



ELSEVIER



Reprocessing endoscopes: United States perspective

W. A. Rutala^{a,*}, D. J. Weber^b

^a*Hospital Epidemiology, University of North Carolina Health Care System, Chapel Hill, NC 27514, USA*

^b*Division of Infectious Diseases, University of North Carolina School of Medicine, Chapel Hill, NC 27599-7030, USA*

KEYWORDS

Endoscopes;
Disinfection; Cross-
infection; Reprocessing

Summary Endoscopes are used frequently for the diagnosis and therapy of medical disorders. For example, greater than 10,000,000 gastrointestinal endoscopic procedures are performed each year in the United States. Failure to employ appropriate cleaning and disinfection/sterilization of endoscopes has been responsible for multiple nosocomial outbreaks and serious, sometimes life-threatening, infections. Flexible endoscopes, by virtue of the site of use, have a high bioburden of microorganisms after use. The bioburden found on flexible gastrointestinal endoscopes following use has ranged from 10^5 to 10^{10} CFU/ml, with the highest levels being found in the suction channels. Cleaning dramatically reduces the bioburden on endoscopes. Several investigators have shown a mean \log_{10} reduction factor of 4 (99.99%) in the microbial contaminants with cleaning alone. Cleaning should be done promptly following each use of an endoscope to prevent drying of secretions, allow removal of organic material, and decrease the number of microbial pathogens. Because the endoscope comes into intimate contact with mucous membranes, high-level disinfection is the reprocessing standard after each patient use. High-level disinfection refers to the use of a disinfectant (e.g., FDA-cleared chemical sterilant or high-level disinfectant) that inactivates all microorganisms (i.e., bacteria, viruses, fungi, mycobacteria) but not high levels of bacterial spores. The disinfection process requires immersion of the endoscope in the high-level disinfectant and ensuring all channels are perfused for the approved contact time (e.g., for ortho-phthalaldehyde this is 12 min in the US). Following disinfection, the endoscope and channels are rinsed with sterile water, filtered water, or tapwater. The channels are then flushed with alcohol and dried using forced air. The endoscope should be stored in a manner that prevents recontamination. A protocol that describes the meticulous manual cleaning process, the appropriate training and evaluation of the reprocessing personnel, and a quality assurance program for endoscopes should be adopted and enforced by each unit performing endoscopic reprocessing.

© 2004 The Hospital Infection Society. Published by Elsevier Ltd. All rights reserved.

*Corresponding author. Tel.: +1-919-843-1397; fax: +1-919-966-1451.
E-mail address: brutala@unch.unc.edu

Introduction

Physicians use endoscopes to diagnose and treat numerous medical disorders. While endoscopes represent a valuable diagnostic and therapeutic tool in modern medicine and the incidence of infection associated with use has been reported to be very low (about 1 in 1.8 million procedures),¹ more healthcare-associated outbreaks have been linked to contaminated endoscopes than to any other medical device.²⁻⁴ In order to prevent the spread of healthcare-associated infections, all heat-sensitive endoscopes (e.g., gastrointestinal endoscopes, bronchoscopes, nasopharyngoscopes) must be properly cleaned and at a minimum subjected to high-level disinfection following each use. High-level disinfection can be expected to destroy all microorganisms, although when high numbers of bacterial spores are present a few spores may survive.

Bioburden on endoscopes and efficacy of cleaning

Flexible endoscopes, by virtue of the types of body cavities they enter, acquire high levels of microbial contamination (bioburden) during each use.⁵ For example, the bioburden found on flexible gastrointestinal endoscopes following use has ranged from 10^5 colony forming units (CFU)/ml to 10^{10} CFU/ml, with the highest levels being found in the suction channels.⁵⁻⁸ The average load on bronchoscopes before cleaning was 6.4×10^4 CFU/ml. Cleaning has been shown to reduce the level of microbial contamination by a \log_{10} factor of 4 to 6 (Table I)⁷⁻¹² unless the level of contamination was initially low (e.g., less than 10^7 CFU/device). Thus, studies have shown that the post-cleaning bioburden was less than 10^5 CFU/endoscope. Some data demonstrate that enzymatic cleaners are more effective cleaners than neutral detergents^{13,14} in removing microorganisms from surfaces. Using HIV contaminated endoscopes, several investigators have shown that cleaning completely eliminates the microbial contamination on the scopes.^{15,16} Similarly, other investigators found that ethylene oxide (ETO) sterilization or high-level disinfection (soaking in 2% glutaraldehyde for 20 min) was effective only when the device was first properly cleaned.¹⁷

High-level disinfectants for use on endoscopes

The Food and Drug Administration (FDA) maintains a list of cleared liquid chemical sterilants/high-level

disinfectants that can be used to reprocess heat-sensitive medical devices in the United States, such as flexible endoscopes. Users can access and view the list at <http://www.fda.gov/cdrh/ode/germlab.html>. At this time, the FDA-cleared formulations include; $\geq 2.4\%$ glutaraldehyde, 0.55% orthophthalaldehyde (OPA), 0.95% glutaraldehyde with 1.64% phenol/phenate, 7.35% hydrogen peroxide with 0.23% peracetic acid, 1.0% hydrogen peroxide with 0.08% peracetic acid, and 7.5% hydrogen peroxide [Food and Drug Administration. Sterilants and high level disinfectants cleared by FDA in a 510 (k) as of January 30, 2002 with general claims for processing reusable medical and dental devices, <http://www.fda.gov/cdrh/ode/germlab.html>, 2001]. These products have excellent antimicrobial activity; however, some oxidizing chemicals (e.g., 7.5% hydrogen peroxide and 1.0% hydrogen peroxide with 0.08% peracetic acid [the latter product is no longer marketed]) have been reported to cause cosmetic and functional damage to endoscopes.¹⁸ Users should check with endoscope manufacturers for information on germicide compatibility with their device. If the germicide is FDA-cleared then it is safe when used according to the label directions; however, professionals should review the scientific literature as new data may become available regarding human safety or material compatibility. ETO sterilization of flexible endoscopes is infrequent because it requires a lengthy processing and aeration time (e.g., 12 h) and is potential hazard to staff and patients. The two products that are most commonly used for reprocessing endoscopes in the United States are glutaraldehyde and an automated, liquid chemical sterilization process that uses peracetic acid.¹⁹ The American Society for Gastrointestinal Endoscopy (ASGE) recommends glutaraldehyde solutions that do not contain surfactants because the soapy residues of surfactants are difficult to remove during rinsing.²⁰ OPA has begun to replace glutaraldehyde in many health-care facilities in the United States as it possesses several potential advantages compared to glutaraldehyde: no known irritation to the eyes and nasal passages, does not require activation or exposure monitoring, and has a 12-minute high-level disinfection claim (at 20 °C) in the United States (5 min in Europe, Asia and Latin America; 10 min in Canada, Australia).¹⁸ Disinfectants that are not FDA cleared and should not be used for reprocessing endoscopes include iodophors, chloride solutions, alcohols, quaternary ammonium compounds, and phenolics. These solutions may still be in use outside the United States, but their use should be strongly discouraged because of lack of proven

Table I Effectiveness of cleaning in eliminating microbial contamination of endoscopes

Investigator	Endoscope type	Pathogen	Initial contamination (log ₁₀ CFU/ml for bacteria)	Post-cleaning contamination ^a (log ₁₀ CFU/ml for bacteria)	Mean log ₁₀ reduction factor
Hanson, 1989 ¹⁵	Gastrointestinal	Mixed bacteria HBV, HIV	4.9 ND (1/20, 7/20)	0 0	4.9
Hanson, 1991 ¹⁶	Gastrointestinal ^b	HIV	4.7-6.5 pg/mL	0-2.2	4.7
Hanson, 1991 ¹⁶	Bronchoscope	Mixed bacteria <i>P. carinii</i> HBV, HCV	2.1-4.3 1.2 cysts/mL ND (1/10, 7/7)	0 0	2.8
Vesley, 1992 ⁸⁸	Gastrointestinal ^b	<i>Bacillus subtilis</i>	6.0-8.0	ND	4.2
Hanson, 1992 ³⁴	Bronchoscope ^b	<i>M. tuberculosis</i>	3.1-4.6	0.11-0.7	3.5
Urayama, 1996 ¹⁰	Gastrointestinal ^b	<i>M. chelonae</i>	8.34-8.75	3.30-4.38	4.7
Chu, 1998 ⁸	Gastrointestinal	Mixed bacteria	9.85 (per device) ^c 5.71 (per device) ^d	5.11 (per device) 4.34 (per device)	4.7 1.4
Vesley, 1999 ⁷	Gastroscope	Mixed bacteria	6.7 (per device)	2.0 (per device)	4.7
	Colonoscope	Mixed bacteria	8.5 (per device)	2.3 (per device)	6.2
Alfa, 1999 ¹¹	Bronchoscope	Mixed bacteria	6.76 (per device)	4.91 (per device)	1.9
	Duodenoscope	Mixed bacteria	6.84 (per device)	4.79 (per device)	2.1
	Colonoscope	Mixed bacteria	8.46 (per device)	4.27 (per device)	4.2
Kovacs, 1999 ¹²	Gastrointestinal ^b	<i>M. chelonae</i>	7.95 (per device)	3.89 (per device)	4.1

CFU, colony forming units; HBV, hepatitis B virus; HIV, human immunodeficiency virus; ND, not determined (numbers in parentheses are number of dirty endoscopes contaminated with HBsAg and HIV per number of endoscopes sampled).

^a A value of zero for bacteria represents the absolute, not logarithmic, count after cleaning.

^b Experimentally contaminated endoscope.

^c Bioburden in suction channels.

^d Bioburden on device surfaces.

efficacy against all microorganisms or materials incompatibility.

The FDA's clearance of the contact conditions listed on germicide labeling is based on the manufacturer's test results. They conduct the testing under worst-case conditions for germicide formulation (i.e., minimum recommended concentration of the active ingredient), and include organic soil. Typically, manufacturers use 5% serum and hard water to simulate organic and inorganic contamination. The soil is used to represent the type of worse-case organic loading to which the device is exposed during actual use and that would remain on the device in the absence of cleaning. This method assures that the contact conditions provides complete elimination of the test mycobacteria (e.g., 10^5 to 10^6 *Mycobacterium tuberculosis* in organic soil and dried on a scope) if inoculated in the most difficult areas for the disinfectant to penetrate and contact in the absence of cleaning and thus, provides a margin of safety {Food and Drug Administration. Content and format of premarket notification [510 (k)] submissions for liquid chemical sterilants/high level disinfectants. www.fda.gov/cdrh/ode/397, 2000}. For 2.4% glutaraldehyde that requires a 45-minute immersion at 25 °C to achieve high-level disinfection (i.e., 100% kill of *Mycobacterium tuberculosis*). FDA itself does not conduct testing, but relies solely on the disinfectant manufacturer's data. Users can find the contact conditions for cleared high-level disinfectants/chemical sterilants at <http://www.fda.gov/cdrh/ode/germlab.html>. It is important to note that data suggest that *M. tuberculosis* levels can be reduced by a \log_{10} factor of at least 8. A \log_{10} reduction factor of 4 is achieved by cleaning⁷⁻¹⁰ and by a further 4-6 if followed by chemical disinfection for 20 min at 20 °C.^{21,22}

Based on these data the Association of Professionals in Infection Control (APIC),²³ the Society of Gastroenterology Nurses and Associates (SGNA),^{24,25} the American Society Gastrointestinal Endoscopy (ASGE),²⁰ and a multi-society guideline²⁶ recommended alternative contact conditions with 2% glutaraldehyde to achieve high-level disinfection based on published literature (e.g., that equipment be immersed in 2% glutaraldehyde at 20 °C for at least 20 min for high-level disinfection.^{9,20,21,27-34} In the absence of several well-designed experimental scientific studies supporting alternative exposure times of high-level disinfectants, the manufacturers' recommendations to achieve high-level disinfection should be followed. Currently, such data are available only for 2% glutaraldehyde solutions.

Lessons learned from outbreak investigations

Flexible endoscopes are particularly difficult to disinfect³⁵ and easy to damage because of their intricate design, including narrow long lumens, and delicate materials.³⁶ Meticulous cleaning must precede any sterilization or high-level disinfection of these instruments. Failure to perform good cleaning may result in a sterilization or disinfection failure and outbreaks of infection may occur. Several studies have demonstrated the importance of cleaning in experimental studies with the duck hepatitis B virus,^{17,37} HIV³⁸ and *Helicobacter pylori*.³⁹

Examining healthcare-associated infections related only to endoscopes up to July 1992, Spach found that 281 infections were transmitted by gastrointestinal endoscopy and 96 were transmitted by bronchoscopy. The clinical spectrum ranged from asymptomatic colonization to death. *Salmonella* species and *P. aeruginosa* repeatedly were identified as causative agents of infections transmitted by gastrointestinal endoscopy, and *M. tuberculosis* (TB), atypical mycobacteria, and *P. aeruginosa* were the most common causes of infections transmitted by bronchoscopy. Major reasons for transmission were inadequate cleaning improper selection of a disinfecting agent, failure to follow recommended cleaning and disinfection procedures,^{2,3,40} and flaws in endoscope design^{41,42} or automated endoscope reprocessors.⁴ Failure to follow established guidelines has continued to lead to infections associated with gastrointestinal endoscopes³ and bronchoscopes.⁴ Potential device-associated problems in the United States should be reported to the FDA's Center for Devices and Radiologic Health. One multi-state investigation found that 23.9% of the bacterial cultures from the internal channels of 71 gastrointestinal endoscopes grew $\geq 100,000$ colonies of bacteria after completion of all disinfection/sterilization procedures (9 of 25 facilities were using a product that has been removed from the marketplace [6 facilities using 1:16 glutaraldehyde phenate], was not FDA-cleared as a high-level disinfectant [an iodophor] or were not using a disinfecting agent) and before use on the next patient.⁴³ It should be acknowledged that the incidence of post-endoscopic procedure infections resulting from an improperly processed endoscope has not been rigorously assessed.

Automated endoscope reprocessors (AER) offer several advantages compared to manual reprocessing: they automate and standardize several important reprocessing steps,⁴⁴⁻⁴⁶ reduce the

likelihood that an essential reprocessing step will be skipped, and reduce personnel exposure to high-level disinfectants or chemical sterilants. Failure of AERs has been linked to outbreaks of infections⁴⁷ or colonization,^{4,48} and the AER water filtration system may not reliably provide bacteria-free rinse water.^{49,50} It is critical that correct connectors between the AER and the device are used to ensure complete flow of disinfectants and rinse water.^{4,51} In addition, some endoscopes such as the duodenoscopes (e.g., endoscopic retrograde cholangiopancreatography [ERCP]) contain features (e.g., elevator-wire channel) that require a flushing pressure that is not achieved by most AERs and must be reprocessed manually using a 2- to 5-ml syringe. New duodenoscopes equipped with a wider elevator-channel that AERs can reliably reprocess may be available in the future.⁴⁶ Outbreaks involving removable endoscope parts^{52,53} such as suction valves and endoscopic accessories designed to be inserted through flexible endoscopes such as biopsy forceps emphasize the importance of cleaning to remove all foreign matter before high-level disinfection or sterilization.⁵⁴ Some types of valves are now available as single use, disposable products (e.g., bronchoscope valves) or steam sterilizable products (e.g., gastrointestinal endoscope valves).

There is a need for further development and redesign of AERs^{4,55} and endoscopes^{36,56} so that they do not represent a potential source of infectious agents. Endoscopes employing disposable components (e.g., protective barrier devices or sheaths) are being evaluated as an alternative to conventional liquid chemical high-level disinfection/sterilization.⁵⁷ Another new technology is a swallowable camera-in-a-capsule that travels through the digestive tract and transmits color pictures of the small intestine to a receiver that is worn outside the body. At present, this capsule cannot replace colonoscopies.

Recommendations for the cleaning, disinfection and sterilization of endoscopes: United states perspective

Recommendations for the cleaning and disinfection of endoscopic equipment have been published and should be strictly followed.^{20,23-26,58-61} Unfortunately, audits have shown that personnel do not adhere to guidelines on reprocessing⁶²⁻⁶⁴ and outbreaks of infection continue to occur.⁶⁵⁻⁶⁷ In order to ensure that reprocessing personnel are properly trained, there should be initial and annual competency testing for each individual who reprocesses endoscopic instruments.^{25,68}

In general, endoscope disinfection or sterilization

with a liquid chemical sterilant involves five steps after leak testing: (1) clean—mechanically clean internal and external surfaces, including brushing internal channels and flushing each internal channel with water and a detergent or enzymatic cleaners (leak testing is recommended for endoscopes before immersion); (2) disinfect—immerse the endoscope in high-level disinfectant (or chemical sterilant) and perfuse (eliminates air pockets and ensures contact of the germicide with the internal channels) disinfectant into all accessible channels such as the suction/biopsy channel and air/water channel and expose for a time recommended for specific products; (3) rinse—rinse the endoscope and all channels with sterile water or filtered water (commonly used with AERs); if this is not feasible use tapwater; (4) dry—rinse the insertion tube and inner channels with alcohol and dry with forced air after disinfection and before storage; and (5) store—store the endoscope in a way that prevents recontamination and promotes drying (e.g., hung vertically). One study demonstrated that reprocessed endoscopes (i.e., air/water channel, suction/biopsy channel) were generally negative (100% after 24 h; 90% after 7 days [1 CFU of coagulase-negative *Staphylococcus* in one channel]) for bacterial growth when stored by hanging in a vertical position in a ventilated cabinet.⁶⁹

Because tapwater may contain low levels of microorganisms some have suggested that only sterile water (which may be prohibitively expensive⁷⁰) or AER filtered water be used. The suggestion to use only sterile water or filtered water is not consistent with published guidelines that allow tapwater followed by an alcohol rinse and forced air-drying^{20,23,25} or the scientific literature.^{22,71} In addition, there has been no evidence of disease transmission when tapwater followed by an alcohol rinse and forced air-drying has been used. AERs produce filtered water via passage through a bacterial filter (e.g., 0.2 μ). Filtered rinse water was identified as a source of bacterial contamination in a recent study that cultured the accessory and suction channels of endoscopes and the internal chambers of AERs between 1996 and 2001 and reported 8.7% of samples collected between 1996 and 1998 had bacterial growth with 54% being *Pseudomonas species*. Following the introduction of a system of hot water flushing of the piping (60 °C for 60 min daily), the frequency of positive cultures fell to approximately 2% with only rare isolation of > 10 CFU/ml.⁷² In addition to the endoscope reprocessing steps, a protocol should be developed that assures the user knows whether an endoscopes has been appropriately cleaned and disinfected (e.g., using a room or cabinet for processed endoscopes

only) or has not been reprocessed. Confusion can result when users leave endoscopes on movable carts and it is unclear whether the endoscopes have been processed or not. While one guideline has recommended that an endoscope (e.g., a duodenoscope) should be reprocessed immediately before its use,⁶⁰ other guidelines do not require this activity^{20,25} and with the exception of the Association of periOperative Registered Nurses (AORN), professional organizations do not recommend that reprocessing be repeated so long as the original processing is done correctly. As part of a quality assurance program, healthcare facility personnel may consider random bacterial surveillance cultures of processed endoscopes to ensure high-level disinfection or sterilization.^{4,73,74} Reprocessed endoscopes should be free of microbial pathogens except for small numbers of relatively avirulent microbes that represent exogenous environmental contamination (e.g., coagulase-negative staphylococci *Bacillus* species, diphtheroids). It has also been suggested that the final rinse water used during endoscopes reprocessing should be microbiologically cultured at least monthly.⁷⁵ The microbiologic standard that should be met has not been set. However, neither the routine culture of reprocessed endoscopes nor the final rinse water has been validated by correlating viable counts on an endoscope to infection following an endoscopic procedure. If culturing of reprocessed endoscopes were done, sampling the endoscope would assess water quality as well as other important steps (e.g., disinfectant effectiveness, exposure time cleaning) in the reprocessing procedure. A number of methods for sampling endoscopes and water has been described.^{69,72,74,76-78}

The carrying case used to transport clean and reprocessed endoscopes outside of the healthcare environment, should not be used to store an endoscope or to transport the instrument within the healthcare facility. A contaminated endoscope should never be placed in the carrying case as the case can also become contaminated. When the endoscope is removed from the case and properly reprocessed and put back in the case, the endoscope can become recontaminated by the case. If the carrying case becomes contaminated, it should be discarded (Olympus America, June 2002, written communication).

Infection control professionals should ensure that institutional policies are consistent with national guidelines and conduct infection control rounds periodically (e.g., annually) in areas where endoscopes are reprocessed to make certain there is compliance with policy. Breaches in policy should be documented and corrective action instituted. In

incidents in which endoscopes were not exposed to a high-level disinfection process, all patients were assessed for possible acquisition of HIV, HBV, and hepatitis C virus (HCV). The highlights the importance of rigorous infection control.^{79,80}

Recommendations

These recommendations closely follow recommendations from a recent consensus guideline of professional organizations²⁶ and the draft CDC guideline on disinfection and sterilization [Rutala W, Weber DJ, Healthcare Infection Control Practices Advisory Committee. Draft CDC Guideline for Disinfection and Sterilization in Healthcare Facilities. www.cdc.gov/ncidod/hip/dsguide.htm, April 2002]. These guidelines have evolved from both the scientific literature and previous guidelines from professional and governmental organizations.^{20,25,58-61,68,81-83} These guidelines were designed for use in the United States and may require adaptation for use in other countries. Recommendations are categorized based on the support of scientific evidence as: *strongly recommended* (supported by epidemiologic, experimental, and clinical studies, and strong theoretic rationale); *suggested* (supported by suggestive epidemiologic or clinical studies or theoretic rationale); and *unresolved issue* (insufficient evidence or no consensus regarding efficacy).

1. Test each flexible endoscope for leaks as part of each reprocessing cycle. Remove any instrument that fails the leak test from clinical use and have it repaired. This recommendation is intended to detect damaged endoscopes. *Suggested.*^{23,25,26}
2. Perform meticulous cleaning of the endoscope with an enzymatic cleaner, compatible with the endoscope, immediately after use. Cleaning is essential prior to automated or manual disinfection. *Strongly recommended.*^{7,9,11,13-17,23,26,37,39,84,85}
3. Disconnect and disassemble endoscopic components (e.g., suction valves) as far as possible and completely immerse components in the enzymatic cleaner. Ideally if heat-stable, steam sterilize these components. *Strongly recommended.*^{13,14,26,53}
4. Flush and brush all accessible channels, to remove all organic (e.g., blood, tissue) and other residue. Clean the external surfaces and accessories of the devices by using a soft cloth, sponge, or brushes. Continue brushing until there is no debris on the brush. *Strongly recommended.*^{2,20,23,25,26,51,58,60,81,83,86,87}

5. Use cleaning brushes appropriate to the size of the endoscope channel or port (e.g., bristles should contact surfaces). Cleaning items (e.g., brushes, cloth) should be disposable or thoroughly cleaned and receive high-level disinfection or sterilization after each use. *Suggested.*^{23,25,26,88}
6. Discard enzymatic cleaners (or detergents) after each use, as these products are not microbicidal and will not retard microbial growth. *Strongly recommended.*^{14,23,25,26}
7. Process endoscopes (e.g., arthroscopes, cystoscopes, laparoscopes) that pass through normally sterile tissues using a sterilization procedure before each use; if this is not feasible, provide at least high-level disinfection. High-level disinfection of arthroscopes, laparoscopes, and cystoscopes should be followed by a sterile water rinse. *Strongly recommended.*^{23,25,83,89-95}
8. Endoscopes that are critical items (e.g., arthroscopes, cystoscopes, laparoscopes) that cannot be steam sterilized should be phased out and replaced with steam sterilizable instruments when feasible. *Suggested.*
9. Mechanically clean reusable accessories inserted into endoscopes (e.g., biopsy forceps or other cutting instruments) that break the mucosal barrier as described above (e.g., ultrasonically clean biopsy forceps) and then sterilize between each patient. *Strongly recommended.*^{2,3,20,23,25,26,52,58,60,66,83,89,96}
10. Use ultrasonic cleaning of reusable endoscopic accessories to remove soil and organic material from hard to clean areas. *Suggested.*^{26,58,61}
11. Endoscopes and accessories that come in contact with mucous membranes are classified as semicritical items and should receive at least high-level disinfection after each patient use. *Strongly recommended.*^{2,3,20,23,25,26,43,52,58-61,65-67,83,89,96}
12. Use an FDA-cleared sterilant or high-level disinfectant for sterilization or high-level disinfection (<http://www.fda.gov/cdrh/ode/germlab.html>). *Strongly recommended.*^{2-4,20,23,25,26,59,83,89}
13. Formulations containing glutaraldehyde, glutaraldehyde with phenol/phenate, orthophthalaldehyde, hydrogen peroxide, peracetic acid, and both hydrogen peroxide and peracetic acid can achieve high-level disinfection if the objects are properly cleaned, disinfected, rinsed and dried. (<http://www.fda.gov/cdrh/ode/germlab.html>). *Strongly recommended.*^{2-4,20,23,25,58-61,83,89}
14. The exposure time for disinfecting semicritical patent-care equipment varies for the Food and Drug Administration (FDA)-cleared high-level disinfectants (<http://www.fda.gov/cdrh/ode/germlab.html>). Extend exposure times beyond the minimum effective time (see below and text) cautiously and conservatively because with extended exposure to a high-level disinfectant it is more likely to damage delicate and intricate instruments such as flexible endoscopes. *Strongly recommended.*^{9,18,83,97-99}
15. Follow the FDA-cleared label claim for high-level disinfection unless several well-designed experimental scientific studies, endorsed by professional societies, demonstrate an alternative exposure time is effective for disinfecting semicritical items. The FDA-cleared labels for high-level disinfection with >2% glutaraldehyde at 25 °C range from 20 to 90 min depending upon the product. However, multiple scientific studies and professional organizations support the efficacy of >2% glutaraldehyde for 20 min at 20 °C *Strongly recommended.*^{9,10,12,15-17,21,22,26-34,37,38,83,97,98,100-114} [Food and Drug Administration. FDA-cleared sterilants and high-level disinfectants with general claims for processing reusable medical and dental devices, March 2003. www.fda.gov/cdrh/ode/germlab.html, 2003].
16. When using other FDA-cleared high-level disinfectants, use the manufacturer's recommended exposure conditions. These products may have a reduce exposure time (e.g., 0.55% orthophthalaldehyde for 12 min of 20 °C, 7.35% hydrogen peroxide plus 0.23% peracetic acid for 15 min at 20 °C) compared to glutaraldehyde at room temperature because of their rapid inactivation of mycobacteria or reduced exposure time due to increased mycobactericidal activity at elevated temperature (2.5% glutaraldehyde for 5 min at 35 °C). *Strongly recommended.*^{6,9,115-118}
17. Select a disinfectant or chemical sterilant that is compatible with the device being reprocessed. Avoid the use of reprocessing chemicals on an endoscope if the endoscope manufacturer warns against use because of functional damage (with or without cosmetic damage). *Strongly recommended.*^{18,23,26}
18. Completely immerse the endoscope in the high-level disinfectant and ensure all channels are perfused. Phase out nonimmersible endoscopes. *Strongly recommended.*^{20,23,24,26,51,81,86,119}
19. After high-level disinfection, rinse endoscopes and the flush channels with sterile water, filtered water, or tapwater, followed by a

- rinse with 70 to 90% ethyl or isopropyl alcohol. Retained disinfectant may adversely affect the patients (e.g. disinfectant induced colitis). *Strongly recommended.*^{20,23,25,26,48,58-61,71,83,92-94,120-132}
20. Following flushing all channels with alcohol, purge the channels using forced-air. This final drying step reduces the likelihood of contamination of the endoscopes by waterborne pathogens. *Strongly recommended.*^{23,25,26,58,60,71}
 21. Hang endoscopes in a vertical position to facilitate drying. *Suggested.*^{20,23,25,26,58,83,133}
 22. Store endoscopes in a manner that will protect the endoscope from damage or contamination. *Suggested.*^{20,23,25,26,58,83}
 23. Sterilize or high-level disinfect the water bottle, used to provide intraprocedural flush solution, and its connecting tube at least daily. Fill the water bottle with sterile water. *Strongly recommended.*^{23,26,92-94,120-122,134}
 24. Maintain a log for each procedure and record the following: the patient's name and medical record number (if available), the procedure, the date, the endoscopist, the system used to reprocess the endoscope (if more than one system could be used in the reprocessing area), and the serial number or other identifier of the endoscope used. *Strongly recommended.*^{23,23,25,26}
 25. Design facilities where endoscopes are used and disinfected to provide a safe environment for healthcare workers and patients. Use air-exchange equipment (e.g., ventilation system, out-exhaust ducts) to minimize the exposure of all persons to potentially toxic vapours (e.g., glutaraldehyde). Do not exceed the allowable limits of the vapour concentration of the chemical sterilant or high-level disinfectant (e.g., those of American Conference of Governmental Industrial Hygienists, OSHA). *Strongly recommended.*^{26,58,135-138}
 26. Perform routine testing of the liquid sterilant/high-level disinfectant to ensure minimal effective concentration of the active ingredient. Check the solution each day of use (or more frequency) and document the results. Discard the solution if the chemical indicator indicates that the concentration is less than the minimum effective concentration. *Strongly recommended.*^{20,23,25,26,97,106,139}
 27. Provide personnel assigned to reprocess endoscopes with device-specific reprocessing instructions to ensure proper cleaning and high-level disinfection or sterilization. Provide competency testing of personnel reprocessing endoscopes on a regular basis (e.g., commencement of employment, annually). *Strongly recommended.*^{2-4,20,23,25,26,58,61,68}
 28. Educate all personal using chemicals about the biological, chemical, and environmental hazards present while performing procedures that use disinfectants. *Strongly recommended.*^{26,140-143}
 29. Make personal protective equipment (e.g., gloves, gowns, eyewear, face mask or shields, respiratory protection devices) available and use appropriately to protect workers from exposure to chemicals or microorganisms (e.g., HBV). *Strongly recommended.*^{26,140,141,144-147}
 30. The selection and use of disinfectants in the healthcare field is dynamic, and products may become available that were not in existence when this guideline was written. As newer disinfectants become available, persons or committees responsible for selecting disinfectants should be guided by products cleared by the FDA, pertinent information from the disinfectant and instrument manufacturers, and information in the scientific literature. *Suggested.*^{26,83}
 31. If an automated endoscope reprocessor (AER) is used, place the endoscope in the reprocessor and attach all channel connectors according to the AER manufacture's instructions to ensure exposure of all internal surfaces with the high-level disinfectant/chemical sterilant. *Strongly recommended.*^{3,4,26,68,81,87}
 32. If an AER is used, ensure that the endoscope can be effectively reprocessed in the automated endoscope reprocessor. Also ensure that any required manual steps are performed (e.g., elevator wire channel of duodenoscopes may not be effectively disinfected by most AERs). *Strongly recommended.*^{3,4,25,26,68,81}
 33. Since design flaws and improper operation and practices have compromised the effectiveness of AERs, the infection control staff routinely should review the FDA advisories and the scientific literature for reports of deficiencies that may lead to infection. *Suggested.*^{4,26,47,48,68,81}
 34. Develop protocols to ensure that users can readily identify that an endoscope has been properly processed and is ready for patient use. *Suggested.*
 35. Do not use the carrying case used to transport clean and reprocessed endoscopes outside of the healthcare environment, to store an endoscope or to transport the instrument within the healthcare environment. *Suggested.*
 36. No recommendation to routinely perform microbiologic testing of endoscopes or rinse

water for quality assurance purposes. *Unresolved Issue*.²⁶

37. If environmental microbiologic testing is conducted, use standard microbiological techniques. *Suggested*.^{26,69,72,76,77}
38. Initiate an investigation to determine potential routes of transmission (e.g., person-to-person, common source) and reservoirs, if a cluster of endoscopy-related infections occurs. *Strongly recommended*.^{3,148}
39. Report outbreaks of endoscope-related infections to persons responsible for institutional infection control, risk management and FDA. *Strongly recommended*.^{2,4,23,26,149} Notify local and state health department, CDC, and the manufacturer(s). *Suggested*.
40. After reprocessing an endoscope according to this guideline, there is no recommendation for a reprocessing just prior to use. *Unresolved issue*.⁶⁹
41. Compare the reprocessing instructions provided by the endoscope and AER manufacturer's instructions and resolve any conflicting recommendations. *Strongly recommended*.^{26,68}

References

1. Schembre DB. Infectious complications associated with gastrointestinal endoscopy. *Gastrointest Endosc Clin N Am* 2000;**10**:215–232.
2. Spach DH, Silverstein FE, Stamm WE. Transmission of infection by gastrointestinal endoscopy and bronchoscopy. *Ann Intern Med* 1993;**118**:117–128.
3. Weber DJ, Rutala WA, DiMarino AJ Jr. The prevention of infection following gastrointestinal endoscopy: the importance of prophylaxis and reprocessing. In: DiMarino AJ Jr, Benjamin SB, editors. *Gastrointestinal diseases: an endoscopic approach*. Thorofare, NJ: Slack Inc; 2002. p. 87–106.
4. Weber DJ, Rutala WA. Lessons from outbreaks associated with bronchoscopy. *Infect Control Hosp Epidemiol* 2001;**22**:403–408.
5. Chu NS, Favero M. The microbial flora of the gastrointestinal tract and the cleaning of flexible endoscopes. *Gastrointest Endosc Clin N Am* 2000;**10**:233–244.
6. Alfa MJ, Sitter DL. In-hospital evaluation of orthophthaldehyde as a high level disinfectant for flexible endoscopes. *J Hosp Infect* 1994;**26**:15–26.
7. Vesley D, Melson J, Stanley P. Microbial bioburden in endoscope reprocessing and an in-use evaluation of the high-level disinfection capabilities of Cidex PA. *Gastroenterol Nurs* 1999;**22**:63–68.
8. Chu NS, McAlister D, Antonoplos PA. Natural bioburden levels detected on flexible gastrointestinal endoscopes after clinical use and manual cleaning. *Gastrointest Endosc* 1998;**48**:137–142.
9. Rutala WA, Weber DJ. FDA labeling requirements for disinfection of endoscopes: a counterpoint. *Infect Control Hosp Epidemiol* 1995;**16**:231–235.
10. Urayama S, Kozarek RA, Sumida S, Raltz S, Merriam L, Pethigal P. Mycobacteria and glutaraldehyde: is high-level disinfection of endoscopes possible? *Gastrointest Endosc* 1996;**43**:451–456.
11. 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**:392–401.
12. Kovacs BJ, Chen YK, Kettering JD, Apreccio RM, Roy I. High-level disinfection of gastrointestinal endoscopes: are current guidelines adequate? *Am J Gastroenterol* 1999;**94**:1546–1550.
13. Merrit K, Hitchins VM, Brown SA. Safety and cleaning of medical materials and devices. *J Biomed Mater Res* 2000;**53**:131–136.
14. Babb JR, Bradley CR. Endoscope decontamination: where do we go from here? *J Hosp Infect* 1995;**30**:543–551.
15. Hanson PJ, Gor D, Clarke JR, et al. Contamination of endoscopes used in AIDS patients. *Lancet* 1989;**2**:86–88.
16. Hanson PJ, Gor D, Clarke JR, et al. Recovery of the human immunodeficiency virus from fiberoptic bronchoscopes. *Thorax* 1991;**46**:410–412.
17. Chaufour X, Deva AK, Vickery K, et al. Evaluation of disinfection and sterilization of reusable angioscopes with the duck hepatitis B model. *J Vasc Surg* 1999;**30**:277–282.
18. Rutala WA, Weber DJ. Disinfection of endoscopes: review of new chemical sterilants used for high-level disinfection. *Infect Control Hosp Epidemiol* 1999;**20**:69–76.
19. Cheung RJ, Ortiz D, DiMarino Jr AJ. GI endoscopic reprocessing practices in the United States. *Gastrointest Endosc* 1999;**50**:362–368.
20. American Society for Gastrointestinal Endoscopy, Position statement: reprocessing of flexible gastrointestinal endoscopes. *Gastrointest Endosc* 1996;**43**:541–546.
21. Jackson J, Leggett JE, Wilson DA, Gilbert DN. *Mycobacterium gordonae* in fiberoptic bronchoscopes. *Am J Infect Control* 1996;**24**:19–23.
22. Lee RM, Kozarek RA, Sumida SE, Raltz SL. Risk of contamination of sterile biopsy forceps in disinfected endoscopes. *Gastrointest Endosc* 1998;**47**:377–381.
23. 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**:138–155.
24. Society of Gastroenterology Nurses and Associates, Guidelines for the use of high-level disinfectants and sterilants for reprocessing of flexible gastrointestinal endoscopes. *Gastroenterol Nurs* 2000;**23**:180–187.
25. Society of Gastroenterology Nurses and Associates, Standards for infection control and reprocessing of flexible gastrointestinal endoscopes. *Gastroenterol Nurs* 2000;**23**:172–179.
26. Nelson DB, Jarvis WR, Rutala WA, et al. Multi-society guideline for reprocessing flexible gastrointestinal endoscopes. *Infect Control Hosp Epidemiol* 2003;**24**:532–537.
27. Rutala WA. APIC guideline for selection and use of disinfectants. *Am J Infect Control* 1990;**18**:99–117.
28. Martin MA, Reichelderfer M, 1991 and 1993 APIC Guidelines Committee. APIC guidelines for infection prevention and control in flexible endoscopy. *Am J Infect Control* 1994;**22**:19–38.
29. Rey JF, Halfon P, Feryn JM, Khiri H, Masseyeff MF, Ouzan D. Risk of transmission of hepatitis C virus by digestive endoscopy. *Gastroenterol Clin Biol* 1995;**19**:346–349.
30. Cronmiller JR, Nelson DK, Jackson DK, Kim CH. Efficacy of conventional endoscopic disinfection and sterilization methods against *Helicobacter pylori* contamination. *Helicobacter* 1999;**4**:198–203.
31. Sartor C, Charrel RN, de Lamballerie X, Sambuc R, De Micco P, Boubli L. Evaluation of a disinfection procedure for

- hysteroscopes contaminated by hepatitis C virus. *Infect Control Hosp Epidemiol* 1999;20:434–436.
32. Hanson PJ, Chadwick MV, Gaya H, Collins JV. A study of glutaraldehyde disinfection of fiberoptic bronchoscopes experimentally contaminated with *Mycobacterium tuberculosis*. *J Hosp Infect* 1992;22:137–142.
 33. Kinney TP, Kozarek RA, Raltz S, Attia F. Contamination of single-use biopsy forceps: a prospective in vitro analysis. *Gastrointest Endosc* 2002;56:209–212.
 34. Best M, Springthorpe VS, Sattar SA. Feasibility of a combined carrier test for disinfectants: studies with a mixture of five types of microorganisms. *Am J Infect Control* 1994;22:152–162.
 35. Merighi A, Contato E, Scagliarini R, et al. Quality improvement in gastrointestinal endoscopy: microbiologic surveillance of disinfection. *Gastrointest Endosc* 1996;43:457–462.
 36. Bond WW. Endoscope reprocessing: problems and solutions. In: Rutala WA, editor. *Disinfection, sterilization, and antiseptics in healthcare*. Champlain, New York: Polyscience Publications; 1998. p. 151–163.
 37. Dava AK, Vickery K, Zou J, West RH, Harris JP, Cossart YE. Establishment of an in-use testing method for evaluating disinfection of surgical instruments using the duck hepatitis B model. *J Hosp Infect* 1996;33:119–130.
 38. Hanson PJ, Gor D, Jeffries DJ, Collins JV. Elimination of high titre HIV from fiberoptic endoscopes. *Gut* 1990;31:657–659.
 39. Wu MS, Wang JT, Yang JC, et al. Effective reduction of *Helicobacter pylori* infection after upper gastrointestinal endoscopy by mechanical washing of the endoscope. *Hepatology* 1996;43:1660–1664.
 40. Weber DJ, Rutala WA. Environmental issues and nosocomial infections. In: Wenzel RP, editor. *Prevention and control of nosocomial infections*. Baltimore: Williams and Wilkins; 1997. p. 491–514.
 41. Kirschke DL, Jones TF, Craig AS, et al. *Pseudomonas aeruginosa* and *Serratia marcescens* contamination associated with a manufacturing defect in bronchoscopes. *N Engl J Med* 2003;348:214–220.
 42. Srinivassan A, Wolfenden LL, Song X, et al. An outbreak of *Pseudomonas aeruginosa* infections associated with flexible bronchoscopes. *N Engl J Med* 2003;348:221–227.
 43. Kaczmarek RG, Moore Jr RM, McCrohan J, et al. Multi-state investigation of the actual disinfection/sterilization of endoscopes in health care facilities. *Am J Med* 1992;92:257–261.
 44. Bradley CR, Babb JR. Endoscope decontamination: automated vs. manual. *J Hosp Infect* 1995;30:537–542.
 45. Muscarella LF. Advantages and limitations of automatic flexible endoscope reprocessors. *Am J Infect Control* 1996;24:304–309.
 46. Muscarella LF. Automatic flexible endoscope reprocessors. *Gastrointest Endosc Clin N Am* 2000;10:245–257.
 47. Alvarado CJ, Stolz SM, Maki DG. Nosocomial infections from contaminated endoscopes: a flawed automated endoscope washer. An investigation using molecular epidemiology. *Am J Med* 1991;91:2725–2805.
 48. Fraser VJ, Jones M, Murray PR, Medoff G, Zhang Y, Wallace Jr RJ. Contamination of flexible fiberoptic bronchoscopes with *Mycobacterium chelonae* linked to an automated bronchoscope disinfection machine. *Am Rev Respir Dis* 1992;145:853–855.
 49. Cooke RP, Whymant-Morris A, Umasankar RS, Goddard SV. Bacteria-free water for automatic washer-disinfectors: an impossible dream? *J Hosp Infect* 1998;39:63–65.
 50. Muscarella LF. Deja Vu...All over again? The importance of instrument drying. *Infect Control Hosp Epidemiol* 2000;21:628–629.
 51. Rutala WA, Weber DJ. Importance of lumen flow in liquid chemical sterilization. *Am J Infect Control* 1999;20:458–459.
 52. Dwyer DM, Klein EG, Lstre GR, Robinson MG, Neumann DA, McCoy GA. *Salmonella newport* infections transmitted by fiberoptic colonoscopy. *Gastrointest Endosc* 1987;33:84–87.
 53. Wheeler PW, Lancaster D, Kaiser AB. Bronchopulmonary cross-colonization and infection related to mycobacterial contamination of suction valves of bronchoscopes. *J Infect Dis* 1989;159:954–958.
 54. Bond WW. Virus transmission via fiberoptic endoscope: recommended disinfection. *JAMA* 1987;257:843–844.
 55. Lynch DA, Porter C, Murphy L, Axon AT. Evaluation of four commercial automatic endoscope washing machines. *Endoscopy* 1992;24:766–770.
 56. Bond WW. Disinfection and endoscopy: microbial considerations. *J Gastroenterol Hepatol* 1991;6:31–36.
 57. Nelson D. Newer technologies for endoscope disinfection: electrolyzed acid water and disposable-component endoscope systems. *Gastrointest Endosc Clin N Am* 2000;10:319–328.
 58. Kruse A, Rey JF. Guidelines on cleaning and disinfection in GI endoscopy. Update 1999. The European Society of Gastrointestinal Endoscopy. *Endoscopy* 2000;32:77–80.
 59. British Thoracic Society, British Thoracic Society guidelines on diagnostic flexible bronchoscopy. *Thorax* 2001;56:1–21.
 60. Association of Operating Room Nurses, Recommended practices for use and care of endoscopes. 2000 standards, recommended practices, and guidelines. Denver, CO: AORN; 2000. pp. 243–247.
 61. British Society of Gastroenterology, Cleaning and disinfection of equipment for gastrointestinal endoscopy. Report of a working party of the British Society of Gastroenterology Endoscope Committee. *Gut* 1998;42:585–593.
 62. 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;6:578–582.
 63. Orsi GB, Filocamo A, Di Stefano L, Tittobello A. Italian national survey of digestive endoscopy disinfection procedures. *Endoscopy* 1997;29:732–738. quiz 739–740.
 64. Honeybourne D, Neuman CS. An audit of bronchoscopy practice in the United Kingdom: a survey of adherence to national guidelines. *Thorax* 1997;52:709–713.
 65. Michele TM, Cronin WA, Graham NM, et al. Transmission of *Mycobacterium tuberculosis* by a fiberoptic bronchoscope. Identification by DNA fingerprinting. *JAMA* 1997;278:1093–1095.
 66. Bronowicki JP, Venard V, Botte C, et al. Patient-to-patient transmission of hepatitis C virus during colonoscopy. *N Engl J Med* 1997;337:237–240.
 67. 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;278:1073–1077.
 68. Food and Drug Administration, Centers for Disease Control and Prevention, FDA and CDC public health advisory: infections from endoscopes inadequately reprocessed by an automated endoscope reprocessing system. Rockville, MD: Food and Drug Administration; 1999.
 69. Riley R, Beanland C, Bos H. Establishing the shelf life of flexible colonoscopes. *Gastroenterol Nurs* 2002;25:114–119.

70. Humphreys H, McGrath H, McCormick PA, Walsh C. Quality of final rinse water used in washer-disinfectors for endoscopes. *J Hosp Infect* 2002;**51**:151–153.
71. Gerding DN, Peterson LR, Vennes JA. Cleaning and disinfection of fiberoptic endoscopes: evaluation of glutaraldehyde exposure time and forced-air drying. *Gastroenterology* 1982;**83**:613–618.
72. Pang J, Perry P, Ross A, Forbes GM. Bacteria-free rinse water for endoscope disinfection. *Gastrointest Endosc* 2002;**56**:402–406.
73. Leung J, Vallero R, Wilson R. Surveillance cultures to monitor quality of gastrointestinal endoscope reprocessing. *Am J Gastroenterol* 2003;**98**.
74. Moses FM, Lee J. Surveillance cultures to monitor quality of gastrointestinal endoscope reprocessing. *Am J Gastroenterol* 2003;**98**:77–81.
75. Muscarella LF. Application of environmental sampling to flexible endoscope reprocessing: the importance of monitoring the rinse water. *Infect Control Hosp Epidemiol* 2002;**23**:285–289.
76. Bond WW, Hedrick ER. Microbiological culturing of environmental and medical-device surfaces. In: Isenberg HD, Gilchrist MJR, editors. *Clinical microbiology procedures, handbook, section 11, epidemiologic and infection control microbiology*. Washington, DC: American Society for Microbiology; 1992. p. 11.10.1–11.10.9.
77. Centers for Disease Control, Guidelines for environmental infection control in health care facilities. *MMWR* 2003;**52**(No. RR-10):1–44.
78. Murray PR, Baron EJ, Pfaller MA, Tenover FC, Tenover RH. In: Murray PR, Baron EJ, Pfaller MA, editors. *Manual of clinical microbiology*. Washington, DC: American Society for Microbiology Press; 1999. p. Press.
79. Murphy C. Inactivated glutaraldehyde: lessons for infection control. *Am J Infect Control* 1998;**26**:159–160.
80. Carsaw H, Debacker N. Recall of patients after use of inactive batch of Cidex disinfection solution in Belgian hospitals, Fifth International Conference of the Hospital Infection Society, Edinburgh: Hospital Infection Society, September 15–18, 2002.
81. Centers for Disease Control and Prevention, Bronchoscopy-related infections and pseudoinfections—New York, 1996 and 1998. *MMWR* 1999;**48**:557–560.
82. Bond WW, Favero MS, Mackel DC, Mallison GF. Sterilization or disinfection of flexible fiberoptic endoscopes. *AORN J* 1979;**30**:350–352.
83. Rutala WA, 1994, 1995, and 1996 APIC Guidelines Committee. APIC guideline for selection and use of disinfectants. Association for Professionals in Infection Control and Epidemiology, Inc. *Am J Infect Control* 1996;**24**:313–342.
84. Chu NS, Chan-Myers H, Ghazanfari N, Antonoplos N, Antonoplos P. Levels of naturally occurring microorganisms on surgical instruments after clinical use and after washing. *Am J Infect Control* 1999;**27**:315–319.
85. Vesley D, Norlien KG, Nelson B, Ott B, Streifel AJ. Significant factors in the disinfection and sterilization of flexible endoscopes. *Am J Infect Control* 1992;**20**:291–300.
86. Rutala WA, Gergen MF, Weber DJ. Comparative evaluation of the sporicidal activity of new low-temperature sterilization technologies: ethylene oxide, 2 plasma sterilization systems, and liquid peracetic acid. *Am J Infect Control* 1998;**26**:393–398.
87. Sorin M, Segal-Maurer S, Urban C, Combest A, Rahal JJ. Nosocomial transmission of imipenem-resistant *Pseudomonas aeruginosa* following bronchoscopy associated with improper connection to the STERIS System 1 Processor. *Infect Control Hosp Epidemiol* 2001;**22**:409–413.
88. Hoffmann KK, Weber DJ, Rutala WA. Pseudoepidemic of *Rhodotorula rubra* in patients undergoing fiberoptic bronchoscopy. *Infect Control Hosp Epidemiol* 1989;**10**:511–514.
89. Garner JS, Favero MS. CDC Guideline for handwashing and hospital environmental control, 1985. *Infect Control* 1986;**7**:231–243.
90. Burns S, Edwards M, Jennings J, et al. Impact of variation in reprocessing invasive fiberoptic scopes on patient outcomes. *Infect Control Hosp Epidemiol* 1996;**17**(Suppl.):P42.
91. Fuselier Jr HA, Mason C. Liquid sterilization versus high level disinfection in the urologic office. *Urology* 1997;**50**:337–340.
92. Wright EP, Collins CH, Yates MD. *Mycobacterium xenopi* and *Mycobacterium kansasii* in a hospital water supply. *J Hosp Infect* 1985;**6**:175–178.
93. Atlas RM. *Legionella*: from environmental habitats to disease pathology, detection and control. *Environ Microbiol* 1999;**1**:283–293.
94. Wallace Jr RJ, Brown BA, Driffith DE. Nosocomial outbreaks/pseudo-outbreaks caused by nontuberculous mycobacteria. *Annu Rev Microbiol* 1998;**52**:453–490.
95. Garner JS, Simmons BP. Guideline for isolation precautions in hospitals. *Infect Control* 1983;**4**:245–325.
96. Graham DY, Osato MS. Disinfection of biopsy forceps and culture of *Helicobacter pylori* from gastric mucosal biopsies. *Am J Gastroenterol* 1999;**94**:1422–1423.
97. Cole EC, Rutala WA, Nessen L, Wannamaker NS, Weber DJ. Effect of methodology, dilution, and exposure time on the tuberculocidal activity of glutaraldehyde-based disinfectants. *Appl Environ Microbiol* 1990;**56**:1813–1817.
98. Rutala WA, Code EC, Wannamaker NS, Weber DJ. Inactivation of *Mycobacterium tuberculosis* and *Mycobacterium bovis* by 14 hospital disinfectants. *Am J Med* 1991;**91**:2675–2715.
99. Rutala WA, Gergen MF, Weber DJ. Sporicidal activity of chemical sterilants used in hospitals. *Infect Control Hosp Epidemiol* 1993;**14**:713–718.
100. Foliente RLKB, Aprecio RM, Bains HJ, Kettering JD, Chen YK. Efficacy of high-level disinfectants for reprocessing gastrointestinal endoscopes in simulated use-testing. *Gastrointest Endosc* 2001;**53**:456–462.
101. Collins FM. Kinetics of the tuberculocidal response by alkaline glutaraldehyde in solution and on an inert surface. *J Appl Bacteriol* 1986;**61**:87–93.
102. Collins FM. Use of membrane filters for measurement of mycobactericidal activity of alkaline glutaraldehyde solution. *Appl Environ Microbiol* 1987;**53**:737–739.
103. Ascenzi JM, Ezzell RJ, Wendt TM. A more accurate method for measurement of tuberculocidal activity of disinfectants. *Appl Environ Microbiol* 1987;**53**:2189–2192.
104. Best M, Sattar SA, Springthorpe VS, Kennedy ME. Efficacies of selected disinfectants against *Mycobacterium tuberculosis*. *J Clin Microbiol* 1990;**28**:2234–2239.
105. Chanzy B, Duc-Bin DL, Rousset B, et al. Effectiveness of a manual disinfection procedure in eliminating hepatitis C virus from experimentally contaminated endoscopes. *Gastrointest Endosc* 1999;**50**:147–151.
106. Mbithi JN, Springthorpe VS, Sattar SA, Pacquette M. Bactericidal, virucidal, and mycobactericidal activities of reused alkaline glutaraldehyde in an endoscopy unit. *J Clin Microbiol* 1993;**31**:2988–2995.
107. Hughes CE, Gebhard RL, Peterson LR, Gerding DN. Efficacy of routine fiberoptic endoscope cleaning and disinfection

- for killing *Clostridium difficile*. *Gastrointest Endosc* 1986; **32**:7–9.
108. Akamatsu T, Tabata K, Hironga M, Kawakami H, Uyeda M. Transmission of *Helicobacter pylori* infection via flexible fiberoptic endoscopy. *Am J Infect Control* 1996; **24**: 396–401.
 109. Dyas A, Das BC. The activity of glutaraldehyde against *Clostridium difficile*. *J Hosp Infect* 1985; **6**:41–44.
 110. Payan C, Cottin J, Lemarie C, Ramont C. Inactivation of hepatitis B virus in plasma by hospital in-use chemical disinfectants assessed by a modified HepG2 cell culture. *J Hosp Infect* 2001; **47**:282–287.
 111. Hanson PJ, Gor D, Jeffries DJ, Collins JV. Chemical inactivation of HIV on surfaces. *Br Med J* 1989; **298**: 862–864.
 112. Rutala WA, Gergen MF, Weber DJ. Inactivation of *Clostridium difficile* spores by disinfectants. *Infect Control Hosp Epidemiol* 1993; **14**:36–39.
 113. Tyler R, Ayliffe GA, Bradley C. Virucidal activity of disinfectants: studies with the poliovirus. *J Hosp Infect* 1990; **15**:339–345.
 114. Mbithi JN, Springthorpe VS, Sattar SA. Chemical disinfection of hepatitis A virus on environmental surfaces. *Appl Environ Microbiol* 1990; **56**:3601–3603.
 115. Gregory AW, Schaalje GB, Smart JD, Robison RA. The mycobactericidal efficacy of ortho-phthalaldehyde and the comparative resistances of *Mycobacterium bovis*, *Mycobacterium terrae*, and *Mycobacterium chelonae*. *Infect Control Hosp Epidemiol* 1999; **20**:324–330.
 116. Walsh SE, Maillard JY, Simons C, Russell AD. Studies on the mechanisms of the antibacterial action of ortho-phthalaldehyde. *J Appl Microbiol* 1999; **87**:702–710.
 117. Walsh SE, Maillard JY, Russell AD. Ortho-phthalaldehyde: a possible alternative to glutaraldehyde for high level disinfection. *J Appl Microbiol* 1999; **86**:1039–1046.
 118. Fraud S, Maillard J-Y, Russell AD. Comparison of the mycobactericidal activity of ortho-phthalaldehyde, glutaraldehyde, and other dialdehydes by a quantitative suspension test. *J Hosp Infect* 2001; **48**:214–221.
 119. Rutala WA, Gergen MF, Weber DJ. Sporicidal activity of a new low-temperature sterilization technology: the Sterrad 50 sterilizer. *Infect Control Hosp Epidemiol* 1999; **20**: 514–516.
 120. Lowry PW, Jarvis WR. Use of tap water and disinfection practices in outpatient settings. A survey of otolaryngologists. *Arch Otolaryngol Head Neck Surg* 1991; **117**:886–888.
 121. 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**:19–23.
 122. Meenhorst PL, Reingold AL, Groothuis DG, et al. Water-related nosocomial pneumonia caused by *Legionella pneumophila* serogroups 1 and 10. *J Infect Dis* 1985; **152**: 356–364.
 123. Castelli M, Qizilbash A, Seaton T. Post-colonoscopy proctitis. *Am J Gastroenterol* 1986; **81**:887.
 124. Jonas G, Mahoney A, Murray J, Gertler S. Chemical colitis due to endoscope cleaning solutions: a mimic of pseudo-membranous colitis. *Gastroenterology* 1988; **95**: 1403–1408.
 125. Levine DS. Proctitis following colonoscopy. *Gastrointest Endosc* 1988; **34**:269–272.
 126. Durante L, Zulty JC, Israel E, et al. Investigation of an outbreak of bloody diarrhea: association with endoscopic cleaning solution and demonstrating of lesions in an animal model. *Am J Med* 1992; **92**:476–480.
 127. Burtin P, Ruget O, Petit R, Boyer J. Glutaraldehyde-induced proctitis after endorectal ultrasound examination: a higher risk of incidence than expected? *Gastrointest Endosc* 1993; **39**:859–866.
 128. Babb RR, Paaso BT. Glutaraldehyde proctitis. *West J Med* 1995; **163**:477–488.
 129. Ryan CK, Potter GD. Disinfectant colitis. Rinse as well as you wash. *J Clin Gastroenterol* 1995; **21**:6–9.
 130. West AB, Kuan SF, Bennick M, Lagarde S. Glutaraldehyde colitis following endoscopy: clinical and pathological features and investigation of an outbreak. *Gastroenterology* 1995; **108**:1250–1255.
 131. Dolce P, Gourdeau M, April N, Bernard PM. Outbreak of glutaraldehyde-induced proctocolitis. *Am J Infect Control* 1995; **23**:34–39.
 132. Rozen P, Somjen GJ, Baratz M, Kimel R, Arber N, Gilat T. Endoscope-induced colitis: description, probable cause by glutaraldehyde, and prevention. *Gastrointest Endosc* 1994; **40**:547–553.
 133. Association of Operating Room Nurses, Recommended practices for sterilization in perioperative practice settings. 2000 Standards, recommended practices, and guidelines. Denver, CO: AORN; 2000.
 134. Lowry PW, Jarvis WR, Oberle AD, et al. *Mycobacterium chelonae* causing otitis media in an ear-nose-and-throat practice. *N Engl J Med* 1988; **319**:978–982.
 135. American Conference of Governmental Industrial Hygienists (ACGIH), Threshold limit values for chemical substances and physical agents and biological exposure indices. Cincinnati: ACGIH; 2001.
 136. Weber DJ, Rutala WA. Occupational risks associated with the use of selected disinfectants and sterilants. In: Rutala WA, editor. *Disinfection, sterilization, and antisepsis in healthcare*. Champlain, New York: Polyscience Publications; 1998. p. 211–226.
 137. Rutala WA, Hamory BH. Expanding role of hospital epidemiology: employee health-chemical exposure in the health care setting. *Infect Control Hosp Epidemiol* 1989; **10**:261–266.
 138. Occupational Safety and Health Administration, Air contaminants final rule. *Fed Regist* 1993; **58**:35338–35351.
 139. Leong D, Dorsey G, Klapp M. Dilution of glutaraldehyde by automatic endoscope machine washers: the need for a quality control program. *Abstracts of the 14th Annual Educational Conference of Association for Practitioners in Infection Control*, vol. **108**.; 1987. p. 130.
 140. Occupational Health and Safety Administration, Hazard Communication Standard. 29 CFR 1910.1200. Washington, DC: OSHA; 1910.
 141. Edens AL. Occupational safety and health administration: regulations affecting healthcare facilities. In: Rutala WA, editor. *Disinfection, sterilization and antisepsis: principles and practices in healthcare facilities*. Washington, DC: Association for Professionals in Infection Control and Epidemiology, Inc; 2001. p. 49–58.
 142. Fahey BJ, Koziol DE, Banks SM, Henderson DK. Frequency of nonparenteral occupational exposures of blood and body fluids before and after universal precautions training. *Am J Med* 1991; **90**:145–153.
 143. Beekmann SE, Vlahov D, Koziol DE, McShalley ED, Schmitt JM, Henderson DK. Temporal association between implementation of universal precautions and a sustained progressive decrease in percutaneous exposures of blood. *Clin Infect Dis* 1994; **18**:562–569.
 144. Occupational Safety and Health Administration, Occupational exposure to bloodborne pathogens; final rule. *Fed Regist* 1991; **56**:64003–64182.
 145. Rutala WA, Weber DJ. A review of the use of gowns and

- drapes (single use and reusable) in healthcare. *Infect Control Hosp Epidemiol* 2001;**22**:248–257.
146. Gerberding JL, Littell C, Tarkington A, Brown A, Schechter WP. Risk of exposure of surgical personnel to patients' blood during surgery at San Francisco General Hospital. *N Engl J Med* 1991;**324**:1788–1793.
147. Mast ST, Woolwine JD, Gerberding JL. Efficacy of gloves in reducing blood volumes transferred during simulated needlestick injury. *J Infect Dis* 1993;**168**:1589–1592.
148. Wendt C, Herwaldt LA. Epidemics: identification and management. In: Wenzel RP, editor. *Prevention and control of nosocomial infections*. Baltimore: Williams and Wilkins; 1997. p. 175–214.
149. Feigl DW, Gardner SN, McClellan M. Ensuring safe and effective medical devices. *N Engl J Med* 2003;**348**:191–192.