



Infection Control During Gastrointestinal Endoscopy

GUIDELINES for Clinical Application

This is one of a series of statements discussing the practice of gastrointestinal endoscopy. The Standards of Practice Committee of the American Society for Gastrointestinal Endoscopy prepared this text. A previous ASGE guideline on this topic was published in 1988⁽¹⁾. In preparing this update, a Medline literature search was performed and additional references were obtained from the bibliographies of the identified articles and from the recommendations of expert consultants. As little or no data exist from well-designed prospective trials, emphasis was given to results from large series and reports from recognized experts.

INFECTION CONTROL DURING GASTROINTESTINAL ENDOSCOPY

The purpose of this statement is to provide a practical basis for the prevention of infection during gastrointestinal (GI) endoscopy and to provide direction to corollary society publications and other resources pertinent to the practice of infection control. Despite the large number and variety of GI procedures performed, documented instances of infectious complications remain very rare⁽²⁻⁴⁾. Endoscopy related infection might occur in several situations:

1. Microorganisms may be spread from patient-to-patient by contaminated equipment. Bacterial (salmonella, pseudomonas) and, rarely, viral (hepatitis B (HBV), hepatitis C (HCV)) infections have been acquired in this manner⁽⁵⁻⁷⁾; however in all recent instances such transmission has been attributable to important lapses in reprocessing of endoscopes and/or accessories. Endoscopic transmission of human immunodeficiency virus (HIV) has not been reported.

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*Requests for reprints of these items and this statement should be addressed to:

American Society for Gastrointestinal Endoscopy
13 Elm Street
Manchester, MA 01944
(978) 526-8330, FAX (978) 526-4018
e-mail: asge@shore.net

2. Microorganisms may spread, during endoscopy, from the gastrointestinal tract through the bloodstream to potentially susceptible tissues or prostheses, possibly resulting in infection (e.g., bacterial endocarditis)⁽⁸⁾.
3. Microorganisms may be transmitted from patients to endoscopy personnel, and vice versa.

DEFINITIONS⁽⁹⁾:

Cleaning. Cleaning is defined as the physical removal of organic material and/or soil from objects, usually using water with detergents designed to remove rather than to kill organisms.

Sterilization. Sterilization is the act of killing all microbial life and the elimination of bacterial spores. It is most commonly done with heat or ethylene oxide gas.

Disinfection. Disinfection accomplishes the killing of most microorganisms including pathogens and is commonly done with the use of liquid chemical germicides (LCGs). Three levels of disinfection are defined: high, intermediate, and low-level, depending on the amount and kind of microbial killing involved. High-level disinfection (HLD) will destroy vegetative microorganisms, tubercle bacilli, and small nonlipid viruses, but not necessarily large numbers of bacterial spores. Chemical germicides registered as 'sterilants' may be used for sterilization or for high-level disinfection depending on such factors as dilution, contact time and frequency of reuse. The specifics of such factors may vary with each product and are included on approved labelling.

Critical Use Items. Items that enter sterile tissue or vascular spaces, and hence carry significant risk for infection if contaminated. This includes needles, surgical instruments, biopsy forceps, urinary catheters, etc. Processing for reuse requires sterilization for this group of items.

Semi-critical Use Items. Items that contact mucous membranes or non-intact skin. This includes thermometers, endoscopes, anesthesia equipment, and others. Processing for reuse requires high level disinfection for these items.

Universal Precautions. Application of blood and body fluid precautions to all patients to prevent exposure of health-care workers to bloodborne pathogens via parenteral, mucous membrane and nonintact skin routes. Specifically intended to minimize risk of HIV, HBV, and HCV. Universal precautions formally apply to blood and "other potentially infectious materials" (OPIM), defined as human tissues, semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid, and amniotic fluid. Universal precautions have not been specified for feces, nasal secretions, sputum, sweat, tears, urine, and vomitus unless they contain visible blood⁽¹⁰⁾.

REPROCESSING OF ENDOSCOPES

The regulation of liquid chemical germicides has been under the purview of the Food and Drug Administration (FDA) since 1993. Confusion regarding the differences between recent labelling changes and usual and standard practices for disinfection times with 2% glutaraldehyde products led to publication of the multi-society *Position Statement on Reprocessing of Flexible Gastrointestinal Endoscopes* (ASGE, ACG, AGA, SGNA - 1995) found in the ASGE Policy and Procedure Manual⁽¹¹⁾. This document underscores the importance of **a**) reliable and consistent mechanical cleaning as the first step in endoscope reprocessing, **b**) development of detailed written reprocessing protocols within each endoscopy unit, and **c**) training and quality assurance programs for endoscope reprocessing. The position statement on endoscope reprocessing also called for development of a 'user-friendly' reprocessing guideline. The appended "*Standards for Infection Control and Reprocessing of Flexible Gastrointestinal Endoscopes*" were developed within the SGNA and endorsed by the ASGE in early 1997 (Appendix I)⁽¹²⁾.

A. Mechanical Cleaning

The first and most important step in the prevention of infection during endoscopy is mechanical cleaning. The efficacy of cleaning and disinfection is personnel-dependent; hence training and quality control are critical for reliable reprocessing. Appendix I provides detailed instructions regarding both the specific steps and rationale for endoscope cleaning and disinfection.

B. Disinfection

High level disinfection (HLD) is the standard of care recommended by governmental agencies and all pertinent professional organizations for the reprocessing of flexible gastrointestinal endoscopes⁽¹³⁻¹⁵⁾. Among the acceptable products, gluteraldehyde-based formulations are the most frequently used liquid chemical germicides for gastrointestinal endoscopes. Current consensus accepts high level disinfection as achievable with a 20 minute soak at room temperature using a 2% gluteraldehyde solution without surfactant or stabilizing additives (e.g. shorter 14-day shelf-life products vs. 30 day products)^(11,16). Serial dilutions occurring during repeated use necessitate regular testing to ensure adequacy of germicidal concentrations. HLD may also be achievable with other parameters or alternate solutions using manual or automated processes^(17,18). Validated reprocessing regimens are available using liquid peracetic acid and hydrogen peroxide. Not all liquid chemical germicides are reusable. Reprocessing costs can be significantly influenced by selection among the manual and automated systems and by type of LCG used. Even while subscribing to widely accepted methods of HLD, it is most important to adopt local quality control methods to ensure performance of the system used.

Sterilization of endoscopes or accessories is appropriate when they are to be used as 'critical' medical devices - i.e. in a method entering sterile tissue or vasculature⁽⁹⁾. For gastrointestinal endoscopes this applies only when they are to be used via a surgical enterotomy and there is potential for contamination of an open surgical field. Autoclaving will destroy flexible endoscopes. Sterilization is usually performed with ethylene oxide gas treatment but may also be accomplished with prolonged exposure to liquid chemical germicides^(17,18). Because of the complexity of instrument channel design, sterility is difficult to accomplish and to monitor, particularly for liquid germicides^(19,20). Universal precautions dictate that endoscope sterilization, as opposed to HLD, is not indicated before or after standard gastrointestinal endoscopy in any patient subgroup or setting. To date there have been no demonstrable benefits to the further reduction in spore counts achieved by sterilization over HLD reprocessing⁽¹⁹⁾. Biopsy forceps, snares, sphincterotomes and other accessories designed to break the mucosal surface all require sterilization.

There is evidence by PCR techniques and/or direct infectivity testing that tuberculosis⁽²¹⁻²²⁾, HBV⁽²³⁾, HCV⁽²⁴⁾ and HIV⁽²⁵⁻²⁷⁾ are readily inactivated by commonly used cleaning methods and chemical germicides. The Center for Disease Control (CDC) states that standard currently recommended sterilization and disinfection procedures for patient care equipment are adequate to sterilize or disinfect instruments contaminated with pathogens, including HIV⁽²⁵⁾. Thus, following endoscopic procedures on infected patients, the

instrument should be cleaned and reprocessed in the usual fashion. So-called "dedicated instruments" are not necessary.

Patients with severe neutropenia, immune deficiency syndromes, or those receiving immunosuppressive chemotherapy may be at increased risk for local or systemic infection as a result of endoscopic translocation of gut organisms to deeper tissues or to the bloodstream. As per usual practice, endoscopes used in these patients should receive HLD reprocessing; biopsy forceps and other accessories should be sterilized. Water bottles should also be disinfected or sterilized and sterile water should be used in the water bottle.

C. Rinsing and Drying

A critical part of the cleaning and disinfecting process involves rinsing and drying of the endoscope channels. Rinsing requires flushing large volumes of water through all channels to accomplish complete evacuation of liquid chemical germicides. Sterilized scopes must have channels purged of ethylene oxide by flushing with room air. Drying is especially important to prevent proliferation of residual bacteria and fungi during storage. After rinsing with sterile or filtered water (0.2-micron pore size) instruments are dried with forced air and stored in an upright hanging position. Alcohol has been shown to promote drying and to inhibit growth of organisms in stored instruments and is particularly advisable for HLD if tap water rinses are used⁽²⁸⁾.

ANTIBIOTIC PROPHYLAXIS FOR GASTROINTESTINAL ENDOSCOPIC PROCEDURES

Antibiotic prophylaxis against endoscopically induced systemic or distant infections (e.g. sepsis, endocarditis, vascular grafts, prosthetic joints, etc.) is discussed in thorough detail in a multi-specialty guideline published by the ASGE, "Antibiotic Prophylaxis for Gastrointestinal Endoscopy"⁽²⁹⁾. The recommendations of this publication are summarized in table 1. More recently the American Heart Association (AHA) published an independent guideline for endocarditis specifically⁽³⁰⁾. Key points of the discussions are that: 1) the risk of infection from most gastrointestinal endoscopic procedures is very low, 2) no prospective controlled trials have shown that antibiotic prophylaxis prevents infective endocarditis, 3) indiscriminate use of antibiotics is to be discouraged, 4) transient bacteremia may occur after gastrointestinal endoscopy at rates similar to those occurring with other activities or procedures (brushing teeth, barium enema, etc.), 5) a relatively higher incidence of bacteremia has been

reported after esophageal stricture dilation and injection sclerotherapy of esophageal varices, 6) the risk of bacteremia does not appear to increase with biopsy, polypectomy or sphincterotomy, and 7) the risk of a transient bacteremia causing seeding and clinically evident distant infection varies with the type of cardiac lesion and the interval after vascular graft placement.

Given these various factors, recommendations for antibiotic prophylaxis have been made procedure and patient specific. Patients are stratified into high, intermediate, and low risk groups based upon the susceptibility of underlying cardiac conditions to infection during bacteremia and the potential outcome should endocarditis develop. Patients with a history of endocarditis, prosthetic cardiac valve placement, systemic-pulmonary surgical shunts, cyanotic congenital heart disease or synthetic vascular grafts less than 1 year old should receive antibiotic prophylaxis prior to those procedures at greatest risk of inducing bacteremia. They are esophageal stricture dilation, variceal sclerotherapy, and cholangiography with biliary obstruction. Prophylaxis should be individualized when high-risk patients undergo lower risk procedures. The AHA guidelines suggest prophylaxis also for those patients with moderate risk cardiac lesions (rheumatic valvular dysfunction, mitral valve prolapse with insufficiency, hypertrophic cardiomyopathy, and most congenital cardiac lesions) undergoing the higher risk procedures. While the endoscopist is given considerable leeway regarding antibiotic use in other clinical scenarios, prophylaxis is not routinely recommended for patients with moderate risk cardiac lesions undergoing low risk procedures or for patients with low risk cardiac lesions (history of coronary bypass grafting, pacemakers, implantable defibrillators) or prosthetic joints undergoing any procedure. Several oral and parenteral antibiotic regimens have been proposed and are noted in the references. The most recent AHA regimen for endocarditis foregoes use of post-procedure dosing.

Antibiotic prophylaxis against soft tissue infection is advised for all patients undergoing percutaneous endoscopic gastrostomy (PEG) placement. Regimens should provide optimal coverage of cutaneous organisms (e.g. cefazolin 1 g IV)⁽³¹⁾. Patients with anticipated biliary obstruction or pancreatic pseudocysts undergoing ERCP should receive prophylaxis with agents providing good biliary penetration. Several acceptable regimens are available. When such patients have high-risk cardiac lesions as well they require standard SBE prophylaxis regimens, which may be more aggressive. Prophylaxis in immunocompromised patients or those with cirrhosis and

Table 1.
Antibiotic prophylaxis in endoscopy

PATIENT CONDITION	PROCEDURE CONTEMPLATED	ANTIBIOTIC PROPHYLAXIS	COMMENTS
Prosthetic Valve Hx Endocarditis Syst-Pulm Shunt Syn Vasc Graft (less than 1 yr old)	Stricture dilation, Varix sclerosis ERCP/obstructed biliary tree	Recommended	High Risk conditions for development of infectious complication; procedures are associated with relatively high bacteremia rates
	Other endoscopic procedures, including EGD and colonoscopy (with or without biopsy / polypectomy), variceal ligation	Insufficient data to make firm recommendation; endoscopists may choose on case-by-case basis	While conditions high risk, procedures are associated with low rates of bacteremia
Rheumatic valvular dysfunction	Stricture dilation, Varix sclerosis ERCP/obstructed biliary tree	Insufficient data to make firm recommendation; endoscopists may choose on case by-case basis	Conditions pose lesser risk for infectious complications than prosthetic valve, etc.
Mitral valve prolapse with insufficiency	_____	_____	_____
Hypertrophic cardiomyopathy	Other endoscopic procedures, including EGD and colonoscopy (with or without biopsy / polypectomy), variceal ligation	Not recommended	Procedures are associated with relatively low bacteremia rates
Most Congenital cardiac malformations	_____	_____	_____
Other cardiac conditions (including CABG, pacemakers, implantable defibrillators)	All endoscopic procedures	Not recommended	Conditions are low risk for infectious complications from endoscopic procedures
Obstructed bile duct Pancreatic pseudocyst	ERCP	Recommended	Prudent, but not substitute for definitive drainage
Cirrhosis and Ascites Immuno-compromised Patient	Stricture dilation, Varix sclerosis ERCP/obstructed biliary tree	Insufficient data to make firm recommendation; endoscopists may choose on case-by-case basis	Risk for infectious complications related to endoscopic procedures unestablished
	Other endoscopic procedures, including EGD and colonoscopy (with or without biopsy / polypectomy), variceal ligation	Not recommended	Procedures are associated with relatively low bacteremia rates
All patients	Endoscopic feeding tube placement	Prophylaxis recommended (see text)	May decrease risk of soft tissue infection
Prosthetic Joints	Any endoscopic procedure	Not recommended	No literature to support infectious risk from endoscopic procedures

ascites should be individualized based on patient and procedure characteristics.

PROTECTION OF PERSONNEL

The Occupational Safety and Health Administration (OSHA) provides broad guidelines as well as

many specific requirements regarding protection of employees from infection in the workplace⁽³²⁾. Mandates include development of an institution wide Infection Exposure Plan defining anticipated exposure risks for each employee task, and outlining risk reduction approaches involving education, changes in

practices, engineering controls and use of protective barriers or personal protective equipment⁽³³⁾.

Universal precautions are at the heart of OSHA regulations⁽¹⁰⁾. Endoscopy personnel should be made aware of the dangers of contaminated equipment and the modes of disease transmission. They should understand that a patient's infectious status might be unknown at the time of endoscopy. It is therefore prudent to apply the same precautions generally. Needles should be discarded in 'sharps' containers without recapping in order to avoid inadvertent sticks. Endoscopy units and institutions should adopt needleless systems for administration of parenteral drugs whenever feasible. Infection control policies of the endoscopy unit should address procedure room work areas, separation of soiled and clean tasks, and handling of specimens, tissues, soiled linens, and contaminated wastes⁽³³⁾. The physical design of the endoscopy unit and rooms significantly influences whether these infection control issues can be adequately and efficiently addressed^(34,35).

A recent Position Paper of the Technology Assessment Committee of the ASGE provides a thorough discussion of personal protective equipment, their rationale and the applicable regulations regarding their use⁽³⁶⁾. There are no endoscopy specific mandates; however, institution-wide policies must define appropriate protective wear for the reasonably anticipated exposure of a given task⁽³³⁾. Gowns and gloves should be worn in all settings wherein contact with blood-borne pathogens or other potentially infectious materials might be anticipated. OSHA requires that employers provide all generally available protective attire, that they instruct employees in their use, and that they ensure use by the employee⁽³³⁾. This includes gloves, gowns, and all variety of face and eye protection. Special precautions are required for patients with known TB.

Following the procedure, exposed surfaces should be thoroughly cleaned of visible contaminants and then disinfected with an Environmental Protection Agency (EPA) registered hospital disinfectant⁽⁹⁾. Hands should be washed before and after each patient interaction, irrespective of whether gloves are worn. Isolation precautions which are otherwise indicated in potentially infected patients should be maintained when they are transported to endoscopy units. For some patients convenience or isolation requirements may prompt or require performance of endoscopy at the bedside.

Although the risk of acquiring HBV infection by endoscopy personnel is small⁽³⁷⁾, OSHA mandates

that all employees should be offered immunization^(32,38). A variety of other measures are indicated for optimal infection control among employees, both prior to and during the period of employment⁽³⁹⁾.

The risk for transmission of serious infection from hospital personnel to patients is also small and task dependent. The CDC has provided guidance regarding assessment of procedure risk and management of privileges in those who are potentially infectious⁽⁴⁰⁾. Health care workers who perform exposure prone invasive procedures should know their HIV and hepatitis serologic status; however, mandatory HIV or hepatitis testing is not recommended. Those who are positive and potentially infectious should not perform exposure-prone procedures unless they have sought counsel of an expert panel and have been advised regarding acceptable circumstances for their performance.

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