoscope distal end and instrument channel	VB	This protocol has not been validated. It is still being developed and evaluated for the major duodenoscope types.	Expert opinion	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
414	413	Interim duodenoscope culture method. Centers for Disease Control and Prevention. http://www.cdc.gov/hai/settings/lab/lab-duodenoscope-culture-method.html . Accessed December 10, 2015.	To provide an interim culture method for the duodenoscope distal end and instrument channel.	VB	This protocol has not been validated. It is still being developed and evaluated for the major duodenoscope types.	Expert opinion	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
415	414	Banerjee S, Nelson DB, Dominitz JA, et al. Reprocessing failure. <i>Gastrointest Endosc</i> . 2007;66(5):869-871.	To provide recommendations for actions to be taken when a breach in processing is discovered.	IVA	The ASGE believes that institutions have an ethical obligation to inform affected patients in a timely manner when a significant breach in reprocessing is discovered.	Guideline	Health care providers and others with an interest in processing flexible endoscopes	N/A	N/A	N/A	N/A
416	415	Patel PR, Srinivasan A, Perz JF. Developing a broader approach to management of infection control breaches in health care settings. <i>Am J Infect Control</i> . 2008;36(10):685-690.	To describe an approach to management of incidents that focuses on risk of bloodborne pathogen transmission and the role of public health and other stakeholders to inform patient notification and testing decisions.	VA	Patient safety experts should examine how best to approach patient notification in the setting of uncertain risk and consider criteria that could be used to make patient notification decisions.	Expert opinion	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
417	416	Weber DJ, Rutala WA. Assessing the risk of disease transmission to patients when there is a failure to follow recommended disinfection and sterilization guidelines. <i>Am J Infect Control</i> . 2013;41(5):S67-S71.	To describe a protocol that can guide an institution in managing potential disinfection and sterilization failures.	VA	The protocol contains 15 steps that form a general approach to the evaluation of a possible failure of disinfection of sterilization that could result in patient exposure to an infectious agent.	Expert opinion	Health care providers and others with an interest in preventing endoscopy-related infection	N/A	N/A	N/A	N/A
418	417	Holodniy M, Oda G, Schirmer PL, et al. Results from a large-scale epidemiologic look-back investigation of improperly reprocessed endoscopy equipment. <i>Infect Control Hosp Epidemiol</i> . 2012;33(7):649-656.	To determine whether high-level disinfection practices during endoscopy procedures resulted in bloodborne viral infection transmission.	IIIA	Exposure to incorrectly processed ENT endoscopes did not result in viral transmission in those patients who had viral genetic analysis performed. Potential transmission from colonoscopy remains unknown.	Case control	Veterans who underwent colonoscopy and laryngoscopy procedures from 2003 to 2009	Serotyping for HIV, HCV, HBV/Viral genetic testing	N/A	9879	Genetic match
419	418	MAUDE—Manufacturer and User Facility Device Experience. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm . Accessed December 9, 2015.		Reg							