

Disinfection and Sterilization

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Disinfection of Endoscopes: Review of New Chemical Sterilants Used for High-Level Disinfection

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ABSTRACT

Chemical sterilants are used to high-level disinfect heat-sensitive semicritical items such as endoscopes. Most endoscopes have been reprocessed between each patient use with glutaraldehyde (>2%) or the Steris System 1. Several new chemical sterilants have been developed recently, including 7.5% hydrogen peroxide, 0.08% peracetic acid plus 1.0% hydrogen peroxide, and

0.55% orthophthalaldehyde. In order to aid the infection control professional in choosing the appropriate disinfection methodology, this article reviews the characteristics, advantages, and disadvantages of high-level disinfectants intended for reprocessing endoscopes (*Infect Control Hosp Epidemiol* 1999;20:69-76).

Endoscopes have been used widely for the diagnosis and therapy of medical disorders and are used increasingly for performing laparoscopic surgery. Currently, greater than 10,000,000 gastrointestinal endoscopic procedures are performed each year.¹ Endoscopes are contaminated routinely by microorganisms during clinical use. Failure to employ appropriate cleaning, disinfection, or sterilization of endoscopes has been responsible for multiple nosocomial outbreaks and serious, sometimes life-threatening, infections.²

Because the endoscope comes into intimate contact with mucous membranes, high-level disinfection is the current reprocessing standard after each patient use. High-level disinfection refers to the use of a chemical sterilant at shorter exposure times than would achieve sterilization; this process inactivates all microorganisms (ie, bacteria, fungi, viruses, mycobacteria), but not high levels of bacterial spores.³⁻⁶ Concern has been raised that failure to sterilize (ie, eliminate all microorganisms including bacterial spores) such equipment may be associated with an increased risk of disease transmission. However, not only is scientific evidence to support this concern lacking, but current data suggest that high-level disinfection provides the same degree of safety as sterilization.⁷⁻¹⁰ First, there have been no outbreaks described in which cross-transmission

occurred when cleaning and high-level disinfection were performed appropriately.¹¹ Second, two studies have been reported that compared the clinical infection risks associated with sterilization versus high-level disinfection.^{9,10} Burns and colleagues used a prospective study design to compare ethylene oxide to high-level disinfection with glutaraldehyde for arthroscopes and laparoscopes. The infection rates (per 1,000 procedures) did not differ statistically: ethylene oxide, 7.5; glutaraldehyde, 2.5.⁹ Fuselier and coworkers compared the Steris System 1 (Steris, Mentor, OH), a sterilization process using peracetic acid, to high-level disinfection with glutaraldehyde for urologic endoscopes and reported no clinical differences between the two systems.¹⁰

The choice of high-level disinfectants is an important concern to infection control professionals and other healthcare professionals. This article reviews new chemical sterilants used as high-level disinfectants to facilitate that decision-making process.

CATEGORIES OF ENDOSCOPES

The uses and types of endoscopes have been reviewed and are summarized briefly below.¹² Flexible endoscopes include the gastrointestinal endoscopes and bronchoscopes. Both share the common features of being

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fragile and heat-sensitive, with small, long lumens, cross-connections, mated surfaces, sharp angles, springs and valves, occluded dead ends, absorbent materials, and rough or pitted surfaces. In contrast to flexible endoscopes, rigid endoscopes, which include laparoscopes and arthroscopies, are small, smooth, easily cleanable, and generally have no lumens. With use, flexible endoscopes become more contaminated microbially^{13,14} than rigid endoscopes,¹⁵ because flexible endoscopes are used on heavily colonized body sites.

NOSOCOMIAL INFECTIONS ASSOCIATED WITH ENDOSCOPES

The incidence of infections following endoscopic procedures has been evaluated by several investigators. For example, a questionnaire survey conducted in the United States in 1974 of more than 240,000 gastrointestinal endoscopies (esophagogastroduodenoscopy and colonoscopy) found 24 infectious complications, including two fatal episodes of cholangitis and two fatal episodes of pancreatic sepsis. The overall infection rate was estimated to be less than 1 per 10,000 procedures. This study was limited by being retrospective, and thus some infections may not have been recognized.^{16,17}

Although there is a low incidence of infection following endoscopy, numerous infections have been associated with endoscopic procedures. For example, a literature review from 1966 to July 1992 reported 281 infections following gastrointestinal endoscopy and 96 infections following bronchoscopy. Pathogens associated with gastrointestinal endoscopy most commonly have included *Salmonella* species and *Pseudomonas aeruginosa*. Pathogens associated with bronchoscopy most commonly have included *Mycobacterium tuberculosis*, atypical mycobacteria, and *P. aeruginosa*.² Clinically significant pathogens continue to be transmitted by gastrointestinal endoscopy or bronchoscopy, including hepatitis C¹⁸ and multidrug-resistant *M. tuberculosis*.¹⁹ Nosocomial transmission of infection has been a result of inadequate cleaning, improper selection of a disinfecting agent, or failure to follow recommended cleaning and disinfection procedures.²

PROBLEMS WITH DISINFECTION OF ENDOSCOPES

Problems with disinfection of endoscopes stem from endoscopes being heat sensitive; hence, one cannot use steam sterilization, the technique with the greatest margin of safety. Walter Bond has summarized the critical problems associated with disinfecting currently available endoscopes.¹² First, these instruments are structurally complex and fragile. Second, there is the critical lack of manufacturer-validated methods for consistently reproducible access, cleaning, and disinfection or sterilization of the instruments and their accessories. Cleaning is essential to remove blood, body fluids, and other organic and inorganic debris prior to the application of any high-level disinfectant. The high-level disinfectants must be flushed through all internal lumens, cavities, and channels to ensure that the necessary contact

time occurs between potential pathogens and the high-level disinfectant. In the absence of such contact, both high-level disinfection and sterilization methods may fail.

Epidemics of endoscopy-associated infections attributed to the use of flawed automated endoscope reprocessors have been reported²⁰ and highlight the need for automated endoscope reprocessors to be designed to resist contamination. In addition, hospitals using reprocessors should ensure that a new chemical sterilant or high-level disinfectant is compatible with reprocessor materials and does not damage the internal parts of the reprocessor.

CHARACTERISTICS OF THE IDEAL CHEMICAL STERILANT USED AS A HIGH-LEVEL DISINFECTANT

The characteristics of an ideal chemical sterilant used as a high-level disinfectant should include broad antimicrobial spectrum, rapid activity, material compatibility, lack of toxicity to humans and the environment, odorless, nonstaining, unrestricted disposal, prolonged reuse life and shelf life, easy to use, resistant to organic material, ability to be monitored for concentration, and cost-effective (Table 1).

CURRENTLY AVAILABLE CHEMICAL STERILANTS USED PRIMARILY AS HIGH-LEVEL DISINFECTANTS

A comparison of the characteristics of currently available chemical sterilants used primarily as high-level disinfectants plus a chemical sterilant awaiting Food and Drug Administration (FDA) clearance is presented in Table 2 and below.

Glutaraldehyde

Glutaraldehyde, a saturated dialdehyde, has been the most widely used chemical for the high-level disinfection of endoscopes. Most aqueous solutions of glutaraldehyde are acidic and must be activated (made alkaline to pH 7.5-8.5) to become sporicidal. Acid glutaraldehydes also are available and do not require activation, but some studies have shown them to have less microbiocidal activity than alkaline preparations.²¹ The biocidal activity of glutaraldehyde is a consequence of its alkylation of sulfhydryl, hydroxyl, carboxyl, and amino groups, which alters RNA, DNA, and protein synthesis within microorganisms.^{4,22}

Glutaraldehyde has broad-spectrum antimicrobial activity.^{4,22} Several investigators have shown that 2% aqueous solutions of glutaraldehyde, buffered to pH 7.5-8.5 with sodium bicarbonate, effectively killed vegetative bacteria in less than 2 minutes, fungi and viruses in less than 10 minutes, *M. tuberculosis* in less than 20 minutes, and spores of *Bacillus* and *Clostridium* species in 3 hours. Microbiocidal activity is affected by age, dilution, and organic stress. Dilution during use is common, and one must ensure that endoscopes or other semicritical items are exposed to an acceptable concentration. Data suggest that 1% to 1.5% glutaraldehyde is the minimum effective concentration when used as a high-level disinfectant.^{4,5}

TABLE 1
CHARACTERISTICS OF IDEAL CHEMICAL STERILANTS USED AS HIGH-LEVEL DISINFECTANTS

Desired Characteristic	Specification
High efficacy	Should be virucidal, bacteriocidal, tuberculocidal, fungicidal, and sporicidal
Rapid activity	Should be able to achieve high-level disinfection quickly (in 20 minutes or less) in order to minimize turnaround time
Material compatibility	Should produce negligible changes in either the appearance or function (especially optical clarity) of processed items, even after repeated cycling. Should not corrode instrument or cause deterioration of rubber, plastics, metals, or other construction materials such as elastomers
Nontoxic	Should present no health risk to the operator or the patient and pose no hazard to the environment
Odorless	Should have either no odor or a pleasant odor
Nonstaining	Should not stain human skin, clothing, or environmental surfaces
Resistant to organic material	Should be able to withstand reasonable organic material challenge without loss of efficacy
Monitoring capability	Should be able to monitor minimum effective concentration using a simple procedure
Ease of use	Should be able to be used with minimal training
Prolonged reuse life	Should be able to be used repeatedly over an extended period of time
Long shelf life	Should be able to be stored prior to use for an extended period of time without loss of activity
Unrestricted disposal	Should have no requirements for special disposal (eg, requirement for collection or neutralization prior to disposal)
Cost-effective	Should have reasonable cost per cycle

Glutaraldehyde vapors are irritating to the eyes, nose, and throat, and, at a sufficient concentration, may cause epistaxis, allergic contact dermatitis, asthma, and rhinitis.^{4,23} For this reason, it is prudent to adhere to a ceiling level of 0.05 ppm.²⁴ Maintaining ambient concentrations below this level can be achieved by using one or more of the following methods: ducted exhaust hoods, air systems that provide 7 to 15 air exchanges per hour, ductless fume hoods with absorbents for the glutaraldehyde vapor, tight-fitting lids on immersion baths, and automated endoscope processors.²⁵ Failure to rinse disinfected equipment thoroughly has led to serious proctitis and mucosal damage in patients.²⁶

Hydrogen Peroxide

Hydrogen peroxide is an oxidizing agent that now is being used to achieve high-level disinfection. It works by the production of destructive hydroxyl free radicals, which can attack membrane lipids, DNA, and other essential cell components.⁴ Although catalase (which is produced by aerobic and facultative anaerobes that possess cytochrome systems) may protect cells from metabolically produced hydrogen peroxide, this defense is overwhelmed by the concentrations used for high-level disinfection.

Inactivation of microorganisms is dependent on time, temperature, and concentration. A 10% concentration of hydrogen peroxide has been shown to inactivate 10⁶ *Bacillus* species in 60 minutes, while a 3% concentration killed 10⁶ *Bacillus* species in 150 minutes in 6 of 7 trials.²⁷ As with glutaraldehyde, failure to rinse disinfected equipment^{28,29} has led to pseudomembrane-like enteritis and colitis in patients.

The currently marketed product, Sporox (Reckitt & Colman, Montvale, NJ), is a premixed, ready-to-use chemical that contains 7.5% hydrogen peroxide and 0.85% phos-

phoric acid (to maintain a low pH).^{30,31} The product formerly was marketed as Spor-o-syl by National Laboratories and Endo-spore by Globe Medical. The manufacturer's recommended contact time for high-level disinfection is 30 minutes at 20°C. Although the product was marketed at 6.0%, based on its minimum effective concentration, the concentration of the unused product was 7.5%. Manufacturer's data demonstrate an ~10⁶ reduction of *Mycobacterium bovis* within 20 minutes.³² The mycobactericidal activity of 7.5% hydrogen peroxide has been corroborated by Sattar, who showed the inactivation of >10⁵ multidrug-resistant *M tuberculosis* after a 10-minute exposure.³³ Thirty minutes were required for >99.9% inactivation of polio and hepatitis A viruses.³² The effectiveness of 7.5% hydrogen peroxide at 10 minutes was compared to 2% alkaline glutaraldehyde at 20 minutes in manual disinfection of endoscopes; no significant difference in germicidal activity was observed.³⁴ There also were no complaints received from the nursing or medical staff in terms of odor or toxicity. Vesley and colleagues demonstrated that 7.5% hydrogen peroxide was more effective in killing or removing *Bacillus subtilis* spores in a 10-minute contact time when compared to 2% glutaraldehyde.³⁵

As with other chemical sterilants, dilution must be monitored by regularly testing the minimum effective concentration (ie, 6.0%). Compatibility testing of Sporox by Olympus (Melville, NY) found no significant functional changes observed with any tested endoscopes, but found some cosmetic changes (eg, discoloration of black anodized metal finishes).³⁶

Peracetic Acid

Peracetic acid or peroxyacetic acid, an oxidizing agent, is thought to function similarly to hydrogen peroxide by denaturing protein, disrupting cell-wall permeability,

TABLE 2
COMPARISON OF THE CHARACTERISTICS OF CHEMICAL STERILANTS USED PRIMARILY AS HIGH-LEVEL DISINFECTANTS

	Chemical Sterilants Comparison				
	Hydrogen Peroxide (7.5%)	Peracetic Acid (0.2%)	Glutaraldehyde ($\geq 2.0\%$)	Peracetic Acid and Hydrogen Peroxide (0.08%/1%)	Orthophthalaldehyde (0.55%)
High-level disinfectant claim	30 min at 20°C	NA	20-90 min at 20°-25°C	25 min at 20°C	10 min at 20°C
Sterilization claim	6 h at 20°, 20 min at 50°C	30 min at 50°C	10 h at 20°-25°C	8 h at 20°C	10 h at 25°C
Activation	No	No	Yes (alkaline glutaraldehyde)	No	No
Reuse life*	21 d	Single use	14-30 d (acid glutaraldehyde, 1 y)	14 d	14 d
Shelf-life stability†	2 y	6 mo	2 y	2 y	2 y
Disposal restrictions	None	None	Local‡	None	Local‡
Materials compatibility	Good	Fair	Excellent	Fair	Excellent
Monitor MEC	Yes (6%)	No (ionic concentration)	Yes (1.5% or higher)	Yes (500 ppm PA)	Yes (0.3% OPA)
Safety	Serious eye damage (safety glasses)	Serious eye and skin damage (concentrated solution)	Respiratory	Eye damage	Eye irritant, stains skin
Processing	Manual or automated	Automated	Manual or automated	Manual or automated	Manual or automated
Organic material resistance	Yes	Yes	Yes	Yes	Yes
Trade name	Sporox	Steris 20	Cidex (Advanced Sterilization Products, Irvine, CA), Metricide (Metrix Research Corp, Parker, CO), Omnicide (Metrix Research Corp), Wavicide (Wave Energy Systems, Wayne, NJ), Procide (Metrix Research Corp)	Cidex PA	Cidex OPA
OSHA exposure limit	1 ppm TWA	PA—none	0.05 ppm ceiling§	PA—none, HP 1 ppm TWA	None
Sterilant Cost	\$24.99/gal	\$4.95/container	\$10.40/gal	\$18.75/gal	No data
Cost profile (per cycle)	\$0.40, manual; \$2.38, automated	\$4.95 (automated)	\$0.25, manual; \$1.49, automated	\$0.45, manual; \$2.68, automated	No data

Abbreviations: HP, hydrogen peroxide; MEC, minimum effective concentration is the lowest concentration of active ingredients at which the product is still effective; NA, not applicable; OPA, orthophthalaldehyde; OSHA, Occupational Safety and Health Administration; PA, peracetic acid; TWA, time-weighted average for a conventional 8-hour workday.

* Number of days a product can be reused as determined by reuse protocol.

† Time a product can remain in storage (unused).

‡ No US Environmental Protection Agency regulations, but some states and local authorities have additional restrictions.

§ American Conference of Governmental Industrial Hygienists recommendation.

|| Figure includes only the cost of the processing solution (suggested list price in August 1998).

¶ Per cycle cost profile assumes maximum use life (eg, 21 days for hydrogen peroxide, 14 days for glutaraldehyde), three reprocessing cycles per day, 1-gal basin for manual processing, and 6-gal tank for automated processing.

and oxidizing sulfhydryl and sulfur bonds in proteins, enzymes, and other metabolites. Peracetic acid can corrode copper, brass, bronze, plain steel, and galvanized iron, but these effects can be reduced by additives and pH modifications. It is unstable when diluted; for example, a 1%

solution loses half its strength through hydrolysis in 6 days, whereas 40% peracetic acid loses 1% to 2% of its activity per month.^{4,37}

Peracetic acid is characterized by a rapid, broad-spectrum antimicrobial activity. It will inactivate gram-

TABLE 3
SUMMARY OF ADVANTAGES AND DISADVANTAGES FOR CHEMICAL STERILANTS* USED PRIMARILY AS HIGH-LEVEL DISINFECTANTS

Sterilization Method	Advantages	Disadvantages
Peracetic acid/hydrogen peroxide	No activation required Odor or irritation not significant	Materials compatibility concerns (lead, brass, copper, zinc), both cosmetic and functional Limited clinical use
Glutaraldehyde	Numerous use studies published Relatively inexpensive Excellent materials compatibility	Respiratory irritation from glutaraldehyde vapor Pungent and irritating odor Relatively slow mycobactericidal activity Coagulates blood and fixes tissue to surfaces
Hydrogen peroxide	No activation required May enhance removal of organic matter and organisms No disposal issues No odor or irritation issues Compatible with metals, plastics, and elastomers (Olympus [Melville, NY] scopes) Does not coagulate blood or fix tissues to surfaces Inactivates <i>Cryptosporidium</i> Use studies published	Material compatibility concerns for brass, zinc, copper, and nickel or silver plating Serious eye damage if contacted
Orthophthalaldehyde	Fast-acting, high-level disinfectant No activation required Odor not an issue Excellent materials compatibility claimed Does not coagulate blood or fix tissues to surfaces claimed	Stains skin, clothing, and environmental surfaces Limited clinical use
Peracetic acid (Steris System 1, Steris, Mentor, OH)	Rapid sterilization cycle time (30-45 min) Low-temperature (50°-55°C) liquid-immersion sterilization Environmentally friendly by-products (acetic acid, O ₂ , H ₂ O) Fully automated No adverse health effects to operators Compatible with wide variety of materials and instruments Does not coagulate blood or fix tissues to surfaces Rapidly sporicidal Provides procedure standardization (constant dilution, perfusion of channel, temperatures, exposure)	Potential material incompatibility (eg, aluminum anodized coating becomes dull) Used for immersible instruments only Biological indicator may not be suitable for routine monitoring One scope or a small number of instruments can be processed in a cycle More expensive (endoscope repairs, operating costs, purchase costs) than high-level disinfection Serious eye and skin damage (concentrated solution) Point-of-use system, no long-term sterile storage

* All products effective in presence of organic soil, relatively easy to use, and have a broad spectrum of antimicrobial activity (bacteria, fungi, viruses, bacterial spores, and mycobacteria). The above characteristics are documented in the literature. Contact the manufacturer of the instrument and sterilant for additional information.

positive and gram-negative bacteria, fungi, and yeasts in 5 or fewer minutes at less than 100 ppm. In the presence of organic matter, 200 to 500 ppm are required. For viruses, the concentration range required for inactivation is wide (12-2,250 ppm), with poliovirus inactivated in yeast extract in 15 minutes with 1,500 to 2,250 ppm. Bacterial spores are inactivated with 500 to 10,000 ppm in 15 seconds to 20 minutes.³⁷

The Steris System 1 processor is a liquid chemical

sterilization process for reprocessing endoscopes. The sterilant, 35% peracetic acid, is diluted to 0.2% with filtered water at a temperature of 50°C. Simulated-use trials have demonstrated excellent microbiocidal activity,^{38,39} and three clinical trials have demonstrated both excellent microbial killing and no clinical failures leading to infection.^{10,40,41} The high efficacy of the Steris system was demonstrated by Alfa and coworkers, who compared the Steris System 1 with ethylene oxide. Only the Steris system

was able to completely kill 6 logs of *Mycobacterium chelonae*, *Enterococcus faecalis*, and *B subtilis* spores with both an organic and inorganic challenge.⁴² An investigation by Fuselier and Mason¹⁰ examined the costs, performance, and maintenance of urologic endoscopic equipment processed by high-level disinfection (with glutaraldehyde) or Steris System 1 and reported no clinical differences between the two systems. However, the use of the Steris System 1 led to increased costs when compared to high-level disinfection, including processing costs (\$6.11 vs \$0.45 per cycle), purchasing and training (\$24,845 vs \$16), installation (\$5,800 vs \$0), and endoscope repairs (\$6,037 vs \$445).¹⁰

An alternative product available in the United Kingdom contains 0.35% peracetic acid (Nu-Cidex, Johnson & Johnson, Ltd, Gargrave, UK). Although this product is rapidly effective against a broad range of microorganisms,⁴³⁻⁴⁵ its use results in tarnishing the metal of endoscopes, and it is unstable, resulting in only a 24-hour use life.⁴⁶

Peracetic Acid and Hydrogen Peroxide

Cidex PA (Advanced Sterilization Products, Irvine, CA), formerly marketed as Peract 20, contains 0.08% peracetic acid plus 1.0% hydrogen peroxide. Manufacturer's data demonstrated that, using the Association of Official Analytical Chemists method, this product inactivated all microorganisms with the exception of bacterial spores within 20 minutes. However, this product has a 25-minute at 20°C claim based on a simulated-use method without pre-cleaning, in which the endoscope was inoculated with *Mycobacterium terrae* suspended in 5% bovine serum.⁴⁷ Olympus does not endorse Cidex PA on any Olympus endoscopes and will not assume any liability for chemical damage as result of the use of Cidex PA.⁴⁸ The manufacturers of Cidex PA currently are reformulating this product (altering the buffer system and changing anticorrosive inhibitors) to improve its material compatibility.

Orthophthalaldehyde

Orthophthalaldehyde (OPA) is a new product that has not yet been cleared by the FDA. It contains 0.55% (1,2-benzenedicarboxaldehyde). Studies have demonstrated excellent microbiocidal activity.⁴⁹⁻⁵¹ In addition, OPA has shown superior mycobactericidal activity (5-log reduction in 5 minutes) compared to glutaraldehyde.⁵⁰⁻⁵² OPA has several potential advantages compared to glutaraldehyde: excellent stability over a wide pH range of 3-9, non-irritating to the eyes and nasal passages, and requires no activation.⁵¹ In a clinical-use study, it was demonstrated that exposure of 100 endoscopes for 5 minutes to OPA resulted in >5-log reduction in bacterial load.¹³

ADVANTAGES AND DISADVANTAGES OF CURRENTLY AVAILABLE CHEMICAL STERILANTS

The ideal chemical sterilant does not exist, as all products have limitations. Table 3 reviews the advantages

and disadvantages of all currently available chemical sterilants used primarily as high-level disinfectants and OPA.

Duration of Exposure to Chemical Sterilants Used as High-Level Disinfectants

Although the FDA does not provide recommendations for the cleaning and disinfection of endoscopes, the package label for all chemical sterilants must be cleared by the FDA. Currently approved package label claims for immersion times of these chemical sterilants used as high-level disinfectants vary from 25 to 90 minutes and 20° to 25°C. We believe that these label claims are overly rigorous, because they do not take into consideration the substantial reduction in microbial load achieved with proper cleaning. In addition, these studies are conducted in the presence of a protein load. Several investigators have demonstrated that cleaning endoscopic equipment is extremely effective in eliminating microbial contaminants.^{11,14} These studies have shown a mean 4.0-log reduction in the level of microbial contaminants with cleaning alone. Cleaning is a very effective adjuvant, because it removes pathogenic microorganisms from inanimate objects, as well as organic and inorganic matter that may interfere with the microbiocidal activity of the sterilant. Thus, cleaning allows the use of shorter exposure times to achieve high-level disinfection. Data exist to demonstrate that each of the following chemical high-level disinfection processes achieves at least a 4-log reduction in microbial load within 20 minutes: glutaraldehyde,²² peracetic acid,³⁷ hydrogen peroxide and peracetic acid,⁴⁷ OPA,^{50,51} and 7.5% hydrogen peroxide (except polio and hepatitis A).³²⁻³⁵ Hydrogen peroxide (7.5%) was able to inactivate >4 logs of hepatitis A and polio in 30 minutes, and it was effective in eliminating >4 logs of other viruses (eg, respiratory syncytial virus, influenza, rotavirus, human immunodeficiency virus [HIV]) in 10 minutes.⁵³ It has been demonstrated that at least an 8-log reduction in *M tuberculosis* can be achieved with cleaning (4 logs) followed by chemical disinfection for 20 minutes with glutaraldehyde (4-6 logs).¹¹ Data published by Hanson and colleagues demonstrated that the level of contamination of any single organism on 10 bronchoscopes and 20 gastrointestinal endoscopes never exceeded 8 logs (means, 1.18-4.34-log colony-forming units/mL for each organism present).^{54,55} For this reason, we believe that disinfection likely can be achieved with all of the FDA-cleared chemical sterilants discussed above with 20-minute exposure times at 20°C (room temperature) if meticulous cleaning precedes disinfection. However, comparative studies by independent investigators are critically needed to validate the combined effectiveness of cleaning and high-level disinfection with new chemical sterilants in eliminating pathogenic microbes.

This discussion presumes that the high-level disinfectant is maintained at or above the minimum effective concentration. Use dilution may occur with any high-level disinfectant. Therefore, monitoring must be done regularly to ensure the minimum effective concentration is exceeded.

RECOMMENDATIONS

To prevent the transmission of potential pathogens, all endoscopes should undergo meticulous cleaning and high-level disinfection after each use. Recommendations for the cleaning and disinfection of endoscopes have been provided for over the past 20 years by professional organizations including the Association for Professionals in Infection Control and Epidemiology,^{3,4} the American Public Health Association,⁵⁶ the Society for Gastrointestinal Nurses and Associates,^{6,57} the American Society for Gastrointestinal Endoscopy,¹ the British Society of Gastroenterology,⁵⁸ the Association of Operating Room Nurses,⁵⁹ the Emergency Care Research Institute,^{60,61} and the American Society for Testing and Materials.⁶² These recommendations should be incorporated into individual institutions' policies.

CONCERNS FOR THE FUTURE

Emerging pathogens are of growing concern to the general public and infection control professionals. Pathogens relevant to endoscopy include *Cryptosporidium parvum*, *Helicobacter pylori*, *Escherichia coli* O157:H7, HIV, hepatitis C, multidrug-resistant *M tuberculosis*, and nontuberculous mycobacteria (eg, *M chelonae*). The susceptibility of each of these pathogens to chemical sterilants has been studied. With the exceptions discussed below, all of these emerging pathogens are susceptible to currently available chemical sterilants.^{4,5,63}

The susceptibility of *C parvum* to multiple chemical sterilants and sterilization processes has been evaluated using an infectivity assay.⁶⁴ The following disinfectants were unable to inactivate *C parvum* completely at standard immersion times: 5.25% sodium hypochlorite, 70% ethyl alcohol, 3% hydrogen peroxide, 2% glutaraldehyde, 0.2% and 0.35% peracetic acid, and 0.55% OPA. Only 6% hydrogen peroxide used for 20 minutes was able to inactivate >3 logs of *C parvum* completely. Standard sterilization methods such as ethylene oxide and steam autoclaving were completely effective. However, there have been no reports of cross-transmission via an endoscope of *C parvum* between patients. This is likely due to the efficacy of cleaning and the rapid die-off of *C parvum* from drying.⁶⁴

There have been two reports of *M chelonae* resistant to 2% glutaraldehyde. In experimental challenge, even a 60-minute exposure provides only limited inactivation.⁶⁵ These strains also were resistant to 0.035% peracetic acid⁶⁵ but were susceptible to Cidex PA (0.07% peracetic acid plus 1.0% hydrogen peroxide).⁶⁶ The clinical significance of these isolates is unclear.

CONCLUSIONS

Data suggest that the products discussed in this review are substantially equivalent in spectrum of microbicidal activity, effectiveness in the presence of organic matter, and relative ease of use. No product possesses all of the characteristics of an ideal high-level disinfectant. Major disadvantages of currently available products include material incompatibility (eg, peracetic acid with hydrogen per-

oxide) and human health toxicity (eg, glutaraldehyde). Infection control professionals should assess their institutional requirements carefully (eg, number of endoscopes processed per day, training, turnaround time required), obtain current cost information (including purchase costs, operating costs, equipment repair, and costs associated with providing safe chemical use), and know state laws regarding disposal restrictions.

Data suggest that glutaraldehyde and hydrogen peroxide are alternative choices for high-level disinfection of semicritical items such as endoscopes. The Steris System 1 is an alternative choice for endoscope reprocessing, which has been FDA-cleared as a sterilization process. OPA will be an option when it is FDA-cleared. The hydrogen peroxide and peracetic acid product (Cidex PA) should be assessed further when the problem of functional damage to the endoscope is alleviated.

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Corrections

In the article "Disinfection of Endoscopes: Review of New Chemical Sterilants Used for High-Level Disinfection" (1999;20:69-76), on page 72, Table 2 (Chemical

cal Sterilants Comparison) listed two sterilization claims for "Hydrogen Peroxide, 7.5%" (Sporox): 6 h at 20°C and 20 min at 50°C. This latter claim has not been cleared by the

Food and Drug Administration, and those parameters should not be used for chemical sterilization.

Two articles in the December 1998 issue, "Resolving the Controversy on Environmental Cultures for *Legionella*: A Modest Proposal" (1998;19:893-897), and "Controlling *Legionella* in Hospital Water Systems: Experience With the Superheat-and-

Flush Method and Copper-Silver Ionization" (1998;19:911-914), mention Liquitech as the source of copper and silver equipment. Those seeking that product should now contact T.P. Technology plc, Tarn House, 2-4 Copyground Ln, High Wycombe,

Buckinghamshire, HP12 3HE, UK, telephone 44(0) 1494 535576, fax 44(0) 1494 464175, <http://www.tarn-pure.com>, and inquire about Tarn-Pure ionization systems.