DISINFECTION OF HEALTHCARE EQUIPMENT

Concerns about Implementing the Spaulding Scheme

One problem with implementing the aforementioned scheme is oversimplification. For example, the scheme does not consider problems with reprocessing of complicated medical equipment that often is heat-sensitive or problems of inactivating certain types of infectious agents (e.g., prions, such as Creutzfeldt-Jakob disease [CJD] agent). Thus, in some situations, choosing a method of disinfection remains difficult, even after consideration of the categories of risk to patients. This is true particularly for a few medical devices (e.g., arthroscopes, laparoscopes) in the critical category because of controversy about whether they should be sterilized or high-level disinfected. [28, 86] Heat-stable scopes (e.g., many rigid scopes) should be steam sterilized. Some of these items cannot be steam sterilized because they are heat-sensitive; additionally, sterilization using ethylene oxide (EtO) can be too time-consuming for routine use between patients (new technologies, such as hydrogen peroxide gas plasma and peracetic acid reprocessor, provide faster cycle times). However, evidence that sterilization of these items improves patient care by reducing the infection risk is lacking[29, 87-91]. Many newer models of these instruments can withstand steam sterilization, which for critical items is the preferred method.

Another problem with implementing the Spaulding scheme is processing of an instrument in the semicritical category (e.g., endoscope) that would be used in conjunction with a critical instrument that contacts sterile body tissues. For example, is an endoscope used for upper gastrointestinal tract investigation still a semicritical item when used with sterile biopsy forceps or in a patient who is bleeding heavily from esophageal varices? Provided that high-level disinfection is achieved, and all microorganisms except bacterial spores have been removed from the endoscope, the device should not represent an infection risk and should remain in the semicritical category [92-94]. Infection with spore-forming bacteria has not been reported from appropriately high-level disinfected endoscopes.

An additional problem with implementation of the Spaulding system is that the optimal contact time for high-level disinfection has not been defined or varies among professional organizations, resulting in different strategies for disinfecting different types of semicritical items (e.g., endoscopes, applanation tonometers, endocavitary transducers, cryosurgical instruments, and diaphragm fitting rings). Until simpler and effective alternatives are identified for device disinfection in clinical settings, following this guideline, other CDC guidelines [1, 22, 95, 96] and FDA-cleared instructions for the liquid chemical sterilants/high-level disinfectants would be prudent.

Reprocessing of Endoscopes

Physicians use endoscopes to diagnose and treat numerous medical disorders. Even though endoscopes represent a valuable diagnostic and therapeutic tool in modern medicine and the incidence of infection associated with their use reportedly is very low (about 1 in 1.8 million procedures) [97], more healthcare–associated outbreaks have been linked to contaminated endoscopes than to any other medical device [6-8, 12, 98]. To prevent the spread of health-care–associated infections, all heat-sensitive endoscopes (e.g., gastrointestinal endoscopes, bronchoscopes, nasopharygoscopes) must be properly cleaned and, at a minimum, subjected to high-level disinfection after each use. High-level disinfection can be expected to destroy all microorganisms, although when high numbers of bacterial spores are present, a few spores might survive.

Because of the types of body cavities they enter, flexible endoscopes acquire high levels of microbial contamination (bioburden) during each use [99]. For example, the bioburden found on flexible gastrointestinal endoscopes after use has ranged from 10^5 colony forming units (CFU)/mL to 10^{10} CFU/mL, with the highest levels found in the suction channels [99-102]. The average load on bronchoscopes before cleaning was 6.4×10^4 CFU/mL. Cleaning reduces the level of microbial contamination by 4–6 $\log_{10}$ [83, 103]. Using human immunovirus (HIV)-contaminated endoscopes, several investigators have shown that cleaning completely eliminates the microbial contamination on the scopes [104, 105]. Similarly, other investigators found that EtO sterilization or soaking in 2% glutaraldehyde for 20 minutes was effective only when the device first was properly cleaned [106].

FDA maintains a list of cleared liquid chemical sterilants and high-level disinfectants that can be used to reprocess heat-sensitive medical devices, such as flexible endoscopes (http://www.fda.gov/cdrh/ode/germlab.html). At this time, the FDA-cleared and marketed formulations include: ≥2.4% glutaraldehyde, 0.55% *ortho*-phthalaldehyde (OPA), 0.95% glutaraldehyde with 1.64% phenol/phenate, 7.35% hydrogen peroxide with 0.23% peracetic acid, 1.0% hydrogen peroxide with 0.08% peracetic acid, and 7.5% hydrogen peroxide [85]. These products have excellent antimicrobial activity; however, some oxidizing chemicals (e.g., 7.5% hydrogen peroxide, and 1.0% hydrogen peroxide with 0.08% peracetic acid [latter product is no longer marketed]) reportedly have caused cosmetic and functional damage to endoscopes [69]. Users should check with device manufacturers for information about germicide compatibility with their device. If the germicide is FDA-cleared, then it is safe when used according to label directions; however, professionals should review the scientific literature for newly available data regarding human safety or materials compatibility. EtO sterilization of flexible endoscopes is infrequent because it requires a lengthy processing and aeration time (e.g., 12 hours) and is a potential hazard to staff and patients. The two products most commonly used for reprocessing endoscopes in the United States are glutaraldehyde and an automated, liquid chemical sterilization process that uses peracetic acid [107]. The American Society for Gastrointestinal Endoscopy (ASGE) recommends glutaraldehyde solutions that do not contain surfactants because the soapy residues of surfactants are difficult to remove during rinsing [108]. *ortho*-phthalaldehyde has begun to replace glutaraldehyde in many health-care facilities because it has several potential advantages over glutaraldehyde: is not known to irritate the eyes and nasal passages, does not require activation or exposure monitoring, and has a 12-minute high-level disinfection claim in the United States [69]. Disinfectants that are not FDA-cleared and should not be used for reprocessing endoscopes include iodophors, chlorine solutions, alcohols, quaternary ammonium compounds, and phenolics. These solutions might still be in use outside the United States, but their use should be strongly discouraged because of lack of proven efficacy against all microorganisms or materials incompatibility.

FDA clearance of the contact conditions listed on germicide labeling is based on the manufacturer's test results (http://www.fda.gov/cdrh/ode/germlab.html). Manufacturers test the product under worst-case conditions for germicide formulation (i.e., minimum recommended concentration of the active ingredient), and include organic soil. Typically manufacturers use 5% serum as the organic soil and hard water as examples of organic and inorganic challenges. The soil represents the organic loading to which the device is exposed during actual use and that would remain on the device in the absence of cleaning. This method ensures that the contact conditions completely eliminate the test mycobacteria (e.g., 10^5 to 10^6 *Mycobacteria tuberculosis* in organic soil and dried on a scope) if inoculated in the most difficult areas for the disinfectant to penetrate and contact in the absence of cleaning and thus provides a margin of safety [109]. For 2.4% glutaraldehyde that requires a 45-minute immersion at 25°C to achieve high-level disinfection (i.e., 100% kill of *M. tuberculosis*). FDA itself does not conduct testing but relies solely on the disinfectant manufacturer's data. Data suggest that *M. tuberculosis* levels can be reduced by at least 8 $\log_{10}$ with cleaning (4 $\log_{10}$) [83, 101, 102, 110], followed by chemical disinfection for 20 minutes at 20°C (4 to 6 $\log_{10}$) [83, 93, 111, 112]. On the basis of these data, APIC [113], the Society of Gastroenterology Nurses and Associates (SGNA) [38, 114, 115], the ASGE [108], American College of Chest Physicians [12], and a multi-society guideline [116] recommend alternative contact conditions with 2% glutaraldehyde to achieve high-level disinfection (e.g., that equipment be immersed in 2% glutaraldehyde at 20°C for at least 20 minutes for high-level disinfection). Federal regulations are to follow the FDA-cleared label claim for high-level disinfectants. The FDA-cleared labels for high-level disinfection with >2% glutaraldehyde at 25°C range from 20-90 minutes, depending upon the product based on three tier testing which includes AOAC sporicidal tests, simulated use testing with mycobacterial and in-use testing. The studies supporting the efficacy of >2% glutaraldehyde for 20 minutes at 20ºC assume adequate cleaning prior to disinfection, whereas the FDA-cleared label claim incorporates an added margin of safety to accommodate possible lapses in cleaning practices. Facilities that have chosen to apply the 20 minute duration at 20ºC have done so based on the IA recommendation in the July 2003 SHEA position paper, "Multi-society Guideline for Reprocessing Flexible Gastrointestinal Endoscopes" [19, 57, 83, 94, 108, 111, 116-121].

Flexible endoscopes are particularly difficult to disinfect [122] and easy to damage because of their intricate design and delicate materials. [123] Meticulous cleaning must precede any sterilization or high-level disinfection of these instruments. Failure to perform good cleaning can result in sterilization or disinfection failure, and outbreaks of infection can occur. Several studies have demonstrated the importance of cleaning in experimental studies with the duck hepatitis B virus (HBV) [106, 124], HIV [125]and *Helicobacter pylori*. [126]

An examination of health-care–associated infections related only to endoscopes through July 1992 found 281 infections transmitted by gastrointestinal endoscopy and 96 transmitted by bronchoscopy. The clinical spectrum ranged from asymptomatic colonization to death. *Salmonella* species and *Pseudomonas aeruginosa* repeatedly were identified as causative agents of infections transmitted by gastrointestinal endoscopy, and *M. tuberculosis*, atypical mycobacteria, and *P. aeruginosa* were the most common causes of infections transmitted by bronchoscopy [12]. Major reasons for transmission were inadequate cleaning, improper selection of a disinfecting agent, and failure to follow recommended cleaning and disinfection procedures [6, 8, 37, 98], and flaws in endoscope design [127, 128] or automated endoscope reprocessors. [7, 98] Failure to follow established guidelines has continued to result in infections associated with gastrointestinal endoscopes [8] and bronchoscopes [7, 12]. Potential device-associated problems should be reported to the FDA Center for Devices and Radiologic Health. One multistate investigation found that 23.9% of the bacterial cultures from the internal channels of 71 gastrointestinal endoscopes grew ≥100,000 colonies of bacteria after completion of all disinfection and sterilization procedures (nine of 25 facilities were using a product that has been removed from the marketplace [six facilities using 1:16 glutaraldehyde phenate], is not FDA-cleared as a high-level disinfectant [an iodophor] or no disinfecting agent) and before use on the next patient[129]. The incidence of postendoscopic procedure infections from an improperly processed endoscope has not been rigorously assessed.

Automated endoscope reprocessors (AER) offer several advantages over manual reprocessing: they automate and standardize several important reprocessing steps[130-132], reduce the likelihood that an essential reprocessing step will be skipped, and reduce personnel exposure to high-level disinfectants or chemical sterilants. Failure of AERs has been linked to outbreaks of infections [133] or colonization [7, 134], and the AER water filtration system might not be able to reliably provide “sterile” or bacteria-free rinse water[135, 136]. Establishment of correct connectors between the AER and the device is critical to ensure complete flow of disinfectants and rinse water [7, 137]. In addition, some endoscopes such as the duodenoscopes (e.g., endoscopic retrograde cholangiopancreatography [ERCP]) contain features (e.g., elevator-wire channel) that require a flushing pressure that is not achieved by most AERs and must be reprocessed manually using a 2- to 5-mL syringe, until new duodenoscopes equipped with a wider elevator-channel that AERs can reliably reprocess become available [132]. Outbreaks involving removable endoscope parts [138, 139] such as suction valves and endoscopic accessories designed to be inserted through flexible endoscopes such as biopsy forceps emphasize the importance of cleaning to remove all foreign matter before high-level disinfection or sterilization. [140] Some types of valves are now available as single-use, disposable products (e.g., bronchoscope valves) or steam sterilizable products (e.g., gastrointestinal endoscope valves).

AERs need further development and redesign [7, 141], as do endoscopes [123, 142], so that they do not represent a potential source of infectious agents. Endoscopes employing disposable components (e.g., protective barrier devices or sheaths) might provide an alternative to conventional liquid chemical high-level disinfection/sterilization[143, 144]. Another new technology is a swallowable camera-in-a-capsule that travels through the digestive tract and transmits color pictures of the small intestine to a receiver worn outside the body. This capsule currently does not replace colonoscopies**.**

Published recommendations for cleaning and disinfecting endoscopic equipment should be strictly followed [12, 38, 108, 113-116, 145-148]. Unfortunately, audits have shown that personnel do not consistently adhere to guidelines on reprocessing [149-151] and outbreaks of infection continue to occur. [152-154] To ensure

reprocessing personnel are properly trained, each person who reprocesses endoscopic instruments should receive initial and annual competency testing [38, 155].

In general, endoscope disinfection or sterilization with a liquid chemical sterilant involves five steps after leak testing:

1. Clean: mechanically clean internal and external surfaces, including brushing internal channels and flushing each internal channel with water and a detergent or enzymatic cleaners (leak testing is recommended for endoscopes before immersion).
2. Disinfect: immerse endoscope in high-level disinfectant (or chemical sterilant) and perfuse (eliminates air pockets and ensures contact of the germicide with the internal channels) disinfectant into all accessible channels, such as the suction/biopsy channel and air/water channel and expose for a time recommended for specific products.
3. Rinse: rinse the endoscope and all channels with sterile water, filtered water (commonly used with AERs) or tap water (i.e., high-quality potable water that meets federal clean water standards at the point of use).
4. Dry: rinse the insertion tube and inner channels with alcohol, and dry with forced air after disinfection and before storage.

Store: store the endoscope in a way that prevents recontamination and promotes drying (e.g., hung vertically). Drying the endoscope (steps 3 and 4) is essential to greatly reduce the chance of recontamination of the endoscope by microorganisms that can be present in the rinse water [116, 156]. One study demonstrated that reprocessed endoscopes (i.e., air/water channel, suction/biopsy channel) generally were negative (100% after 24 hours; 90% after 7 days [1 CFU of coagulase-negative *Staphylococcus* in one channel]) for bacterial growth when stored by hanging vertically in a ventilated cabinet[157]. Other investigators found all endoscopes were bacteria-free immediately after high-level disinfection, and only four of 135 scopes were positive during the subsequent 5-day assessment (skin bacteria cultured from endoscope surfaces). All flush-through samples remained sterile [158]. Because tapwater can contain low levels of microorganisms[159], some researchers have suggested that only sterile water (which can be prohibitively expensive) [160] or AER filtered water be used. The suggestion to use only sterile water or filtered water is not consistent with published guidelines that allow tapwater with an alcohol rinse and forced air-drying [38, 108, 113] or the scientific literature. [39, 93] In addition, no evidence of disease transmission has been found when a tap water rinse is followed by an alcohol rinse and forced-air drying. AERs produce filtered water by passage through a bacterial filter (e.g., 0.2 μ). Filtered rinse water was identified as a source of bacterial contamination in a study that cultured the accessory and suction channels of endoscopes and the internal chambers of AERs during 1996–2001 and reported 8.7% of samples collected during 1996–1998 had bacterial growth, with 54% being *Pseudomonas* species. After a system of hot water flushing of the piping (60°C for 60 minutes daily) was introduced, the frequency of positive cultures fell to approximately 2% with only rare isolation of >10 CFU/mL [161]. In addition to the endoscope reprocessing steps, a protocol should be developed that ensures the user knows whether an endoscope has been appropriately cleaned and disinfected (e.g., using a room or cabinet for processed endoscopes only) or has not been reprocessed. When users leave endoscopes on movable carts, confusion can result about whether the endoscope has been processed. Although one guideline recommended endoscopes (e.g., duodenoscopes) be reprocessed immediately before use [147], other guidelines do not require this activity [38, 108, 115] and except for the Association of periOperative Registered Nurses (AORN), professional organizations do not recommended that reprocessing be repeated as long as the original processing is done correctly. As part of a quality assurance program, healthcare facility personnel can consider random bacterial surveillance cultures of processed endoscopes to ensure high-level disinfection or sterilization[7, 162-164]. Reprocessed endoscopes should be free of microbial pathogens except for small numbers of relatively avirulent microbes that represent exogenous environmental contamination (e.g., coagulase-negative *Staphylococcus*, *Bacillus* species, diphtheroids). Although recommendations exist for the final rinse water used during endoscope reprocessing to be microbiologically cultured at least monthly [165], a microbiologic standard has not been

set, and the value of routine endoscope cultures has not been shown [166]. In addition, neither the routine culture of reprocessed endoscopes nor the final rinse water has been validated by correlating viable counts on an endoscope to infection after an endoscopic procedure. If reprocessed endoscopes were cultured, sampling the endoscope would assess water quality and other important steps (e.g., disinfectant effectiveness, exposure time, cleaning) in the reprocessing procedure. A number of methods for sampling endoscopes and water have been described [23, 157, 161, 163, 167, 168]. Novel approaches (e.g., detection of adenosine triphosphate [ATP]) to evaluate the effectiveness of endoscope cleaning [169, 170] or endoscope reprocessing [171] also have been evaluated, but no method has been established as a standard for assessing the outcome of endoscope reprocessing.

The carrying case used to transport clean and reprocessed endoscopes outside the health-care environment should not be used to store an endoscope or to transport the instrument within the health-care facility. A contaminated endoscope should never be placed in the carrying case because the case can also become contaminated. When the endoscope is removed from the case, properly reprocessed, and put back in the case, the case could recontaminate the endoscope. A contaminated carrying case should be discarded (Olympus America, June 2002, written communication).

Infection-control professionals should ensure that institutional policies are consistent with national guidelines and conduct infection-control rounds periodically (e.g., at least annually) in areas where endoscopes are reprocessed to ensure policy compliance. Breaches in policy should be documented and corrective action instituted. In incidents in which endoscopes were not exposed to a high-level disinfection process, patients exposed to potentially contaminated endoscopes have been assessed for possible acquisition of HIV, HBV, and hepatitis C virus (HCV). A 14-step method for managing a failure incident associated with high-level disinfection or sterilization has been described [Rutala WA, 2006 #12512]. The possible transmission of bloodborne and other infectious agents highlights the importance of rigorous infection control[172, 173].

Laparoscopes and Arthroscopes

Although high-level disinfection appears to be the minimum standard for processing laparoscopes and arthroscopes between patients [28, 86, 174, 175], this practice continues to be debated [89, 90, 176]. However, neither side in the high-level disinfection versus sterilization debate has sufficient data on which to base its conclusions. Proponents of high-level disinfection refer to membership surveys [29] or institutional experiences [87] involving more than 117,000 and 10,000 laparoscopic procedures, respectively, that cite a low risk for infection (<0.3%) when high-level disinfection is used for gynecologic laparoscopic equipment. Only one infection in the membership survey was linked to spores. In addition, growth of common skin microorganisms (e.g., *Staphylococcus epidermidis*, diphtheroids) has been documented from the umbilical area even after skin preparation with povidone-iodine and ethyl alcohol. Similar organisms were recovered in some instances from the pelvic serosal surfaces or from the laparoscopic telescopes, suggesting that the microorganisms probably were carried from the skin into the peritoneal cavity [177, 178]. Proponents of sterilization focus on the possibility of transmitting infection by spore-forming organisms. Researchers have proposed several reasons why sterility was not necessary for all laparoscopic equipment: only a limited number of organisms (usually $\leq$10) are introduced into the peritoneal cavity during laparoscopy; minimal damage is done to inner abdominal structures with little devitalized tissue; the peritoneal cavity tolerates small numbers of spore-forming bacteria; equipment is simple to clean and disinfect; surgical sterility is relative; the natural bioburden on rigid lumened devices is low[179]; and no evidence exists that high-level disinfection instead of sterilization increases the risk for infection [87, 89, 90]. With the advent of laparoscopic cholecystectomy, concern about high-level disinfection is justifiable because the degree of tissue damage and bacterial contamination is greater than with laparoscopic procedures in gynecology. Failure to completely dissemble, clean, and high-level disinfect laparoscope parts has led to infections in patients[180]. Data from one study suggested that disassembly, cleaning, and proper reassembly of laparoscopic equipment used in gynecologic procedures before steam sterilization presents no risk for infection[181].