SPECIAL COMMUNICATIONS

APIC guideline for infection prevention and control in flexible endoscopy

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The 1997, 1998, and 1999 APIC Guidelines Committees

The Association for Professionals in Infection Control and Epidemiology, Inc (APIC), is a multidisciplinary organization of more than 12,000 health care professionals who practice infection control and epidemiology within a variety of health care settings.

Fiber-optic endoscopy of the upper gastrointestinal tract was developed in the mid 1950s after the realization that the optical properties of coherent glass fiber bundles allowed the construction of flexible instruments to diagnose and treat human disease in ways not possible with rigid instruments. This breakthrough, followed in the 1960s by the introduction of similar instruments for colonoscopy and bronchoscopy, produced a revolution in the fields of gastroenterology and pulmonary medicine. Currently, it is estimated that more than 10 million endoscopic procedures are performed each year in the United States.[1,2] More recently, video endoscopes, which have a computer chip at the tip to transmit electronic data to a computer and video monitor, have replaced fiberscopes for almost all indications. The field continues to grow as endoscopes are developed for use in other fields such as urology, otolaryngology, and cardiology (to deliver ultrasonographic transducers closer to the heart).

However, as with any new technology, unanticipated problems soon arose and, in particular, the potential for transmission of infectious agents to patients undergoing endoscopic procedures became evident. A number of such cases, including significant outbreaks, were reported. These situations revealed the critical need for appropriate cleaning and high-level disinfection or ster-

ilization to ensure infection prevention and control.[3,4] As a result, a number of guidelines specific to the processing of endoscopes were published.[5–10] Despite these publications, surveys continued to document wide variation in practice with poor outcomes as a result.[11–16] For example, a multicenter study showed that 23% of the bacterial cultures from the internal channels of 71 gastrointestinal endoscopes grew 100,000 colonies or more of bacteria after completion of all disinfection procedures.[12]

Because of the obvious importance of preventing nosocomial infection, the original APIC guideline for infection prevention and control in flexible endoscopy was published in 1994.[17] This guideline was followed by a multisociety position statement endorsed by the American Society for Gastrointestinal Endoscopy, the Society of Gastroenterology Nurses and Associates, the American Gastroenterological Association, the American College of Gastroenterology, and the Association for Professionals in Infection Control and Epidemiology.[18] In 1997, a monograph on standards for infection control and reprocessing of flexible gastrointestinal endoscopes developed by the Society for Gastroenterology Nurses and Associates offered specific recommendations in a highly detailed, step-by-step fashion.[19] This APIC guideline reflects all these efforts and provides an update in this important area.

INFECTIOUS COMPLICATIONS OF FLEXIBLE ENDOSCOPY

I. Endogenous infections related to flexible endoscopy

Both endogenous and exogenous microbes cause infections related to endoscopic procedures. Infections caused by endogenous microbes occur when the microflora colonizing the mucosal surfaces of the gastrointestinal or respiratory tract gain access to the bloodstream or other normally sterile body sites as a consequence of the procedure. Examples of such endogenous infections include cholangitis after the

Table 1. Microorganisms transmitted by (or shown to contaminate) endoscopes

	Major factor(s) involved in incident					
	Infection (I) or Contam (C)	Cleaning procedure	Disinfection process	Rinsing process	Automated processor	Contaminated processing or water bottle
Before guidelines						
A. Gram-negative bacilli						
P aeruginosa	I	X	X	X	X	X
Klebsilla sp	I	X	X			
Enterobacter sp	I	X	X			
Serratia marcesans	I	X	X			
Salmonella sp incl *typhi*	I	X	X			X
Helicobacter pylori	I	X	X			X
Bacillus sp	C	X	X			
Proteus sp	C	X	X			
B. Mycobacteria						
Mycobacterium tuberculosis	I	X	X			
Atypical mycobacteria	I	X	X	X	X	
C. Fungi						
Trichrosporon sp	C		X		X	X
Rhodotorula rubra	C	X			X	X
D. Parasites						
Strongyloides	I	X	X			
E. Viruses						
Hepatitis B	I	X	X			
After Guidelines						
A. Gram-negative bacilli						
P aeruginosa	I	X	X		X	
B. Mycobacteria						
Mycobacterium tuberculosis	I	X	X		X	X
Atypical mycobacteria	C				X	
C. Viruses						
Hepatitis C	I	X	X			X

manipulation of an obstructed biliary tract and pneumonia resulting from aspiration of oral secretions in a sedated patient. Importantly, endocarditis may occur as a result of bacteremia induced by endoscopic procedures (particularly those involving treatments, which penetrate the mucosal barrier), and standards for bacterial prophylaxis in high-risk persons have been established.[20]

II. Exogenous infections related to flexible endoscopy

The Technology Assessment Committee of the American Society for Gastrointestinal Endoscopy found 28 reported cases of endoscopy-related transmission of infections between 1988 and 1992.[18] During that period, approximately 40 million procedures were performed nationally, with the reported incidence of transmission therefore being approximately 1 in 1.8 million procedures. The exogenous microorganisms most frequently associated with transmission during endoscopy have been gram-negative bacteria or mycobacteria (Table 1).[4] These organisms were transferred from pre-vious patients or the inanimate environment with contaminated endoscopes or accessories (Fig 1).[4] The most common factors associated with transmission have involved inadequate manual cleaning, inadequate exposure of surfaces to the disinfectant, inadequate rinsing and drying, and use of automated endoscope reprocessors.

Recent reports of endoscope-related transmission continue to appear and include the hepatitis C virus (HCV), *Pseudomonas aeruginosa, Mycobacterium tuberculsosis,* and *Mycobacterium intracellulare.* In a recent report from France, two patients undergoing colonoscopy after a patient with active hepatitis C acquired HCV infection.[21] The genotype was identical in all three cases. Review of cleaning procedures indicated that the biopsy suction channel had never been cleaned with a brush and that accessories had not been autoclaved. The endoscope was immersed in 2% glutaraldehyde for only 5 minutes.

Transmission of *Mycobacterium tuberculosis* (MTB) from bronchoscopy was reported from two centers in 1997.[22–24] In the first case, a patient developed active
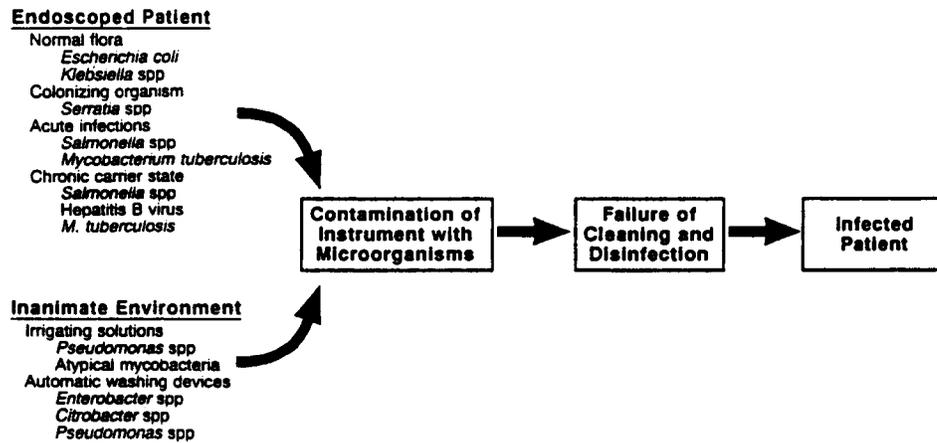
Endoscoped Patient
Normal flora
  Escherichia coli
  Klebsiella spp
Colonizing organism
  Serratia spp
Acute infections
  Salmonella spp
  Mycobacterium tuberculosis
Chronic carrier state
  Salmonella spp
  Hepatitis B virus
  M. tuberculosis

Inanimate Environment
Irrigating solutions
  Pseudomonas spp
  Atypical mycobacteria
Automatic washing devices
  Enterobacter spp
  Citrobacter spp
  Pseudomonas spp

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Contamination of   →   Failure of      →   Infected
Instrument with        Cleaning and        Patient
Microorganisms         Disinfection
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Fig 1. Nosocomial transmission of microorganisms by endoscopes. Flow diagram shows major routes and sources of nosocomial transmission of microorganisms by endoscopes. From Spach DH, Silverstein FE, Stamm WE: Transmission of infection by gastrointestinal endoscopy, Ann Intern Med 1993;118:117-28. Used with permission.

pulmonary tuberculosis (TB) 6 months after bronchoscopy for lung cancer.[22] It was determined that he had undergone bronchoscopy 2 days after a patient with active TB. Genetic analysis of the organisms showed matching patterns. Multiple problems were identified with the disinfection process, including only partial immersion of the bronchoscope and failure to sterilize the biopsy forceps. In the second report, a drug-resistant strain of MTB was transmitted from a patient with active TB to three subsequent patients undergoing bronchoscopy within a 17-day period.[23] The strains were found to be identical. There were multiple breakdowns in manual disinfection procedures, including poor manual cleaning, lack of full immersion in glutaraldehyde, and failure to rinse with alcohol and appropriately dry the bronchoscope.

Unfortunately, clusters of infections and pseudoinfections have been, and continue to be, reported with the use of automated endoscope reprocessors. Alvarado et al described an outbreak of infections with *P aeruginosa* serotype 10 related to a contaminated automatic endoscope reprocessor.[25] The design of the reprocessor did not allow adequate disinfection of the water inlet lines, the air vents, or the detergent holding tank. These portions of the reprocessor were covered with a thick biofilm of *P aeruginosa* serotype 10. The outbreak was terminated by rinsing 70% alcohol through machine-processed endoscopes, followed by adjunct forced-air drying.[25] Similar problems have also been described by others.[26,27] Newer reprocessors have water filters to reduce the risk of organisms being transmitted from tap water to the machine.

More recently, bronchoscopy-related clusters of infections and pseudoinfections caused by MTB, *Mycobacterium avium-intracellulare,* and *P aeruginosa*

were reported from three facilities in New York State.[28,29] In each case, the investigations revealed that bronchoscopes were improperly connected to the automated endoscope reprocessor resulting in inadequate disinfection.

These reports document the need to strictly adhere to endoscope-specific reprocessing instructions to ensure proper cleaning and disinfection or sterilization.

III. Microbial reservoirs and mechanisms of transmission

Throughout the years, there has been progress in our understanding of microbial reservoirs and mechanisms of transmission. The ability of bacteria to form biofilms is an important factor in the pathogenesis of endoscopy-related infections, particularly as biofilms interfere with disinfection.[30,31] Biofilms consist of colonies of organisms forming structures to maximize growth potential. Development of a biofilm begins when free-swimming bacteria attach to a surface (Fig 2). Cell-to-cell communication then signals formation of a biofilm with pillar and mushroom-like structures around which water can circulate. This allows both maximal exposure of the bacteria to circulating nutrients and a decrease in the accumulation of waste products. Strategies aimed at decreasing biofilm formation and viability will have an important role in endoscope disinfection because biofilms have been found to adhere to the internal channels of endoscopes (Fig 3). This finding emphasizes the importance of thorough mechanical cleaning.

Nontuberculous mycobacteria may occur naturally and grow in tap water and cause nosocomial infections, particularly in immunocompromised persons. These mycobacteria may be more resistant to disinfectants than MTB and may require longer exposure times for
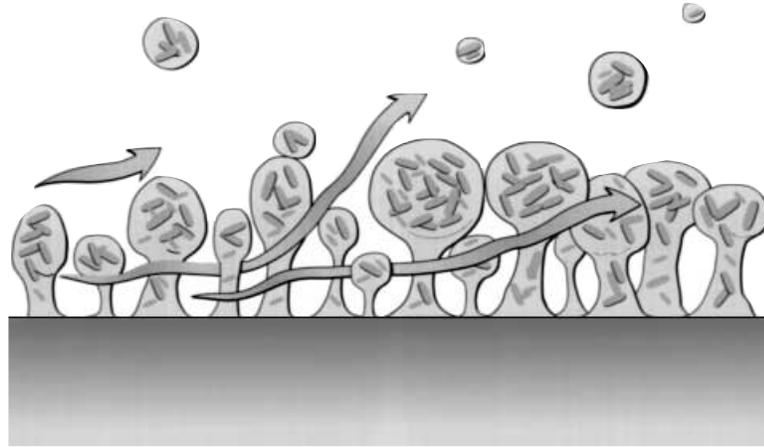
Fig 2. A biofilm develops from free-swimming bacteria, which then attach to a surface and via cell-cell communication form colonies composed of organisms and extracellular material. The structures allow for circulation of fluid supplying nutrients and the removal of waste products. Illustration by Joan Kozol, University of Wisconsin–Madison, Medical Illustrations Department.
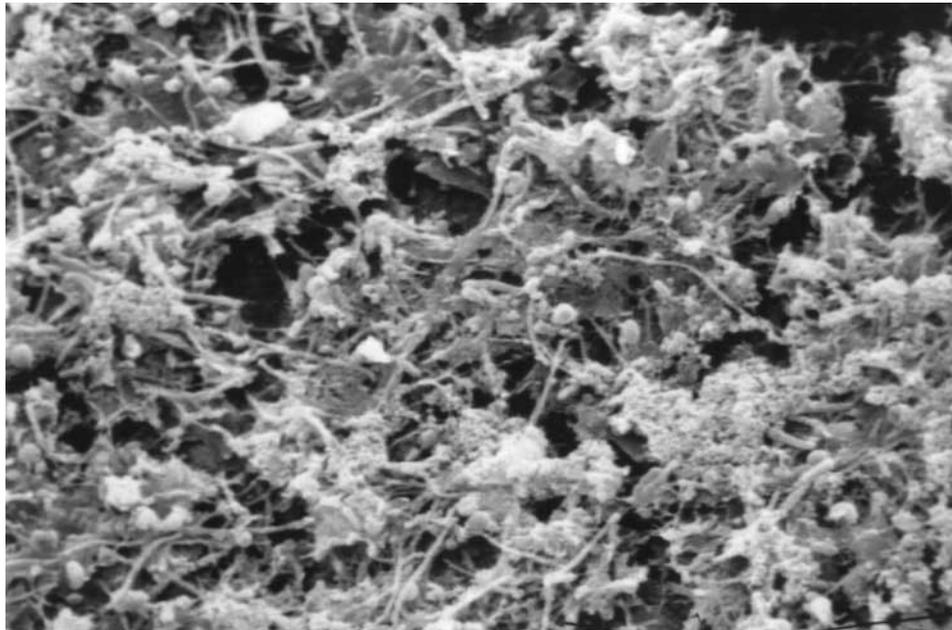

Fig 3. A biofilm imaged by scanning electron micrography. Organisms are tightly attached to each other and the underlying surface. Scanning micrographs by Walter Bond.

killing.[32] Given the ubiquity of the nontuberculous mycobacteria in aqueous environments (ice, tap water, etc) and the increasing numbers of immunocompromised patients with infections caused by these organisms, their inactivation by hospital disinfectants is an area of great importance.[33]

High-level disinfection is adequate for endoscopes contaminated with viruses including HIV, hepatitis B (HBV), and HCV because these agents are inactivated by commonly used chemical germicides.[32] HIV has not been reported to be transmitted by endoscopes. A number of authors have raised the theoretic concern that

Clostridium difficile may be transmitted by endoscopes. Although the inoculum size required to cause disease is small, there are no reported cases of such transmission. Likewise, transmission of Cryptosporidia has not been reported, perhaps because of advances in cleaning and the susceptibility of the organism to drying.[32]

Although Creutzfeldt-Jakob Disease (CJD) has been transmitted from patient to patient via contaminated tissues or fluids, there have been no cases of cross contamination from endoscopic equipment. A recent Centers for Disease Control and Prevention draft statement on CJD and endoscopes concludes that "the cur-
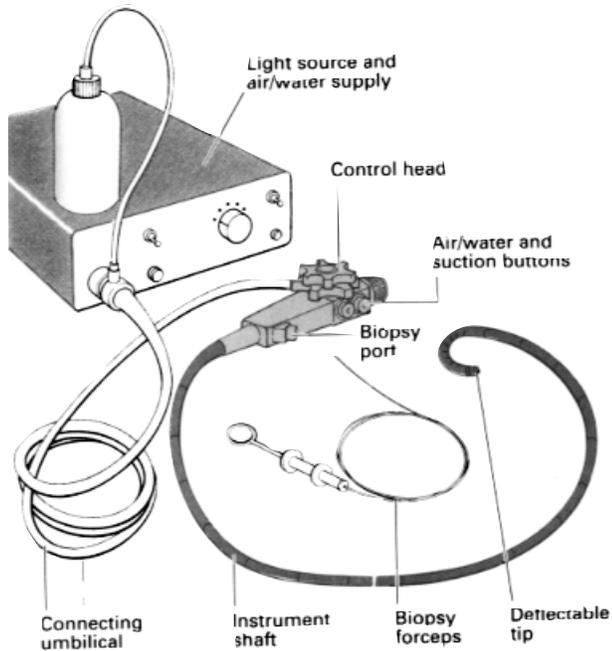
Fig 4. The flexible endoscope is a complex tool. It consists basically of a control head and a flexible shaft which has a maneuverable tip. The head is connected to a light source via a connecting "umbilical" cord, through which pass other channels transmitting, air, water, and suction. Accessories include the flexible biopsy forceps shown here. From Cotton PB, Williams CB: Practical gastrointestinal endoscopy. 4th ed. Boston: Blackwell Scientific Publications; 1996. p. 2, Fig 1.1. Used with permission.

rent guidelines for cleaning and disinfection of these instruments need not be changed." Accessories should be discarded if not reprocessed by thorough ultrasonic cleaning and steam autoclaving.[34]

FLEXIBLE ENDOSCOPES STRUCTURE AND DESIGN

The standard gastrointestinal videoendoscope consists of a head with controls and a flexible shaft (insertion tube) with a maneuverable tip (Fig 4). The image is collected by a charge coupled device (CCD) computer chip, which converts photons into electrons and sends the image to a computer processor for reconstruction and viewing (Fig 5). Certain endoscopes, particularly very narrow endoscopes used for direct viewing of the bile and pancreatic ducts, remain fiber optic. Endoscopes range in length from the standard 65 cm sigmoidoscope to the new 2.4 m endoscope capable of visualizing most of the small intestine. The endoscope head is connected by an "umbilical cord" to a light source, an air pump, and a water supply (Fig 6). The instrument shaft contains the image-conducting cable, fiber bundle for transmitting light, control wires for dis-

tal tip movement, and several other channels. The larger operating channel (2 mm to 4 mm in diameter) allows the passage of flexible accessory instruments (eg, biopsy forceps) from a port in the head of the scope through to the tip and out into the field of view. The operating channel is also used for suction. Other channels (air and water) transmit air to distend the organ being examined and jets of water to clean the distal lens (Fig 4). Newer models allow for the ability to access such channels with a cleaning brush, which represents a very significant advance. Specialized endoscopes have channels and mechanisms in addition to those described above, such as the elevator mechanism to allow for cannula manipulation during endoscopic retrograde cholangiopancreatography (ERCP).

Various accessories can be introduced into the operating channel and passed through the distal end to perform diagnostic and therapeutic maneuvers (Fig 7). Biopsy forceps consist of a pair of sharpened cups or "jaws" attached to a flexible coiled wire cable (Fig 8). The tissue is grasped between the closed jaws and removed by pulling on the forceps. A cytology brush consists of a plastic tube ensheathing a coiled wire with a brush on its distal end. This accessory is introduced through the biopsy channel and the bristles are rubbed against the mucosal surface to obtain exfoliated cellular material. Other accessories include snares for removal of polyps, balloons, sphincterotomes (with exposed wires for incising the Oddi's sphincter to allow increased access to the bile and pancreatic ducts for therapy such as removal of stones), needles for injecting drugs for local control of bleeding, banding devices for treatment of bleeding varices, laser fibers, and cautery probes for coagulation with monopolar or bipolar cautery or heat.

The flexible bronchoscope became commercially available in 1967. The basic design is similar to that of a gastrointestinal endoscope, with the only significant differences being the smaller size and the lack of air and water channels. The typical length of the shaft is 60 cm, with an outside diameter of 5 mm to 6 mm.

Newer endoscopes have been developed with similar technology for ear, nose, and throat and urology indications. Angioscopes with very small fiber bundles are in development for direct visualization of vascular structures. Endoscope-like devices with ultrasonographic transducers are now in common use for transesophageal echocardiography. Therefore, it is important to be aware of all areas in which these devices are used and reprocessed.

As suggested by Bond et al,[35] certain points should be taken into consideration by persons involved in the design and manufacture of endoscopes, and advances in such design remains an important goal for the
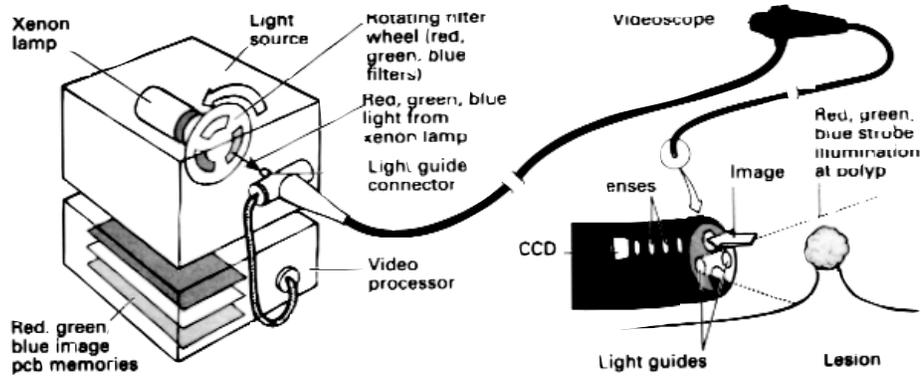
Fig 5. Videoendoscopy involves collecting of an image by a videochip, which converts photons to electrons. By sequential strobe illumination of color, in one method of color video, a color image can be collected and reconstructed by the image processor. From Cotton PB, Williams CB: Practical gastrointestinal endoscopy. 4th ed. Boston: Blackwell Scientific Publications; 1996. Used with permission.
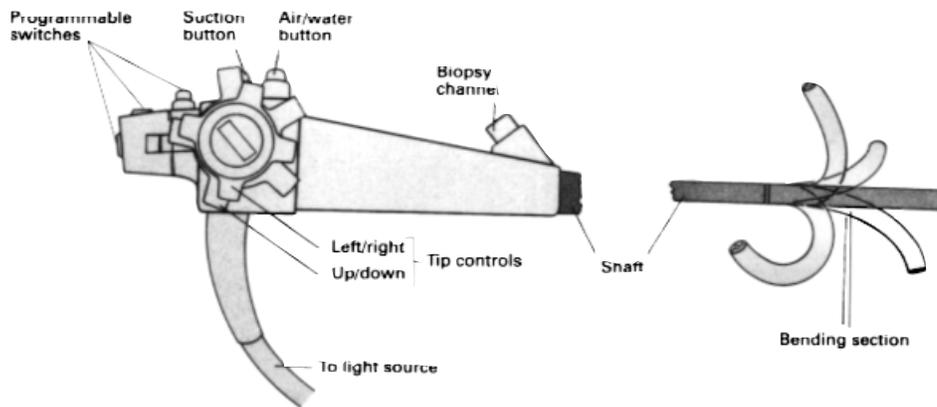

Fig 6. The head of the videoendoscope contains controls for suction and air/water channels and switches for photodocumentation. An external suction pump is connected to the cord of the instrument near the light source, and suction is diverted into the instrument channel by pressing the suction button. The air is supplied from a pump in the light box and is controlled by another button. The air system incorporates a water bottle so that a jet of water can also be squirted across the distal lens to clean it. Tip movement depends on pull wires, attached at the tip just beneath its outer protective cap and passing back through the length of the instrument shaft to the angling controls in the control head. From Cotton PB, Williams CB; Practical gastrointestinal endoscopy. 4th ed. Boston: Blackwell Scientific Publications; 1996. Used with permission.

future. Ultimately, equipment should be designed to be totally steam sterilizable because this time-proven technique is quick, effective, and inexpensive. However, short of this goal, it is critical that manufacturers continue to develop instruments that facilitate disinfection. Because mechanical cleaning is critical to the success of subsequent disinfection or sterilization, endoscopes should be designed to allow easier cleaning, with elimination of acute angles and rough, porous, or occluded surfaces. Such portions of the instrument allow for the collection of organic material (Fig 9).[36] This potential for sequestered organic material poses the greatest risk of cross-contamination for patients undergoing endoscopic procedures. Recent studies indicate problems with gas and plasma sterilization of long, narrow lumens in the presence of organic soil and salts.[37] If parts and accessories such as valves, forceps, brushes, snares, tubing, and water bottles cannot be adequately cleaned before further processing, then sterile, disposable items should be used.

PROCESSING OF ENDOSCOPES AND ACCESSORIES

I. Cleaning of flexible endoscopes

Organic soil (eg, blood, feces, and respiratory secretions) may contribute to disinfection failures by harboring embedded microbes and preventing the penetra-
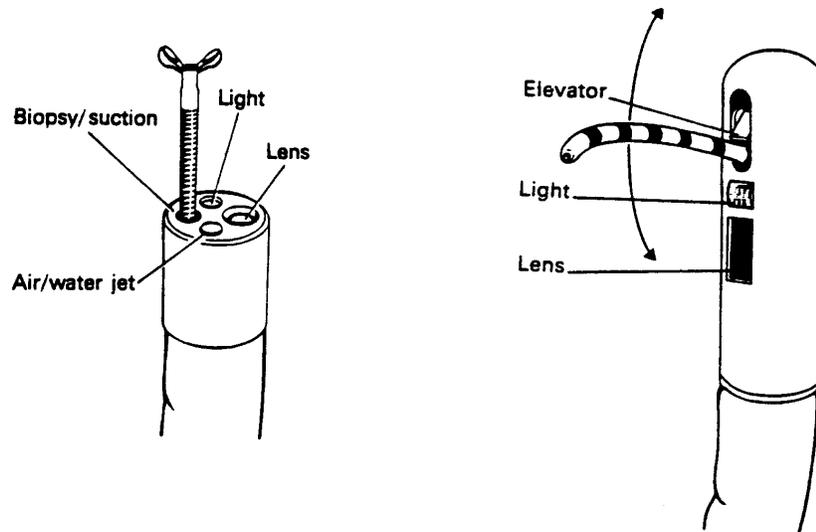
Fig 7. In addition to the light source, the videochip, and the control wires for tip movement, the instrument shaft also contains two or more channels. The larger operating channel (usually 2 mm to 3 mm in diameter) allows the passage of accessories from a port in the endoscope control head through to the tip and out into the field of view. This channel is also used for suction. The smaller channel transmits air and water. In instruments with a lateral-viewing lens system, the tip of the channel incorporates a small, deflectable elevator or bridge, which permits some directional control of the forceps and other accessories independent of the instrument tip. Redrawn from: Cotton PB, Williams CB: Practical gastrointestinal endoscopy. 4th ed. Boston: Blackwell Scientific Publications; 1996. Used with permission.

A   **Biopsy cups open.**

B   **Cytology brush with outer sleeve.**

Fig 8. Biopsy forceps *(A)* consist of a pair of sharpened cups controlled by a flexible cable. Their maximum diameter is limited by the size of the operating channel of the specific instrument. Cytology brushes *(B)* have a covering plastic sleeve to protect the specimen during withdrawal. Redrawn from Cotton PB, Williams CB: Practical gastrointestinal endoscopy. 4th ed. Boston: Blackwell Scientific Publications; 1996. Used with permission.
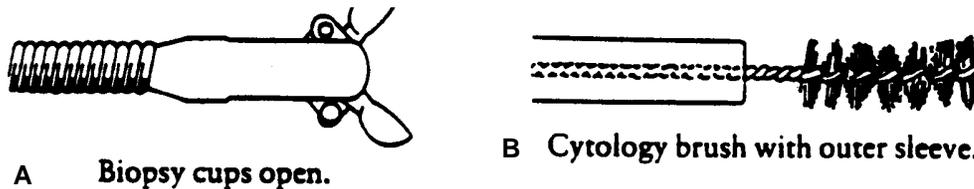
tion of germicides. Moreover, some disinfectants are inactivated by organic material. Rigorous mechanical cleaning to remove such material from the outside of the insertion tube and from the lumens of all accessible channels is therefore imperative before disinfection or sterilization.[36–38] An impressive illustration shows the interior surface of a segment of suction channel (Fig 10). Holes and heavy encrustations of patient material (blood, feces, gastric mucin) are seen in and on the interior surface even though the instrument had been routinely flushed and brushed before disinfection. This was also demonstrated by Bond and Moncada,[39] who found that the shafts of two endoscopes and a cytology brush were massively contaminated in vitro by immersion in blood positive for hepatitis B surface antigen. Cleaning with 0.1% Haemo-Sol (Haemo-Sol, Inc, Baltimore, Md)

was effective in removing blood and hepatitis B surface antigen from the shafts and biopsy channels. However, the cytology brush was still heavily contaminated with blood positive for hepatitis B surface antigen.

Cleaning of endoscopes and accessories should be performed with nonabrasive, manufacturer-recommended enzymatic detergents for medical instruments promptly after use to prevent drying of secretions (this portion of reprocessing takes place in the procedure room).[19] Before mechanical cleaning, all channels should be irrigated with copious amounts of detergent and tap water to soften, moisten, and dilute the organic debris, and the air-water channel cleared with forced air in the manner recommended by the manufacturer. All detachable parts (eg, hoods and suction valves) should be removed and soaked in a detergent solution.

The insertion tube should be washed with detergent solution and rinsed. Accessible channel(s) should be brushed to remove particulate matter, and the detergent solution must be suctioned or pumped through all channels to remove dislodged material. Channel irrigators[40] and some automated endoscope reprocessors[41–43] may be useful in this step. Meticulous attention must be given to crevices, which are likely to harbor contaminated organic material. The tip of the endoscope must be gently wiped/brushed to remove debris or tissue lodged in or around the air and water nozzle. When cleaning an ERCP endoscope, the distal tip must be brushed with the elevator both up and down to ensure that no matter is lodged in that movable part. Detachable parts must be thoroughly cleaned with detergent. Irregular surfaces of the detachable parts should be brushed to ensure complete removal of all organic debris. The cleaning brushes should be disposable or thoroughly cleaned and receive high-level disinfection or sterilization after each use.[19] After mechanical cleaning, immersible equipment should be thoroughly rinsed with water. Nonimmersible endoscopes should not be in service today because newer models of endoscopes are totally immersible.

At all stages of handling, the equipment should be inspected for damage,[38] and a leak test should be performed before submerging the entire instrument. A leak test involves applying air pressure to the inside of the endoscope insertion tube and watching for air bubbles identifying leaks either in the covering or internally into one of the channels. If damage is detected, the equipment should not be submerged or reused and the manufacturer should be consulted. An endoscope sent for repairs should be considered a contaminated medical device and labeled as such for shipping. Follow the Occupational Safety and Health Administration's *Occupational Exposure to Bloodborne Pathogens: Final Rule (29CRF 1910.1030)* for labeling of contaminated equipment for repair.[44]

II. Automated endoscope reprocessing

Automated reprocessors have been developed for endoscopic instruments. Meticulous manual cleaning as described previously must precede the use of automated endoscope reprocessors (AERs). Currently available machines vary in certain fundamental aspects including the chemical agents used, mechanisms of channel irrigation, time and temperature controls, alarm systems, and reuse of chemical agents. Although expensive, automated reprocessors are useful, especially in clinics performing large numbers of procedures. In addition, AERs may reduce exposure of personnel to toxic chemicals and standardize the contact time with the disinfecting agent.
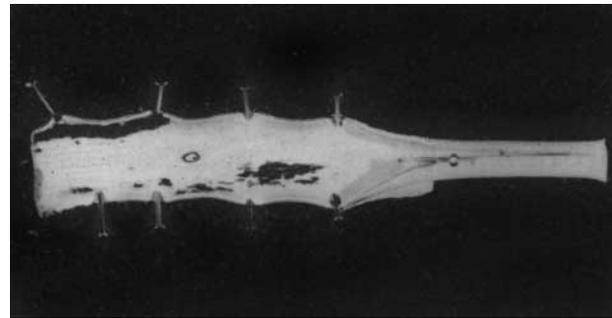

Fig 9. Interior surface of a flexible endoscope suction channel (2.8 mm in diameter) removed during leak repair. Holes in the channel are visible in the center and upper left portions of the segment. Apparently, a raised area in the intact channel had caused the distal tip of cleaning brushes to be deflected away from a central course down the channel during cleaning operations. The deflected brushes not only resulted in holes being abraded in the wall but also left areas untouched during the cleaning process. Shown here are heavy encrustations (upper right) of patient material (eg, feces, blood, gastric mucin). From Bond WW, Ott BJ, Franke KA, McCracken JE: Effective use of liquid chemical germicides on medical devices: instrument design problems. In: Block SS, editor. Disinfection, sterilization, and preservation. 4th ed. Philadelphia: Lea & Febiger; 1991. p. 1097-106. Used with permission of Beverly Ott, Mayo Clinic, Rochester, Minn.

AERs are designed to irrigate most channels (biopsy, suction, air/water) of the instrument. The air/water channel is the most likely to become occluded with organic debris during use.[41] Channel blockage is particularly difficult to clean manually; however, a blockage of one channel may be missed by a channel irrigator because the flow is maintained in at least one channel. AERs differ in their capacity to detect blockage, diversion of fluid, and flow through the various internal lumens of the scope. The elevator wire channel of most duodenoscopes cannot be accessed by the AER and must be cleaned and disinfected manually. Device-specific instructions remain critical to ensure adequate function of the reprocessing equipment.

III. Sterilization and disinfection

When developing infection control procedures for endoscopic equipment, it is useful to use a well-established classification system for making decisions about whether to use sterilization or high-level disinfection between each patient use. The following is an overview of the Spaulding Classification System and its relevance for endoscopic equipment.

In 1968, Dr Earl Spaulding[45] proposed that medical devices be classified among 3 groups, stratified by the risk of infection involved in their use. Moreover, he rec-
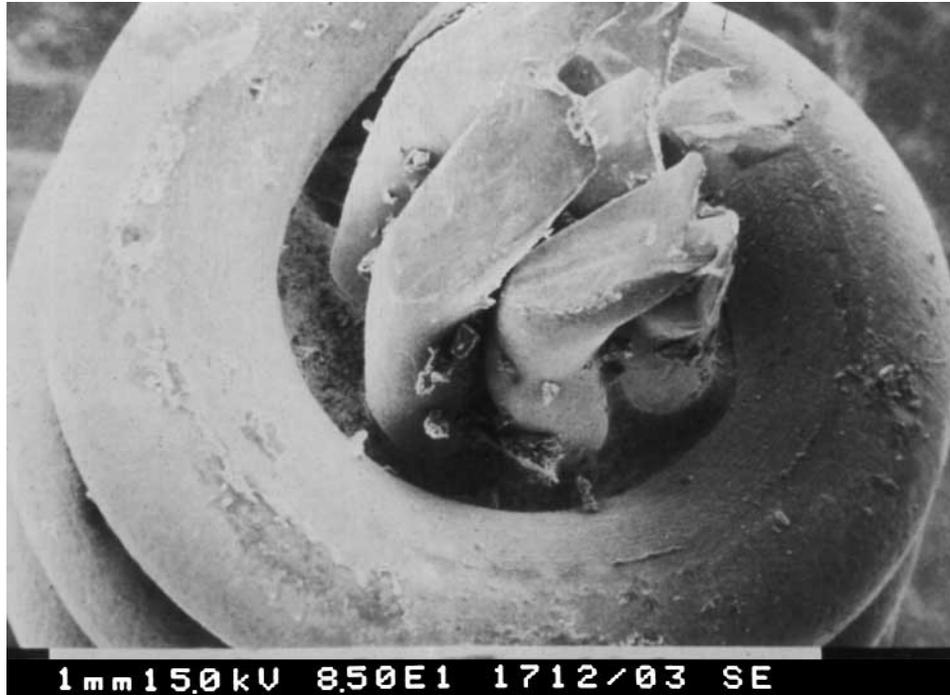
Fig 10. A scanning electron micrograph of a cross-section of a biopsy forceps after cleaning demonstrating residual organic soil. This image demonstrates the difficulty of cleaning all of the internal surfaces of these complex devices. Scanning micrographs by Walter Bond.

ommended generic categories of chemical germicides, by their microbicidal potency that could be used on critical or semicritical items incapable of being sterilized with heat. He not only defined the terms "sterilant" and "high-level disinfectant," but also characterized their attributes. Briefly, critical devices are those that enter sterile tissue or body spaces (eg, surgical instruments, cardiac catheters, and prosthetic heart valves). They should undergo sterilization (defined as a procedure that inactivates all microbes, including bacterial endospores) between uses. Semicritical devices (eg, laryngoscopes) come into contact with mucous membranes or nonintact skin during use and should either be sterilized or at least receive high-level disinfection (defined as the inactivation of all vegetative bacteria, mycobacteria, fungi, and viruses, but not necessarily all bacterial endospores).[7,45–47] Noncritical devices, such as blood pressure cuffs and stethoscopes, are those that come into contact with intact skin. They require either disinfection with an intermediate or low-level germicide or simple cleaning with detergent and water, depending on the nature of the device and the degree of contamination.[7,45–47] Endoscopes that come into contact with mucous membranes are classified as semicritical equipment.[7,45–47] Endoscopes that enter sterile body cavities would be classified as critical in the Spaulding scheme. Some endoscopic accessories (eg, sclerothera-

py needles, cutting forceps) are classified as critical equipment.[7]

The minimum recommended practice for endoscopes is high-level disinfection with a liquid sterilant/disinfectant approved by the Food and Drug Administration (FDA) *(http://www.fda.gov/cdrh/ode/germlab.html).* An extensive review of such chemicals has recently been published.[32] A number of well-established and emerging sterilization and disinfection products are recommended.

Agents recommended for high-level disinfection of flexible endoscopes. A high-level disinfectant must be expected to destroy all microorganisms, with the exception of high numbers of bacterial spores. Its microbicidal properties should not be significantly decreased by the presence of organic matter. Likewise, it should not damage the endoscope or cause toxicity to personnel. An agent meeting all of these criteria has yet to be described. Several novel disinfectant and sterilization processes are under development. One or a number of these may emerge as the process of choice. For a more in-depth discussion of the composition and properties of various agents recommended for high-level disinfection of flexible endoscopes, the user of this guideline should refer to the "APIC Guideline for Selection and Use of Disinfectants."[7]

1. Glutaraldehyde preparations.

a. Alkaline glutaraldehyde**.** When aqueous solutions

of glutaraldehyde are "activated" by adding bicarbonate to raise the pH to 7.5 to 8.5, their microbicidal (including sporicidal, fungicidal, and viricidal) activity is greatly enhanced.[48,49] Several preparations of glutaraldehyde are marketed as a 2.4% solution to which a separately packaged "activating" preparation containing an alkaline buffer, a surface-tension depressant, an anticorrosive compound, and a water-soluble dye are added.[50,51]

Glutaraldehyde is noncorrosive to metal and does not damage endoscopes. In contrast to many disinfectants, it is highly resistant to neutralization by organic soil.[52] Although alkalinization enhances the microbicidal activity of glutaraldehyde, it also promotes the polymerization, with subsequent loss of free aldehyde groups.[51] This limits the shelf life of activated solutions to about 14 days. Chemically stabilized solutions have a shelf life (ie, a period during which they maintain adequate glutaraldehyde concentrations) of at least 14 days and of 28 days when in-use dilution does not exceed 50%.[48,53–55]

b. *Acid glutaraldehyde*. Compared with alkaline preparations, some acid solutions are more corrosive to metal.[55] Acid solutions of glutaraldehyde (pH 3.0 to 6.3) are stable for long periods, without loss of active aldehyde groups.[48,51] A 2% acid glutaraldehyde acts as a chemical sterilant and is acceptable for high-level disinfection (and therefore endoscope reprocessing).

To achieve adequate high-level disinfection with glutaraldehyde, all internal and external surfaces and channels must be in contact with the disinfecting agent for at least 20 minutes.[7,32]

Glutaraldehyde is irritating to the skin, can cause allergic contact dermatitis, and exposure to glutaraldehyde vapor at 0.3 ppm may result in irritation of the eyes and nasal mucosa.[56–59] In an investigation conducted by the National Institute for Occupational Safety and Health, air samples were collected from the personal breathing zones of hospital employees working with glutaraldehyde.[57] Glutaraldehyde concentrations ranged from nondetectable to 1.5 mg/m³; 6 of 8 samples exceeded the threshold limit value of 0.8 mg/m³. Nine of eleven nurses surveyed reported symptoms of irritation including dermatitis in 8 and eye irritation in 7; throat discomfort, nasal irritation, and cough also occurred. In a Swedish study, Norback[59] determined the prevalence of various symptoms among cases exposed to glutaraldehyde and unexposed controls. Rashes on the hands, eczema, nasal and throat irritation, as well as nausea and headache were significantly more frequent among the exposed group. He quantified the exposure of the cases by measuring glutaraldehyde concentrations in their breathing zone. All values ranged from undetectable to 0.18 mg/m³ except for one very high value of 0.57 mg/m³ (during chemical reprocessing of

a gastroscope with glutaraldehyde). There was a significant dose-response relationship between the mean number of symptoms and frequency of exposure. He found no significant difference in airborne glutaraldehyde exposure between manual and automatic machine disinfection. A poorly ventilated ward had higher levels (0.13 to 0.18 mg/m³) than did a well-ventilated ward (0.01 to 0.03 mg/m³). Importantly, his study showed a significantly increased frequency of symptoms among the exposed group, despite almost all measured values being well below the threshold limit value of 0.8 mg/m³. According to the recommendation of the American Conference of Governmental Industrial Hygienists, the ceiling limit on the permissible level of glutaraldehyde in the air is 0.05 ppm.[56,57] These limits are subject to change by state and federal regulatory agencies. Ultrasonic cleaning and raising the temperature of the immersion tank may increase the activity of the disinfectant, but they will also increase staff exposure to glutaraldehyde.[60] It is therefore critical that areas where glutaraldehyde is in use be extremely well ventilated. Maintaining ambient glutaraldehyde concentrations below 0.05 ppm 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 vapor, tight fitting lids on immersion baths, and automated endoscope processors.[32]

2. Hydrogen peroxide. Hydrogen peroxide has been used as a germicide for more than a century. Early preparations were dilute and unstable, and they decomposed rapidly in the presence of trace amounts of impurities.[61] Since the 1950s it has been possible to produce concentrated solutions with stabilizers added to deactivate impurities. Hydrogen peroxide is a rapid oxidizer, which facilitates removal of organic debris and is relatively free of toxic fumes. Although hydrogen peroxide is a potent antimicrobial agent, it can damage rubber and plastics and corrodes copper, zinc, and brass.[61] A 7.5% hydrogen peroxide/0.85% phosphoric acid solution, classified as a high-level disinfectant, is acceptable for endoscope preprocessing[6,55] unless incompatible with endoscopic equipment. As with other chemical sterilants, dilution must be monitored by regularly testing the minimum effective concentration (ie, 6.0%).[6]

3. Peracetic acid. Peracetic acid is a component of an equilibrium mixture of acetic acid, hydrogen peroxide, and water. A 1% peracetic acid solution has broad-spectrum activity against bacteria, fungi, spores, and enteroviruses.[61–63] Although this peroxyacid can also be corrosive, an automated endoscope reprocessing system has been designed that dilutes 35% peracetic acid to a final concentration of 0.2% and adds a buffer and

an anticorrosive agent. The system is designed only for reprocessing totally immersible endoscopes.

There are several health hazards associated with peracetic acid. Severe burns may result from direct skin contact, irreversible damage or blindness from direct contact of the chemical to the eyes, and inhalation of peracetic acid vapor or mist will irritate the nose, throat, and lungs. Currently there are no National Institute for Occupational Safety and Health/Occupational Safety and Health Administration ceiling limits on the permissible level of peracetic acid in the air.

4. Peracetic acid and hydrogen peroxide. A product containing 0.08% peracetic acid plus 1.0% hydrogen peroxide has been cleared by the FDA as a liquid chemical sterilant for use on semicritical medical devices. However, as with all liquid chemical sterilants, endoscope manufacturers should be consulted for product compatibility.[32]

5. Orthophalaldehyde. Orthophalaldehyde is a new product that has been cleared by the FDA and is used extensively in other countries for endoscope disinfection. It contains 0.55% 1,2-benzenedicarboxaldehyde. Orthophalaldehyde has several potential advantages when compared with glutaraldehyde. Not only does it have excellent stability over a wide pH range of 3-9, but it also is nonirritating to the eyes and nasal passages. In addition, orthophalaldehyde requires no activation before use.[32] This product has FDA clearance for use as a liquid sterilant/high-level disinfectant on flexible endoscopes.

B. Agents not recommended for disinfection of endoscopes. Specific agents are not recommended for use on endoscopes and endoscopic equipment because of incomplete microbiologic coverage (ie, failure to meet the definition of a high-level disinfectant), toxic exposure to personnel, or physical damaging to the equipment.

1. Products not cleared by the FDA for use on semicritical or critical medical devices
2. Skin antiseptics
   A common problem in health care facilities is the inappropriate use of povidone-iodine, chlorhexidine gluconate, or other antiseptics for disinfection of equipment. These products, which are formulated, registered, and intended as skin antiseptic agents, should not be used as disinfectants.[64]
3. Hypochlorite
   Hypochlorites are not appropriate for disinfecting endoscopes. Their corrosiveness and inactivation by organic matter limit their use.
4. Quaternary ammonium compounds
   Contaminated quaternary ammonium compounds have been associated with nosocomial infections, not only when used as antiseptics,[65-67] but also when used as disinfectants.[68-70] In general, they are not

sporicidal, tuberculocidal, or viricidal against hydrophilic viruses.[71-72] They are adequate for use on noncritical surfaces but are not appropriate for the disinfection of endoscopes.

5. Phenolics
   Phenolics are intermediate-level disinfectants[7] commonly used to clean floors and laboratory work surfaces. Phenolics are absorbed through porous materials. Even after disinfected articles are thoroughly rinsed, residual phenolics have caused tissue irritation and injury to mucous membranes.[46] Hazardous concentrations in the air have been noted in laboratories.[46] For these reasons, and because phenolics are not sporicidal, they are not recommended for the disinfection of semicritical equipment, including endoscopes.

C. New technologies for which there are insufficient data regarding sterilization/disinfection of endoscopes. There are a number of sterilization and disinfection products emerging in the field for which there are insufficient published data with which to formulate a recommendation at this time of publication. The following technologies and products are under investigation and may prove useful in the reprocessing of endoscopes: (1) chlorine dioxide, (2) ozone, (3) vapor-phase hydrogen peroxide, (4) plasma technology, (5) superoxidized water,[73,74] and (6) disposable, sterile-sheathed flexible endoscopes with the exception of the new sigmoidoscope. The latter has been systematically evaluated in a randomized controlled trial and found to be clinically equivalent to standard models, with a significant decrease in reprocessing work and turnaround time. No infection or contamination has been associated with this new technology.[75]

V. TREATMENT OF THE ENDOSCOPE AFTER DISINFECTION OR STERILIZATION

A. Rinsing. To prevent toxic effects of residual chemicals after disinfection, the equipment must be adequately rinsed. Chemical colitis mimicking pseudomembranous colitis, caused by 3% hydrogen peroxide[76] and glutaraldehyde,[77] has been reported. Ordinary tap water may contain microbes, including *Pseudomonas* and mycobacteria. In several reports, contaminated rinse water was the suspected source of *P aeruginosa* transmission to patients through previously disinfected endoscopes.[27,78-80] For these reasons, rinsing should be done with sterile water. If sterile water is not used, an alcohol rinse followed by complete drying is essential. Only sterile water should be used for endoscopes that pass through sterile tissues.

B. Drying. To prevent microbial growth or transmission in a moist environment, the insertion tube and channels should be thoroughly dried. Rinsing channels with 70%

alcohol and directing compressed air through the damp lumens will facilitate drying.[25,78] Allen et al[78] described an outbreak of colonization and infection with *P aeruginosa* associated with ERCP. Clinical manifestations ranged from asymptomatic carriage to fatal infection. The organism was able to proliferate in the channels of the endoscope until the investigators adopted a procedure of suctioning 70% alcohol through all channels, followed by compressed air to completely dry the instrument. Therefore, drying with alcohol and compressed air should be done between each patient use when tap water is used to rinse the endoscope channels and before storage whether tap water or sterile water is used.

C. Storage. Endoscopes should be stored in a manner to prevent recontamination or damage. Endoscopes should be stored without control valves, distal hoods, caps, etc, in place. There should be adequate space to keep the endoscopes and other equipment from coming into contact with each other. Endoscopes should be hung vertically to facilitate drying.

VI. Processing endoscopic accessory equipment

Items that penetrate mucosal barriers (eg, biopsy forceps) are considered critical and therefore must be sterile before use. Biopsy forceps are heat stable and must be cleaned with an ultrasonic cleaner and steam sterilized. Because of their tightly wound, spring-like configuration, they are extremely difficult to clean mechanically, and sterilization attempts may fail if organic debris is not scrupulously removed (Fig 10). In an outbreak of 8 cases of *Salmonella newport* infection among patients undergoing colonoscopy, the epidemic strain was recovered from the spiral-wound spring of one pair of biopsy forceps but not from the colonoscopes or other environmental specimens.[81] Bond and Moncada[39] also illustrated the importance of this spiral-wound configuration in harboring organic matter and rendering disinfection ineffective against hepatitis B virus. In general, all endoscopic accessories that enter sterile tissue should either be disposable or sterilized between uses.

Sterile water should be used to fill the bottle for endoscopic irrigation. The water bottle and connecting tubes are difficult to clean and disinfect and are often colonized with *Pseudomonas* species and may serve as important reservoirs of cross-infection.[82,83] The water bottle and its connecting tubing should be sterilized or receive high-level disinfection at least daily. The need for more frequent bottle and tubing processing has not been established.

REUSE OF SINGLE-USE ENDOSCOPY DEVICES/ACCESSORIES

In 1996 the FDA issued a final rule requiring "device user facilities" to submit reports to the FDA of deaths, serious illnesses, and injuries related to medical devices. Moreover, the FDA defined a device "manufacturer" as "any person who processes a device by chemical, physical, biologic, or other procedure."[84] If a person elects to reuse a disposable item, the responsible institution must demonstrate that the safety, effectiveness, and integrity of the product have not been compromised by reprocessing.[85,86] The standards of the Joint Commission on the Accreditation of Healthcare Organizations call for policies and procedures specifically addressing the reprocessing of disposable items for reuse.[87]

Recent attention has been focused on the possibility that "single-use" devices could be reprocessed and reused both safely and cost effectively. Such savings can be considerable, but studies to date have included only a few such devices. As a result, this approach remains controversial, and implementation of such a strategy requires a major institutional commitment, including a monitoring committee with clearly defined protocols.[88] Manufacturers need to improve the design of endoscope accessories to ensure the ability to be safely and effectively cleaned and sterilized.

QUALITY CONTROL-ASSESSMENT OF THE ADEQUACY OF DISINFECTION/STERILIZATION

Continuous use of a disinfectant solution for long periods eventually results in dilution or decreased activity.[89] Commercial test kits are available for chlorine, hydrogen peroxide, glutaraldehyde, and peracetic acid to determine whether an effective concentration of active ingredients is present despite repeated use and dilution. However, the reliability of such test kits has not been established.

With the exception of hemodialysis water and fluids, the Centers for Disease Control and Prevention (CDC) does not recommend routine microbiologic sampling of the inanimate hospital environment and patient care items.[47] On the other hand, focused microbiologic testing is warranted if clinical or epidemiologic findings suggest endoscopy-related transmission of infection. Culturing should be based on the epidemiologic data and follow a plan that specifies the specimens to be obtained for culture and the action to be taken on the basis of the results.[90] Aliquots of sterile, nonbacteriostatic, saline solution flushed through the suction and biopsy, air, water, elevator, and carbon dioxide channels may be quantitatively cultured to determine the adequacy of disinfection. However, few organisms will be obtained from washings alone. Brushing of the suction and biopsy channel with a sterile brush is more likely to release viable organisms attached to the inner lumen of the channel and is a more sensitive sampling technique.[91,92] Specimens should be inoculated onto appro-

priate media. The criterion of acceptability is the absence of growth of vegetative bacteria.[92]

Whenever epidemiologic data suggest infection transmission by endoscopes, observation of the technique being followed by personnel in the endoscopy unit may provide insight. For monitoring of adverse events, it is useful to maintain a logbook in the unit with a list indicating for each procedure the patient's name and medical record number, the procedure, the endoscopist, and the serial number or other identifier of the endoscope used.[39]

Hospitals and clinics in which endoscopy is performed should have policies and procedures assigning the responsibility of reporting all types of adverse occurrences resulting from endoscopy to the appropriate internal (eg, safety, infection control, and risk-management programs) and external (eg, local and state public health departments) regulatory bodies.

OUTBREAK MANAGEMENT

When an outbreak of endoscopy-related infections is suspected, certain procedures should be followed.[93]

A case definition should be formulated. All persons involved, including the infection control professional, the hospital epidemiologist, the director of the endoscopy unit, appropriate microbiology personnel, heads of clinical departments, and administrators, should be informed of the outbreak. The laboratory should be asked to save all relevant isolates. The charts of all cases should be reviewed to search for potential risk factors, those related to the suspect procedure as well as other known risk factors for the infection under consideration. If the initial review suggests that the infections are indeed endoscopy-related, the records of all patients undergoing the procedure(s) should be reviewed for evidence of postendoscopy infection or colonization with the epidemic strain. Cultures of endoscopes, obtained as described previously, as well as cultures of rinse water, fluid from automatic machines, and any other clinically relevant items (eg, water bottles and vials of intravenous sedatives used for the procedure) should be collected. All isolates should be saved and compared with the patient isolates by means of the most appropriate technique to determine strain relatedness (eg, antibiogram, serotype, plasmid profile, ribotyping).

Once a hypothesis for the suspected outbreak has been formulated, control measures should be instituted and revised while the workup is in progress. It may be necessary to stop endoscopic procedures depending on the severity of the situation. The investigation should ultimately lead to microbiologic confirmation of the reservoir of the epidemic strain and the mode of transmission. Epidemiologic findings should be evaluated on the strength of causal association. As the investigation progresses, specific control measures can then be reevaluated and their efficacy can be confirmed by continued surveillance for new cases as well as microbiologic monitoring of the endoscopy equipment.

Under the Safe Medical Devices Act of 1990, facilities are required to report to the FDA instances when endoscopes or endoscope reprocessing systems may have caused or contributed to serious injury or a patient's death. Questions concerning this mandatory reporting requirement can be directed to FDA's Center for Devices and Radiological Health, Office of Surveillance and Biometrics (310-827-0360). In addition, the FDA has requested that health care workers report bronchoscopy-related colonization episodes, infection, or pseudoinfection to their state health department, to FDA's MedWatch program, telephone (800) 332-1088, fax (800) 332-0178, or World Wide Web site, http://www.fda.gov/medwatch, and to the CDC's Hospital Infections Program, telephone (404) 639-6413 or fax (404) 639-6459.[29,94]

DESIGN OF FACILITIES FOR PERFORMING ENDOSCOPIC PROCEDURES, INCLUDING SUPPORT SPACE

There are a number of factors to be considered in the design and use of space for endoscopic procedures and the cleaning, disinfection, sterilization, and storage of endoscopes and endoscopic equipment. Patient volume, traffic flow, and types of endoscopic procedures (eg, bronchoscopy, gastrointestinal endoscopy) performed should all be taken into account during space planning.

Space for the performance of procedures should be separate from space used for cleaning and disinfection or sterilization of equipment. There should be a designated sink for handwashing. The room should be equipped with adequate utilities to support the patient during the procedure (eg, suction, oxygen). Procedure areas should have space available for charting, logbooks, procedure manuals, equipment manuals, and other administrative materials.

Because of the potential for MTB transmission, the air handling in procedure rooms, especially for bronchoscopies, should conform to the latest CDC guidelines for preventing the transmission of tuberculosis in health care facilities.[95]

Space used for the cleaning and disinfection or sterilization should have adequate ventilation to exhaust toxic vapors[48,56,57] and airborne pathogens. If large volumes of glutaraldehyde in basins are used, basins should be covered with tight-fitting lids. Consideration should be given to the installation of an exhaust hood, or ductless fume hoods with absorbents for the vapor and air systems that provide 7 to15 air exchanges per hour.[32]

There should be separate handwashing and utility sinks. The utility sink must be large enough to accommodate the cleaning and rinsing of endoscopes and accessories. If machines are used for disinfection, the area must be designed with adequate space and appropriate utilities specific to the machines being used. There must be adequate space for the storage of chemical sterilants, some of which have special handling requirements as hazardous materials. The area should be designed so that the workflow can facilitate sound infection control practices (eg, avoid the commingling of contaminated with clean equipment).

There are important design features to consider in the storage of clean endoscopes and accessories. Closets or cabinets used for drying and storage should be constructed of materials that can be cleaned easily. Endoscopes must not be stored in foam-lined cases because the foam lining is impossible to clean should it become contaminated. Endoscopes should be stored in a manner that will protect the endoscope and minimize the potential for residual moisture accumulation. The storage should accommodate a sufficient number of endoscopes to support the patient volume.

There are additional support issues to be addressed during the development of an endoscopic service. Patients should have private changing and bathroom facilities. Staff should have lounge space because eating and drinking in procedure or utility rooms should be prohibited. Personal protective equipment should be readily accessible. Policies and procedures should be developed for the cleaning of procedure rooms and all support space.

ENDOSCOPY PERSONNEL

The federal government enacted the Hazard Communication Standard (29 CFR 1910.1200) in response to the dramatic increase in the use of chemicals in the workplace. The standard requires the employer to provide employees with the information and training needed to protect the employees from chemical hazards in the workplace. The institution must provide the following for the endoscopy area:

- Written hazard communication program
- Hazard evaluation
- Hazardous materials inventory
- Material safety data sheets
- Labeling of all containers containing hazardous materials
- Employee training must include explaining the standard, identification of the hazards and their health effects, location of the written hazard communication program and material safety data sheets, procedures to detect and measure contaminants, safe work practices, appropriate personnel protective gear, and an explanation of the labeling system.

Everyone who handles chemicals should be aware of the hazards associated with the materials and how to manage any spills of these materials. This information is found in the material safety data sheets supplied with the purchased chemicals. At a minimum, the endoscopy setting should have a spill containment plan addressing preparation for spills, assessment of spills (ie, simple or high hazard), personal protective equipment for spill cleanup, cleanup procedure and response supplies, and notification of emergency responders (institution's chemical hazard response team, institution's safety department, local fire department's hazardous materials incident team).

Because of the delicate and complex structure of endoscopes, only well-trained personnel should conduct cleaning and disinfection or sterilization procedures. The training should include close observation until competency is demonstrated. Endoscopy personnel should be educated about the hazards of exposure to toxic chemicals used in disinfection or sterilization.[58]

Endoscopy personnel should understand the risk of infection with agents such as *M tuberculosis,* hepatitis B virus, HIV, *Herpes simplex,* and enteric pathogens.[95] They should also understand that a patient's infectious status may be unknown at the time of endoscopy. The same precautions should therefore be applied to all patients. During the endoscopic procedure and while cleaning endoscopes, endoscopy personnel should wear protective attire (including gloves, masks, eye protection, and moisture-resistant gowns or aprons) as needed to protect themselves from exposure to blood and body fluids. Such items of personal protective equipment should be readily accessible in the endoscopy area. Thorough handwashing should be performed before and after each procedure, even if gloves are worn.[95] All endoscopy personnel who are susceptible to infection with hepatitis B virus should be immunized with the hepatitis B vaccine.[95] Nonimmune personnel exposed to hepatitis B virus should be given postexposure prophylaxis with hepatitis B immune globulin, followed by vaccine. The procedure to be followed when the hepatitis B virus status of either the source or the recipient in a potential exposure is unknown is outlined in guidelines published by the CDC.[95] Similar guidelines have also been published for HIV postexposure follow-up.[96] After exposure to a documented case of tuberculosis, exposed hospital personnel should be screened for purified protein derivative skin test conversion.[95] In addition to an annual Mantoux purified protein derivative skin test, some authorities also recommend that personnel at risk for acquiring tuberculosis (eg, bronchoscopy personnel) be tested more frequently.[95]

PRODUCT DEVELOPMENT AND AREAS FOR FUTURE INVESTIGATION

The major infection control problem in the reprocessing of endoscopes is the instrument design. Recent design advances have greatly improved the diagnostic and therapeutic capabilities of the flexible endoscope. However, there have been relatively few improvements in the instrument materials and design to facilitate thorough cleaning and disinfection or sterilization. The development of endoscopes manufactured from materials capable of withstanding steam sterilization would obviate many of the current infection control dilemmas in endoscopy.

A secondary problem is the need for disinfectant/sterilant agents that combine rapid microbicidal activity against common vegetative bacteria, atypical mycobacteria, fungi, nonenveloped hydrophilic viruses, parasitic cysts, and even bacterial endospores, with minimal toxicity for personnel exposed to them. Such product development would obviously represent a major advance.

Despite the elegant logic of Spaulding's classification,[45] clinical trials are needed to determine whether high-level disinfection (rather than sterilization) is sufficient for endoscopes that enter sterile tissue. As new products emerge, including endoscopes, endoscopic accessories, disinfectants, sterilants, and automated endoscope reprocessors, the collection of data from well-designed epidemiologic studies, in addition to in vitro data, will be necessary to assess their impact on reducing the infectious complications of endoscopy and improving the quality of patient care.

RECOMMENDATIONS

These guidelines represent minimum standards of care. Facilities may wish to adopt more stringent criteria. These recommendations should be followed for all patients, regardless of whether they are suspected or known to be infected.

1. Meticulous cleaning of the endoscope with an enzymatic detergent recommended by the endoscope manufacturer should be performed immediately after use. All of the channels should be irrigated and brushed, if accessible, to remove particulate matter. Irrigation adapters should be used to facilitate cleaning of all channels. All immersible parts of the endoscope should then be rinsed with water. Detergent solutions should be discarded after each use. Cleaning brushes should be disposable or thoroughly cleaned and receive high-level disinfection or sterilization after each use.

2. Leak testing is recommended for flexible endoscopes before immersion.

3. Endoscopes that pass through normally sterile tissue should be subjected to a sterilization procedure before each use; if this is not feasible, they should receive at least high-level disinfection. Disinfection should be followed by a rinse with sterile water.

4. Endoscopes that come in contact with mucous membranes are classified as semicritical items and should receive at least high-level disinfection.

5. An FDA-cleared sterilant/disinfectant should be used for sterilization or high-level disinfection.

6. Products and methods for cleaning and disinfection/sterilization should be compatible with the endoscopic equipment and design. Contact instrument manufacturer(s) to confirm compatibility.

7. If glutaraldehyde is used, all immersible internal and external surfaces should be in contact with the disinfectant for not less than 20 minutes to achieve high-level disinfection.

8. Personnel assigned to reprocess endoscopes must receive device-specific reprocessing instructions to ensure proper cleaning and disinfection or sterilization.

9. Nonimmersible endoscopes should be phased out immediately.

10. After chemical disinfection, endoscopes must be rinsed with sterile water or with tap water followed by a 70% ethyl or isopropyl alcohol rinse.

11. The instrument and its channels should be thoroughly air-dried. A final drying step that includes flushing all channels with alcohol followed by purging the channels with air greatly reduces the possibility of recontamination of the endoscope by waterborne microorganisms.

12. Endoscopes should be stored in a manner that will protect the endoscope and minimize the potential for accumulation of residual moisture. They should not be coiled stored in cases that cannot be properly cleaned. Endoscopes should be hung in a vertical position to facilitate drying.

13. Reusable accessories that penetrate mucosal barriers (eg, biopsy forceps, cytology brushes) should be mechanically cleaned (ie, by ultrasonics) and then steam sterilized between each patient or used once and discarded.

14. Sterile water should be used to fill the water bottle. The water bottle and its connecting tube should be sterilized or receive high-level disinfection at least daily.

15. Flexible endoscopes that cannot withstand the processes described in these guidelines because of age, design, or damage should not be used.

16. A log should be maintained indicating for each procedure the patient's name and medical record number, the procedure, the endoscopist, and the

serial number or other identifier of the endoscope used.

17. In the setting of an outbreak caused by a suspected infectious or chemical etiology, the investigation should be performed according to standard methods of outbreak investigation.

18. Endoscopy related infection or pseudoinfection should be reported to: (1) persons responsible for institutional infection control and risk management, (2) FDA, (3) state health department, (4) CDC, and (5) manufacturer(s).

19. Facilities where endoscopes are used and disinfected should be designed to provide a safe environment for health care workers as well as patients. Air-exchange equipment (ventilation system, exhaust hoods, etc) should be used to minimize the exposure of all persons to potentially toxic vapors. The concentration of glutaraldehyde, if it is used, in the air should never exceed allowable limits. There should be adequate space for drying and storage of endoscopes and endoscopic accessories.

20. Personal protective equipment (gloves, eyewear, respiratory protective devices, etc) should be readily available and should be used to protect workers from exposure to infectious agents (HIV, hepatitis B virus, *M tuberculosis,* etc) and toxic chemicals.

21. All endoscopy personnel must be educated about the biologic and chemical hazards present while performing or assisting at endoscopic procedures and during the reprocessing of endoscopic equipment.

22. Endoscopy personnel should be trained according to the Occupational Safety and Health Administration's hazardous communications Standard. A spill containment plan specific for the liquid chemical sterilant/disinfectant being used should be available whenever and wherever endoscope reprocessing occurs.

23. Personnel should be vaccinated against preventable diseases such as hepatitis B. Those at risk for exposure to tuberculosis should be screened for infection by Mantoux skin testing with purified protein derivative.

24. Routine testing of liquid sterilants/high-level disinfectants should be performed to ensure minimal effective concentration of the active ingredient.

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