



TECHNOLOGY STATUS EVALUATION REPORT

Transmission of infection by gastrointestinal endoscopy

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INTRODUCTION

In order to promote the appropriate use of new or emerging endoscopic techniques, the ASGE Technology Committee has developed a series of status evaluation papers. By this process relevant information about these technologies may be presented to practicing physicians for the education and care of their patients. In many cases, data from randomized control trials are lacking and only preliminary clinical trials are available. Practitioners should continue to monitor the medical literature for subsequent data about efficacy, safety, and socioeconomic aspects of the technologies.

BACKGROUND

Flexible gastrointestinal endoscopes are complex reusable instruments that require unique consideration with respect to cleaning and disinfection. In addition to the external surface, internal channels for air, water, and accessories are exposed to body fluids and other contaminants. In contrast to rigid endoscopes and some reusable accessories, flexible endoscopes are heat-labile and cannot be autoclaved. Professional organizations including the American Society for Gastrointestinal Endoscopy, the American College of Gastroenterology, the American Gastroenterological Association, the Society for Gastroenterology Nurses and Associates, the British Society of Gastroenterology, the Association for Professionals in Infection Control and Epidemiology, the American Society for Testing and Materials, and the Association of Operating Room Nurses have issued guidance documents for the reprocessing of gastrointestinal endoscopes.¹⁻⁵ These documents are intended to aid users of endoscopy equipment to achieve the accepted standard of high-level disinfection, defined as the destruction of

all microorganisms with the exception of high levels of bacterial spores.⁶

The transmission of infectious organisms during gastrointestinal endoscopy is a concern both to the medical profession and the general public. However, such transmission is a rare event, with the frequency estimated to be 1 in 1.8 million cases.⁷ When bacterial and viral transmissions have been reported, such instances have resulted from failure to adhere to currently established reprocessing guidelines.⁴

TRANSMISSION OF MICROORGANISMS

A 1993 review article cited 281 cases of transmission of microorganisms by gastrointestinal endoscopy.⁸ The majority of these cases predated the adoption of guidelines established in 1988, which stressed the importance of adequate manual cleaning before disinfection. Between 1988 and 1992, 28 cases of infections related to endoscopy were reported. It was estimated that approximately 40 million gastrointestinal endoscopies were done during that same period in the United States, resulting in an estimated transmission rate of infection by gastrointestinal endoscopy of 1 in 1.8 million.⁷ This infection rate may be an underestimate due to factors such as incomplete surveillance, underreporting, asymptomatic infections, and infections with a long incubation period, but transmission of infection via gastrointestinal endoscopy appears to be rare.

Various classes of infectious agents have different patterns of resistance to germicides, the recognition of which is important for developing strategies for endoscope and accessory reprocessing. The most resistant organisms are bacterial spores (*Bacillus* and *Clostridium*) followed by, in descending order, mycobacteria and nonlipid viruses (e.g., poliovirus, hepatitis A virus), vegetative fungi and bacteria, and

finally lipid-containing viruses such as HBV and HIV that are highly sensitive to germicides. Hepatitis C virus (HCV) is also a lipid-containing virus and is likely to be similarly sensitive.⁹ Processes that eliminate high numbers of bacterial spores will likely eliminate all other microbial life as well.

In addition to the type of microorganism, factors important in the transmission of infection during gastrointestinal endoscopy include the concentration of microorganism, efficacy and compliance with cleaning and disinfection procedures, and equipment design. Infections can be transmitted either patient-to-patient, health care worker-to-patient, or patient-to-health care worker.

Episodes of transmission of infection to patients can be traced, in most cases, to procedural errors in cleaning and disinfection of the endoscope or its accessories. Bacteria or viruses have been transmitted by (1) inadequately cleaned endoscopes in which organisms may be concentrated in surface irregularities or other areas of limited accessibility, (2) contaminated water bottles and irrigating solutions, (3) improper use of or inadequately designed automated endoscope reprocessors, (4) use of substandard disinfectant solutions, and (5) inadequate drying of endoscope channels before storage.

VIRAL TRANSMISSION

Much concern exists regarding the possible transmission of viruses at the time of endoscopy. There has been only one report of patient-to-patient hepatitis B virus transmission via flexible endoscopy. This occurred with a nonimmersible endoscope that is no longer recommended for use. Because the endoscope was not fully immersible, the air-water channel was not exposed to the disinfecting solution.¹⁰ When current standards of endoscope design and reprocessing are applied, prospective studies of patients harboring hepatitis B have failed to demonstrate its transmission to subsequent patients during gastrointestinal endoscopy.⁸

Isolated cases of patient-to-patient transmission of HCV related to colonoscopy were reported in 1997.¹¹ A patient known to be infected with HCV underwent colonoscopy and biopsy; two subsequent patients had colonoscopy immediately after the index patient and were later shown to have contracted HCV of an identical genotype and nucleotide sequence. Transmission of viral infection in this case occurred because of (1) failure to brush the biopsy channel, (2) failure to ultrasonically clean and steam sterilize reusable biopsy forceps, (3) and an inadequate exposure to the liquid chemical germicide. Adherence to current reprocessing guidelines effectively eliminates the risk of HCV transmission from endoscopy.^{12,13}

HIV is readily destroyed by high-level disinfection. No documented cases of HIV transmission have occurred related to gastrointestinal endoscopy. It has been demonstrated that in endoscopes deliberately contaminated with HIV, the virus is eliminated in all cases by using standard manual cleaning and high-level disinfection protocols.¹⁴ The Center for Disease Control stated that currently recommended procedures for disinfection of endoscopes are adequate for instruments contaminated with HIV.¹⁵

BACTERIAL TRANSMISSION

Transmission of bacterial infections to patients is rarely encountered in current endoscopic practice. Organisms reported to have been transmitted include gram-negative bacilli such as *Salmonella* spp,^{16,17} *Escherichia coli*,¹⁸ *Pseudomonas*,^{19,20} *Klebsiella*,¹⁸ *Enterobacter* spp,²⁰ *Serratia marcescens*,²¹ and *Helicobacter pylori*.²² Infections occur as a consequence of inadequate endoscope reprocessing or because of contaminated water sources. A study published in 1999 reaffirmed that use of accepted reprocessing guidelines effectively eliminates bacteria and other microorganisms from endoscopes.²³

Endoscopic transmission of *Salmonella* has been reported in 84 patients.^{16,17,24-27} Suboptimal reprocessing was implicated in each case. There have been no reports of *Salmonella* infection when current guidelines for high-level disinfection have been followed.

Forty-five cases of endoscopic transmission of *Pseudomonas* have been reported. Infection with this organism generally occurs as a consequence of contamination of the water source (either an inadequately disinfected water bottle feeding the endoscope or contamination of an automated reprocessing machine) as well as a breach in accepted cleaning, disinfection, and storage procedures.^{8,28-30}

There are isolated reports of transmission of other bacteria including *Staphylococcus*,¹⁸ *Serratia*,²¹ *Klebsiella*,¹⁸ *Enterobacter*,³¹ and *Helicobacter pylori*.^{22,32} However, in each instance manual cleaning, disinfection, or storage techniques were found to have been inadequate.

Although bacterial spores are the most resistant to liquid chemical germicides, there have been no reported cases of endoscopic transmission of infections with these organisms.⁴ Studies have shown that *C difficile* spores can be completely inactivated by standard reprocessing techniques.³³

Although easier to eradicate than bacterial spores, mycobacteria are also difficult to eliminate with chemical sterilants or disinfectants. Although cases of mycobacterial transmission have been documented during bronchoscopy,^{34,35} there are no

reported cases of transmission by gastrointestinal endoscopy. Gluteraldehyde, hydrogen peroxide, and peracetic acid, used appropriately in association with mechanical cleaning, have all been demonstrated to adequately eradicate mycobacteria, both *Mycobacterium tuberculosis* and the atypical mycobacteria.^{36,37}

MISCELLANEOUS MICROBIAL TRANSMISSION

There have been 4 cases of *Strongyloides* esophagitis reported from a single contaminated endoscope.³⁸ There have been no reported cases of transmission of fungi resulting from gastrointestinal endoscopy.

Concern has been raised over possible endoscopic transmission of prions and other transmissible spongiform encephalopathies (TSE), including Creutzfeldt-Jakob disease, kuru, and bovine spongiform encephalopathy. There have been no reported cases of transmission of these agents by endoscopy. The World Health Organization recommends that the decontamination of medical instruments should be guided by the infectivity level of the tissue contaminating the instrument. Saliva, gingival tissue, intestinal tissue, feces, and blood are classified as having no detectable infectivity and, for the purposes of infection control for these agents, are regarded as noninfectious.³⁹ A draft statement on TSE and endoscopes from the Centers for Disease Control (CDC) concluded that current guidelines for cleaning and disinfection of the instruments need not be changed.^{4,40}

RISKS TO OR FROM HEALTH-CARE WORKERS

Transmission of infection from a health care worker to a patient at the time of gastrointestinal endoscopy has not been reported. In contrast, transmission of infection from patient to staff is suggested by the higher prevalence of *H pylori* infection among gastroenterologists compared with other physicians.⁴¹ Additional concerns include body fluid exposures from needle stick injuries (hypodermic needles and other sharp objects (such as spiked biopsy forceps) and splash injuries.⁴² CDC guidelines state that all patients be treated as potential carriers of blood-borne pathogens; universal precautions should be followed at all times in the care of patients.⁴³

ENDOSCOPE DESIGN ISSUES

Flexible gastrointestinal endoscopes are complex instruments. They have channels and ports that may acquire surface breaks and irregularities with use over time, as well as movable parts (such as the elevator on a duodenoscope) where organic debris and possibly microorganisms may become lodged. These areas may be relatively inaccessible to contact with

liquid chemical germicides. Because endoscopes are heat-sensitive instruments and cannot be autoclaved, sterilization cannot be guaranteed. Thus, although the available evidence suggests that the rate of transmission of infection via gastrointestinal endoscopy is extremely low, potential risk exists. Manufacturers have been encouraged to redesign endoscopes to facilitate the cleaning and disinfection process. Quality control and assessment of the adequacy of high-level disinfection is particularly important if clinical or epidemiologic findings suggest an endoscopy-related transmission of infection.⁴⁴

ENDOSCOPE REPROCESSING

The importance of strict adherence to reprocessing guidelines cannot be overemphasized.^{1-5,45} Components of a successful program for reprocessing GI endoscopes must include all of the following: (1) mechanical cleaning and rinsing of all exposed internal and external surfaces; (2) use of an effective liquid chemical germicide (LCG) at an for recommended duration and at recommended temperature (which includes monitoring the LCG's minimum effective concentration [MEC]); (3) further rinsing; and (4) proper drying and storage technique.^{45,46} Appropriate training in these techniques, as well as strict compliance with policies based on published guidelines, are required.

MECHANICAL CLEANING

Mechanical cleaning is a vital step in endoscope reprocessing and has been shown to remove over 99.9% of microbes from the endoscope (a 3- to 4-log₁₀ reduction).^{23,37,47,48} After use, an endoscope retains organic materials such as blood, mucus, and saliva, which may be rich in microorganisms. If this debris is allowed to remain, ineffective contact and penetration of the disinfectant may result. Immediately after completion of an endoscopic procedure, a low-sudsing detergent solution should be suctioned through the channels. After transferring the endoscope to the reprocessing area, the suction, air/water valves, and biopsy port cap should be removed. The endoscope, valves, and cap should then be submerged in a fresh detergent solution. Manual cleaning with cloths, sponges, and soft wire brushes of various sizes should be utilized to mechanically dislodge debris. The detergent solution should then be suctioned and flushed through the endoscope channels. Automated reproprocessors used for disinfection of endoscopes do not replace the need for manual cleaning.^{37,49} Endoscopic accessories that penetrate the gastrointestinal mucosa should be mechanically cleaned and sterilized after each use. Those that are heat stable should be heat sterilized.^{50,51}

CHEMICAL DISINFECTION

After thorough manual cleaning has been performed, the next step is high-level chemical disinfection. High-level disinfection is a process that results in the destruction of all vegetative bacteria, viruses, fungi, and mycobacteria but not necessarily all bacterial spores. The Food and Drug Administration (FDA) has approved 5 chemicals for use as high-level disinfectants or sterilants in the reprocessing of endoscopes (reusable medical devices): glutaraldehyde, peracetic acid, hydrogen peroxide, peracetic acid/hydrogen peroxide, and orthophthalaldehyde.⁵² Glutaraldehyde, hydrogen peroxide, peracetic acid/hydrogen peroxide and orthophthalaldehyde are reusable products. The number of appropriate reuses for each of these products must be determined by testing that the solution is at or above its MEC. Product-specific test strips should be used to monitor the MEC depending on solution use, but at least daily. Solutions should be discarded whenever the MEC fails or the use life expires, whichever comes first.⁵¹ Users should consult with manufacturers of endoscopes and reprocessors for results of compatibility studies before selecting a product.

Complete immersion of the endoscope is essential, and each endoscope channel must be thoroughly irrigated and filled with solution during the disinfection cycle. The use of nonimmersible endoscopes is not acceptable.¹ After high-level disinfection, the instrument should be thoroughly rinsed with clean water (water that has been filtered by passage through a 0.2-micron filter or otherwise treated by a method documented to improve the microbiological quality of the water may be preferable).⁵ This step should be followed by forced air drying, with a final 70% isopropyl alcohol rinse and a second air drying.² Endoscopes should be stored without coiling (to prevent the possible pooling of residual water) in a well-ventilated closet.

DISINFECTION PROCEDURE COMPLIANCE

Adherence to established guidelines for the cleaning and disinfection of endoscopes is imperative. Reprocessing of endoscopes should be limited to trained personnel who understand the importance of strict adherence to established protocols. Only individuals who are able to read, understand, and implement instructions on the proper cleaning and high-level disinfection of endoscopes should be given the responsibility of reprocessing these instruments. Such individuals must meet competency standards for endoscope reprocessing. Untrained personnel should not be allowed to participate in cleaning or disinfection of instruments with either a manual or automated reprocessing methods.^{2,5}

SUMMARY

Although endoscopes have potential sites for microorganism accumulation, transmission of infection is extremely rare. Since 1988, the estimated rate of transmitted infection is 1 in 1.8 million procedures; all of these cases can be attributed to improper cleaning and disinfection. Adherence to current guidelines for the cleaning and disinfection of endoscopes and their accessories is essential.

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