

Prevention of disease transmission during flexible laryngoscopy

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The medical literature was reviewed to evaluate the risk of disease transmission and nosocomial infection associated with flexible laryngoscopes. These instruments have been reported to be contaminated with blood, body fluids, organic debris, and potentially pathogenic microorganisms during routine clinical use. Failure to reprocess properly a flexible laryngoscope may, therefore, result in patient-to-patient disease transmission. Different types of biocidal agents, including 70% isopropyl alcohol, quaternary ammonium compounds, and 2% glutaraldehyde have been reported to be used to disinfect flexible laryngoscopes. A logic, or algorithm, was developed to evaluate the adequacy of these and other types of biocidal agents used during instrument reprocessing. This review determined that flexible laryngoscopes are *semicritical* instruments that require high-level disinfection (or sterilization) to prevent nosocomial infection. Whereas 70% isopropyl alcohol, quaternary ammonium compounds, and other products that achieve intermediate-level or low-level disinfection are contraindicated for reprocessing flexible laryngoscopes, 2% glutaraldehyde and other products that achieve high-level disinfection (or sterilization) are recommended for reprocessing these instruments to prevent nosocomial infection. A formal set of step-by-step guidelines for reprocessing flexible laryngoscopes is provided. Use of a disposable sheath to cover and protect the flexible laryngoscope from contamination during clinical use is discussed. (Am J Infect Control 2007;35:536-44.)

Flexible laryngoscopes are medical devices used to examine and evaluate the normal physiologic and pathologic conditions of the larynx, vocal cords, and pharynx. These instruments, which may use fiberoptic or video technology, are often referred to as ENT (or "ear-nose-throat") endoscopes. Examples of flexible laryngoscopes include rhinolaryngoscopes and nasopharyngolaryngoscopes. Reports indicate that, during clinical use, flexible laryngoscopes may become soiled and contaminated with blood, body fluids, organic debris, and potentially pathogenic microorganisms.¹⁻⁶ Effective reprocessing of these instruments is, therefore, crucial to the prevention of disease transmission during flexible laryngoscopy. Several professional organizations have published formal step-by-step instructions for reprocessing flexible gastrointestinal (GI) endoscopes.⁷⁻¹⁰ Like many other types of reusable medical instruments, however, a formal and endorsed set of step-by-step guidelines for reprocessing flexible (and rigid) laryngoscopes and other types of flexible endoscopes, although equally crucial to the prevention of the transmission of disease, including tuberculosis and AIDS, have not been published.^{6,11}

METHODS

The risk of nosocomial infection associated with flexible laryngoscopes was evaluated by reviewing published reports of nosocomial infections associated with flexible laryngoscopy; reprocessing instructions provided by manufacturers of flexible laryngoscopes; and guidelines for infection control and the reprocessing of other types of flexible endoscopes including GI endoscopes. Specifically, the purpose of this review was to (1) establish the minimum requirements for reprocessing flexible laryngoscopes to prevent patient-to-patient disease transmission; (2) develop a logic, or algorithm, to evaluate the adequacy of any biocidal agent or decontamination process for reprocessing flexible laryngoscopes (eg, determine whether 70% isopropyl alcohol or a quaternary ammonium compound is adequate for disinfecting flexible laryngoscopes and preventing disease transmission); and (3) develop a formal set of step-by-step guidelines, such as those developed for GI endoscopes, for reprocessing flexible laryngoscopes. To achieve these 3 goals, focus was placed on the following: (a) the 3 categories into which medical instruments are classified, based on the risk of nosocomial infection associated with their use; (b) sterilization and the 3 "levels" of disinfection; and (c) the biocidal claims and effectiveness of different types of disinfectants.

RESULTS

Although reports of contamination of flexible laryngoscopes after clinical use have been documented, few reports of nosocomial infections linked to inadequately

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reprocessed flexible laryngoscopes have been published. The reported low number of reports of disease transmission associated with contaminated laryngoscopes notwithstanding, failure to reprocess properly a flexible laryngoscope, like a bronchoscope and GI endoscope, violates the standard of care and increases the risk of disease transmission.^{1-6,11} Despite the paucity of reports linking disease transmission to inadequately reprocessed flexible laryngoscopes, this review found that practices for reprocessing flexible laryngoscopes are often inadequate, inconsistent, and may vary significantly from one health care facility to another (as well as within the same facility).^{3,5,6,12,13} This finding is understandable, considering that surveys indicate that the majority of responding health care facilities do not have on file a written policy and procedure for reprocessing flexible laryngoscopes,³ and, as a result, there is often confusion among health care personnel regarding the minimum requirements for reprocessing these flexible instruments.⁵ Reports describe the clinical use of single-use, disposable sheaths to cover and protect the flexible laryngoscope from patient contact and contamination,¹² but this technology does not obviate reprocessing.

Table 1 presents the widely accepted 3-tiered scheme for classifying different types of medical instruments.¹⁴ According to this classification scheme developed by Spaulding, the risk of nosocomial infection associated with a medical instrument depends on its clinical uses, applications and functions, and contact with the patient. An assessment of this risk and the determination that the medical instrument poses a low, moderate, or high risk of nosocomial infection dictate whether the instrument requires sterilization or disinfection. Table 2 defines, compares, and differentiates between sterilization and the 3 "levels" of disinfection. In conjunction with Table 1, Table 2 can be used to determine the minimum reprocessing requirements for virtually any type of reusable medical instrument. Figure 1 provides a logic, or algorithm, to evaluate the adequacy of any biocidal agent (or decontamination process)—from those with a sporicidal label claim to cleaner/disinfectants without a tuberculocidal label claim—for reprocessing virtually any type of reusable medical instrument, including flexible laryngoscopes. A formal step-by-step set of guidelines for reprocessing flexible laryngoscopes was developed and is presented in Table 3.

DISCUSSION

The following discussion provides guidance to evaluate whether a biocidal agent is adequate to prevent flexible laryngoscopes from transmitting disease during clinical use.

Table 1. Classification scheme for medical instruments

Critical instruments
<ul style="list-style-type: none"> • Penetrate sterile tissue, enter the vasculature, or contact bone or blood • Examples: cardiac catheters, biopsy forceps, and implants
Semicritical instruments
<ul style="list-style-type: none"> • Contact mucous membranes or nonintact skin • Examples: Flexible laryngoscopes (eg, rhinolaryngoscopes, nasopharyngolaryngoscopes), blades and handles of rigid laryngoscopes, gastrointestinal (GI) endoscopes, bronchoscopes, and cystoscopes¹⁵⁻¹⁹
Noncritical instruments
<ul style="list-style-type: none"> • Do not directly contact the patient or only contact intact skin • Examples: blood pressure cuffs, stethoscopes, and bedpans; and environmental surfaces, such as walls, floors, and sink tops

Classification of medical instruments, based on the risk of disease transmission

As displayed in Table 1, flexible laryngoscopes—like GI endoscopes, bronchoscopes, and cystoscopes—are designed and intended to contact mucous membranes or nonintact skin. Indeed, these instruments can transmit disease from one patient to another if improperly reprocessed and contaminated at the time of use. According to the Spaulding scheme, flexible laryngoscopes are classified as *semicritical* instruments (Table 1).¹⁴⁻¹⁸ Medical instruments that penetrate sterile tissue, enter the vasculature, or contact bone or blood pose a greater risk of nosocomial infection than *semicritical* instruments and are classified as *critical* instruments. Medical instruments that do not directly contact the patient, or only contact intact skin, pose a lower risk of nosocomial infection than *semicritical* instruments and are classified as *noncritical* instruments. Like all types of medical instruments, establishment of the minimum reprocessing requirements for flexible laryngoscopes is crucial to prevent disease transmission.

Sterilization and the 3 levels of disinfection

After having established that flexible laryngoscopes are *semicritical* instruments, an understanding of the definitions of, and differences between, *sterilization* and *disinfection* is necessary to evaluate the adequacy of 70% alcohol, quaternary ammonium compounds, 2% glutaraldehyde, or another biocidal agent for reprocessing flexible laryngoscopes (and other types of reusable medical instruments). Whereas *sterilization* is an absolute term and refers to a process that destroys *all* types of microorganisms including resistant bacterial endospores, *disinfection* is a relative term and is categorized into 1 of 3 different "levels," depending on biocidal effectiveness. The 3 levels of disinfection are defined in Table 2 and are referred to, in decreasing order of biocidal effectiveness, as *high-level disinfection*

Table 2. The definitions, characteristics, and relative effectiveness of sterilization and disinfection*

Sterilization	
•	Destroys all types of microorganisms, including bacterial endospores
•	Uses bacterial endospores as biologic indicators
•	Examples: pressurized steam, ethylene oxide gas, hydrogen peroxide plasma
•	Primarily used for <i>critical</i> instruments
High-level disinfection (HLD)	
•	Destroys mycobacteria, lipid or medium-sized viruses, nonlipid or small viruses, fungal spores, vegetative bacteria, and some, but not all, types of bacterial endospores during relatively short exposure times
•	Can be expected to destroy high numbers of bacterial endospores during long exposures times
•	Sporicidal (limited), tuberculocidal, virucidal, fungicidal and bactericidal
•	Uses mycobacteria as indicators of effectiveness
•	Examples: 2% glutaraldehyde, 7.5% hydrogen peroxide, 0.2% peracetic acid
•	Primarily used for <i>semicritical</i> instruments
Intermediate-level disinfection (ILD)	
•	Destroys mycobacteria, lipid or medium-sized viruses, most nonlipid or small viruses, fungal spores, and vegetative bacteria
•	Not sporicidal; tuberculocidal, virucidal, fungicidal and bactericidal
•	May use mycobacteria or viruses as indicators of effectiveness
•	Examples: 70% isopropyl alcohol, iodophor and phenolic compounds, concentrated quaternary ammonium compounds (eg, hospital cleaner/disinfectants with a tuberculocidal claim)
•	Primarily used for <i>noncritical</i> instruments and environmental surfaces when a tuberculocidal agent is necessary
•	May be used to preclean (but not terminally disinfect) <i>critical</i> and <i>semicritical</i> medical instruments prior to terminal HLD (or sterilization)
Low-level disinfection (LLD)	
•	Destroys lipid or medium-sized viruses, some fungal spores, vegetative bacteria
•	Neither sporicidal nor tuberculocidal; virucidal, fungicidal and bactericidal
•	May use the hepatitis B virus and HIV as indicators of effectiveness
•	Examples: diluted quaternary ammonium compounds (eg, hospital cleaner/disinfectants without a tuberculocidal claim)
•	Primarily used for <i>noncritical</i> instruments and environmental surfaces when a tuberculocidal agent is <i>not</i> necessary
•	May be used to preclean (but not terminally disinfect) <i>critical</i> and <i>semicritical</i> medical instruments prior to terminal HLD (or sterilization)

*Sterilization or the level of disinfection appropriate for critical, semicritical, and noncritical medical instruments is listed.

(HLD), *intermediate-level disinfection* (ILD), and *low-level disinfection* (LLD).¹⁶⁻¹⁹ Sterilization and each of these 3 levels of disinfection can be differentiated from one another on the basis of specific marker or indicator microorganisms that each can (and cannot) reliably destroy. As displayed in Table 2, HLD has limited sporicidal properties and destroys all types of pathogenic microorganisms encountered in the endoscopic setting, whether antibiotic-resistant or -susceptible, including, for example, atypical mycobacteria, tuberculocidal mycobacteria, and *Clostridium difficile*, a spore-forming bacillus. Almost all types of spore-forming bacteria are nonpathogenic, and those few that do produce disease either are destroyed by HLD (eg, *C difficile*) or have not been associated with disease transmission and nosocomial infection in the endoscopic setting (eg, *Bacillus anthracis*).¹⁹ HLD of virtually all types of flexible endoscopes is typically achieved by completely immersing the instrument in a liquid chemical sterilant/disinfectant (LCS) for a relatively short period of time (eg, 5-45 minutes).

Evaluation of the adequacy of a biocidal agent

An evaluation of the adequacy of a biocidal agent or decontamination process for reprocessing flexible

laryngoscopes and other types of reusable instruments can be simplified by dovetailing Table 1's 3-tiered classification scheme for medical instruments with Table 2's 4-tiered classification scheme for sterilization and disinfection. The result can be used to establish the minimum reprocessing requirement for virtually any type of reusable medical instrument, and it is routinely used in the development of infection control and instrument reprocessing guidelines. For example, sterilization of *critical* instruments, such as cardiac catheters, biopsy forceps, and implants, is recommended to prevent nosocomial infection (Tables 1 and 2).^{9,14,18,20-22} (Steam sterilization is ideal, although under some conditions low-temperature sterilization processes, such as those that use ethylene oxide gas, may be acceptable for *critical* instruments damaged by heat. If sterilization is not feasible, HLD of some types of *critical* instruments may be acceptable and recommended.^{14,18,20}) Similarly, HLD (or sterilization) of *semicritical* instruments, which include flexible laryngoscopes, is recommended to prevent nosocomial infection (Tables 1 and 2).^{14-18,20} LCSs labeled to achieve HLD include 2% glutaraldehyde, 7.5% hydrogen peroxide, and 0.2% peracetic acid. (A heat-based or low-temperature sterilization process may also be acceptable for *semicritical* instruments, depending on the sterilization process's label claims and

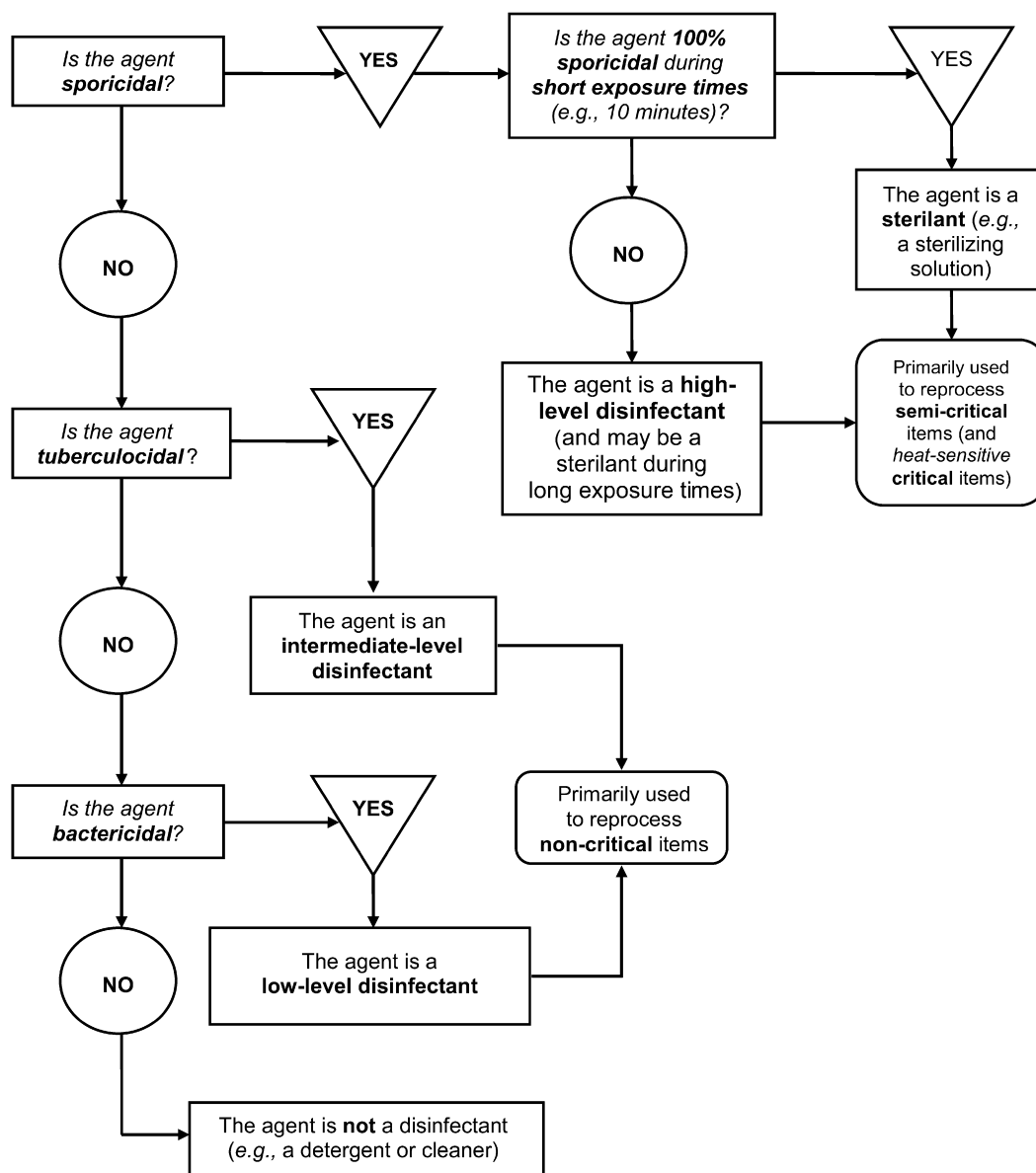


Fig 1. An algorithm that evaluates the adequacy of a biocidal agent (or decontamination process) for reprocessing reusable medical instruments including flexible laryngoscopes.

restrictions, as well as the instrument's physical design, construction and, manufacturers' instructions.¹⁸⁾ In addition, ILD or LLD is recommended for cleaning and disinfecting *noncritical* instruments and environmental surfaces (Tables 1 and 2). Examples of products that achieve ILD or LLD include 70% isopropyl alcohol and quaternary ammonium compounds.

Figure 1 displays the contents of Tables 1 and 2 reformatted and organized into a multistep logic, or algorithm, that can be used to evaluate the effectiveness and adequacy of any biocidal agent (or decontamination process), based on its label's claim, for reprocessing different types of medical instruments, whether classified

as *critical*, *semicritical*, or *noncritical*. Reports indicate that some health care facilities, apparently unaware that flexible laryngoscopes and other types of flexible endoscopes are *semicritical* instruments for which HLD (or sterilization) is necessary, reprocess these instruments using only soap and water or by simply wiping the exterior of their insertion tube using a gauze or sponge soaked in 70% isopropyl alcohol, a quaternary ammonium compound, or another general purpose cleaner/disinfectant, sometimes without having first cleaned the laryngoscope.^{3-6,13,18,23-26} The label claims of these products (and soap and water) indicate that none are sporicidal and that each is limited to ILD or

Table 3. Step-by-step guidelines for reprocessing flexible laryngoscopes**Step 1. Precleaning** (in the procedure room)

Purpose: To remove patient debris and prevent its drying and hardening on the laryngoscope after the procedure.

- 1.a. Immediately after removing the laryngoscope from the patient, with the laryngoscope still connected to the light source, wipe the insertion tube using a gauze pad or sponge soaked in a freshly prepared solution of detergent.
- 1.b. If the laryngoscope features a suction valve, place the distal end of the insertion tube into the detergent solution and, with the biopsy port inlet covered, suction detergent up through the instrument channel for several seconds. Alternate between suctioning detergent and air to create agitation and to enhance cleaning. Finish by suctioning the instrument channel with air.
- 1.c. Disconnect the laryngoscope from the light source (and suction source, if necessary). Transport the laryngoscope in an enclosed container to the reprocessing room.

Step 2. Leak testing (in the reprocessing room)

Purpose: To determine whether the watertight design of the laryngoscope is intact. Also, to determine whether the instrument channel is damaged and may be harboring pathogens that could be transmitted to the patient during the procedure.

2. Before cleaning the laryngoscope, perform both a dry and wet leak test using the proper equipment and techniques described in the laryngoscope's reprocessing instructions. If no leakage is detected, proceed with cleaning ("Step 3," below). If, however, leakage is detected, dry the laryngoscope, remove it from service, and contact its manufacturer for repair instructions.

Step 3. Cleaning

Purpose: To remove patient debris and reduce the number of microorganisms on the laryngoscope. Also, to ensure that the instrument channel is not occluded or impacted with debris.

- 3.a. Fill a sink or basin with fresh, clean potable water mixed with a low-sudings detergent (eg, an enzymatic detergent). Ensure the dilution and temperature of the detergent are in accordance with its labeling. Use a sink or basin whose size and diameter are sufficiently large to prevent undue stress to the laryngoscope. Use a fresh solution of detergent for each laryngoscope.

Note 1: Ensure all of the necessary personal protective equipment is available for staff during instrument reprocessing as required by standard precautions (eg, gloves, impervious gown).

Note 2: Refer to the labeling and reprocessing instructions of the laryngoscope for specific instructions and a list of recommended and compatible detergents.

- 3.b. Immerse the laryngoscope in the detergent solution. Use a soft brush and sponge or wipe to wash manually the exterior of the laryngoscope, including its body, insertion tube, and umbilical cable. Completely immerse the laryngoscope during the cleaning process.
- 3.c. If the laryngoscope features an instrument channel, detach the biopsy port cap (or seal) and brush and wash the channel by advancing a long, appropriately sized brush down through the channel via the biopsy port inlet. When it is seen exiting the laryngoscope's distal tip, rinse the brush to remove any visible debris. Retract the brush up through the channel, remove it, rinse it, and reinsert it. Repeat this step until there is no more visible debris on the brush. Also, brush and wash the biopsy port inlet and the biopsy port cap. (Discard the biopsy port cap if it is disposable.) A different and unique brush will likely be required for cleaning different sections and components of the laryngoscope.
- 3.d. If the laryngoscope features a suction valve, detach it and brush and wash it in the detergent solution using a small, soft brush. (Discard the suction valve if it is disposable.) Also, brush and wash the suction-valve housing (or cylinder) on the laryngoscope's control head, as well as the suction nipple and the sections of the laryngoscope between the suction nipple and the biopsy port inlet. Repeat this step several times.
- 3.e. In addition to brushing, wash the instrument channel (if featured) by flushing it with the detergent solution using a syringe (eg, a 20-cc syringe) that is connected to the end of the suction nipple (or biopsy port inlet if the laryngoscope does not feature a suction nipple). Repeat this step several times. When flushing this channel via the suction nipple, cover the biopsy port inlet with the biopsy port cap. Depending on the laryngoscope's manufacturer and model, it may be necessary during this step to use a cleaning/disinfecting adapter—for example, one that may attach to the suction-valve housing. Once this step is completed, detach the syringe (and the biopsy port cap).

Note 1: Apply to sections 3.g, 3.h, 3.i, 4.c, 4.e, 4.f, 4.g, 5.a, and 5.b, below, the technique described in this section (3.e) for flushing/purging the instrument channel, using a cleaning/disinfecting adapter and covering the biopsy port inlet with the biopsy port cap, such as for Pentax flexible laryngoscopes (Pentax Medical Company, Montvale, NJ). Other manufacturers of laryngoscopes may provide different types of cleaning/disinfecting adapters. Refer to the reprocessing instructions of each laryngoscope model for specific details.

Note 2: Confirm fluid flow through the laryngoscope's instrument channel (if featured) during reprocessing.

- 3.f. Soak the laryngoscope, including (if featured) the instrument channel and detached components (eg, suction valve and biopsy port cap), in the detergent solution for the time indicated on the detergent's label.
- 3.g. Purge the instrument channel (if featured) with forced air (eg, using an empty syringe or compressed air) to remove the detergent. Refer to section 3.e. Remove the laryngoscope from the detergent solution. Discard the detergent solution and all disposable cleaning brushes. Clean and high-level disinfect (or sterilize) reusable cleaning brushes between cases. Do not use worn, bent, or damaged brushes.

Table 3. Continued

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- 3.h. Immerse the laryngoscope and detached components in a large volume of fresh, clean potable rinse water. Also, rinse the instrument channel (if featured) by flushing it with a large volume (eg, 200 mL) of fresh, clean potable water to remove detergent. Refer to section 3.e.
 - 3.i. Purge the instrument channel (if featured) with forced air to remove the rinse water. Refer to section 3.e. Dry the laryngoscope's exterior and detached components using a clean, dry, soft, lint-free cloth. Drying is important to prevent the rinse water from diluting the disinfectant (next step).

Step 4. High-level disinfection

Purpose: To destroy microorganisms remaining on the laryngoscope after cleaning. Cleaning and high-level disinfection are both necessary to prevent disease transmission.

- 4.a. Fill a basin with a FDA-cleared, recommended high-level disinfectant/sterilant ("germicide") listed as a compatible agent in the laryngoscope's reprocessing instructions (eg, 2% glutaraldehyde). If reusable, check the date when the germicide was first used to confirm that its reuse life has not yet expired. Some germicides may require preparation in accordance with their labeling prior to use (eg, an elevation in temperature or "activation"). Refer to the labeling of the germicide for specific instructions.
- 4.b. Use a chemical test strip or indicator per its instructions to monitor the concentration of the germicide to ensure it is equal to or above the germicide's *minimum effective concentration* ("MEC"). Document the results. Discard the germicide whenever its concentration is below its MEC because high-level disinfection cannot be assured. Depending on several factors, including inadvertent dilution with rinse water, the concentration of a reusable germicide may drop below its MEC and require that the germicide be discarded in fewer days than the maximum number of reuse days indicated on its labeling (eg, 14 days). Per its instructions, the germicide may require monitoring before each use.
- 4.c. Immerse the laryngoscope in the germicide and flush the instrument channel (if featured) with the germicide. Refer to section 3.e. Continue flushing until the germicide can be seen flowing out of the laryngoscope's distal tip. Once this step is completed, detach the syringe (and the biopsy port cap). Completely immerse the laryngoscope during this step.
- 4.d. Soak the laryngoscope, including (if featured) the instrument channel and detached components, in the germicide (monitored to ensure it is above its MEC; see above) for the required time and at the required temperature to achieve high-level disinfection. It may be necessary to use a timer and thermometer. Cover the basin with a securely fitting lid to minimize exposure of the environment to the germicide and its vapor during soaking.
- 4.e. Purge the instrument channel (if featured) with forced air to remove the germicide. Refer to section 3.e. Remove the laryngoscope from the germicide.
- 4.f. Immerse the laryngoscope and detached components in a large volume of fresh, clean potable rinse water. Also, rinse the instrument channel by flushing it with a large volume (eg, 200 mL) of fresh, clean potable water to remove the germicide. Refer to section 3.e. Review the germicide's water-rinsing instructions to confirm the number of required water rinses (eg, 3 rinses) and the volume and duration of each rinse. Do not reuse the rinse water.
- 4.g. Purge the instrument channel (if featured) with forced air to remove the rinse water. Refer to section 3.e.

Note 1: Refer to the labeling and reprocessing instructions of the laryngoscope for specific instructions and a list of recommended and compatible biocidal agents.

Note 2: Although fresh, clean potable water may be acceptable, sterile or bacteria-free water is recommended for rinsing. (Irrespective of the rinse water's microbiological quality, always dry the laryngoscope after reprocessing; see below.)

Step 5. Drying using 70% alcohol, forced air

Purpose: To prevent the colonization and transmission of waterborne bacteria during flexible laryngoscopy.

- 5.a. Flush the instrument channel (if featured) with 70% alcohol to facilitate drying. Refer to section 3.e. Continue flushing until alcohol can be seen flowing out of the laryngoscope's distal tip.
- 5.b. Purge the instrument channel (if featured) with forced air to remove the alcohol and rinse water. Refer to section 3.e. Continue this step until the channel is dry.
- 5.c. Dry the laryngoscope's exterior and detached components, first with soft gauze moistened with 70% alcohol, and then with a clean, dry, soft, lint-free cloth. Remove any attached cleaning/disinfecting adapter(s).
- 5.d. If the laryngoscope is to be stored, proceed to "Step 6" below. Otherwise, reattach the suction valve and the biopsy port cap (if either is featured). The laryngoscope is now ready for reuse.

Note 1: Drying the laryngoscope using 70% alcohol and forced air is recommended immediately after reprocessing both between patient procedures and before storage. Refer to The Society of Gastroenterology Nurses and Associates' (SGNA) guidelines for more details.^{9-11,30}

Step 6. Storage and handling

Purpose: To prevent bacterial colonization and damage to the laryngoscope during storage.

Table 3. Continued

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| 6.a. | Store the laryngoscope by hanging it vertically in a clean, dry, well-ventilated, dust-free area or storage cabinet. Do not reattach the suction valve and the biopsy port cap (if either is featured) during storage. Do not coil the laryngoscope horizontally during storage or store the laryngoscope in a carrying case or a closed container. |
| 6.b. | When needed for a procedure, carefully remove the laryngoscope from storage. Examine the laryngoscope and confirm it is dry and has not been damaged. Reattach the suction valve and the biopsy port cap (if either is featured). Handle the laryngoscope with care during its transportation to the procedure room to prevent damage and recontamination. Breaches in proper storage and handling of the laryngoscope can result in nosocomial infection and/or instrument damage. |
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This review found that, in general, a formal set of published guidelines for reprocessing flexible laryngoscopes is lacking. The above step-by-step set of instructions is provided to assist in the development of minimum standards for the adequate reprocessing of flexible laryngoscopes, to standardize patient care by minimizing variations in the reprocessing practices of flexible laryngoscopes, and to minimize the risk of nosocomial infection. Some of these instructions, which are based in part on published guidelines for reprocessing flexible GI endoscopes,⁷⁻¹⁰ may also be applicable to other types of flexible endoscopes, such as bronchoscopes, hysteroscopes, and cystoscopes. These instructions may lack some details and are to be used in conjunction with, not as a replacement for, the reprocessing instructions provided by the laryngoscope's manufacturer. Because flexible laryngoscopes are *semicritical* instruments, cleaning followed by high-level disinfection is recommended.

LLD. The integration of the label claims of these products into Fig 1 demonstrates that each product is indicated for and limited to reprocessing *noncritical* instruments. The use of a product that is limited to ILD or LLD to disinfect terminally a flexible laryngoscope or another *semicritical* instrument is contraindicated and may result in nosocomial infection. In contrast, 2% glutaraldehyde is tuberculocidal and sporicidal, albeit during a relatively long exposure time, and can be used to achieve either HLD or "sterilization,"¹⁹ depending on the exposure time and immersion temperature. According to Fig 1, 2% glutaraldehyde is indicated for reprocessing flexible laryngoscopes, other types of *semicritical* instruments, and, under some circumstances, heat-sensitive *critical* instruments.²⁶

Step-by-step guidelines for reprocessing flexible laryngoscopes

Surveys and reports indicate that reprocessing practices for flexible laryngoscopes may be inadequate and vary from one health care facility to another (as well as within the same facility).^{3,5,6,12,13,26} Several factors may be responsible for these reported inadequacies and inconsistencies in current practices for reprocessing flexible laryngoscopes. For instance, based on the paucity of published reports documenting patient-to-patient transmission of disease during flexible laryngoscopy, health care professionals may (erroneously) conclude that the risk of nosocomial infection associated with contaminated flexible laryngoscopes is sufficiently low to permit complacency and limited, if any, knowledge of minimum reprocessing standards. Adding to the confusion about reprocessing flexible laryngoscopes, some of the reprocessing instructions provided by manufacturers of these instruments are incomplete and inadequate and vary from one manufacturer to another.^{18,27-29} Arguably the most significant factor responsible for these reported reprocessing shortcomings is the lack of a comprehensive set of published

and endorsed step-by-step guidelines for reprocessing flexible laryngoscopes.

Unlike flexible laryngoscopes, several formal sets of detailed step-by-step guidelines for reprocessing GI endoscopes have been published.⁷⁻⁹ For the most part, these guidelines provide consistent recommendations (except with regard to the importance of endoscope drying³⁰), and their contribution to the prevention of disease transmission during GI endoscopy is indisputable. Although some reports and surveys discuss the importance of reprocessing flexible laryngoscopes,^{1-6,14-16,18} none provides a specific set of comprehensive step-by-step instructions similar to those for reprocessing GI endoscopes. Publication of a detailed and formal set of reprocessing guidelines for flexible laryngoscopes, however, is crucial to prevent disease transmission and nosocomial infection, as well as to promote compliance and standardize patient care.^{4,5,14} A formal and thorough set of step-by-step guidelines for reprocessing flexible laryngoscopes was, therefore, developed and is provided in Table 3. (This Table appears to be the first published set of step-by-step guidelines for flexible laryngoscopes.) Strict adherence to these instructions (or another comparable set of guidelines) and their inclusion in the medical facility's policies and procedures are recommended to prevent disease transmission and to standardize and improve the reprocessing practices for flexible laryngoscopes.^{4,5,31} These guidelines may also be used and adopted by manufacturers of flexible laryngoscopes (and other similar types of flexible endoscopes, such as cystoscopes) to provide consistent reprocessing instructions and recommendations.

Disposable sheaths

Offering some of the same potential advantages as disposable instruments, single-use (disposable) sheaths designed to cover and prevent the contamination of, and patient contact with, flexible laryngoscopes and

other types of endoscopes and *semicritical* instruments may be used in clinical practice.^{5,12,18,32,33} In addition to increasing patient throughput and potentially reducing the importance of, dependence on, and downtime associated with reprocessing and its associated chemicals, these protective barriers might further reduce the reported low risk of patient-to-patient disease transmission associated with reprocessed reusable laryngoscopes used without a sheath. Despite the potential benefits of using a disposable sheath to cover a flexible (and rigid) laryngoscope, the margin of safety provided by this technology is controversial. Concerns that disposable sheaths may provide a false level of assurance, protection, and patient safety have been expressed.^{4,18,34,35} Not only might the sheath (unknowingly) become breached or break or tear during use resulting in contamination of the “protected” laryngoscope, but assurances or guarantees that the laryngoscope was not contaminated by soiled hands or gloves during either improper application of the sheath onto the laryngoscope prior to laryngoscopy or removal of the sheath and mishandling of the laryngoscope following laryngoscopy cannot be made. As guidelines published by the Food and Drug Administration (FDA) and others acknowledge, sheaths reduce, but do not eliminate, the risk of instrument contamination.^{4,18,34,35} Nor do sheaths eliminate instrument reprocessing after each use.³⁴

Specifically, the FDA recommends that the flexible laryngoscope be cleaned, followed by “intermediate-level disinfection” after removal of the potentially contaminated sheath and before application of a new sheath, provided the manufacturer has shown that the sheath provides a barrier sufficiently “protective” to prevent contamination of the laryngoscope under worst-case conditions; otherwise, HLD or sterilization would be required.¹⁸ Although consistent with guidelines published by the Centers for Disease Control and Prevention for reprocessing specific types of barrier-protected *semicritical* devices used in dentistry, this recommendation by the FDA may be inadequate and pose an infection risk. Indeed, ILD is not sufficiently effective to prevent patient-to-patient transmission of all types of pathogenic microorganisms, including *C difficile*, a spore-forming bacillus that has been identified in the endoscopic setting and that could contaminate the laryngoscope during, for example, removal of the sheath. Although it is tuberculocidal (Table 2), ILD is not sporicidal and, therefore, as displayed in Fig 1, it is contraindicated for reprocessing (unsheathed) flexible laryngoscopes and other types of *semicritical* instruments. After removal of the sheath, ILD arguably would only be indicated if the *semicritical* instrument, because of, for example, its design or construction, could not “tolerate”²² either high-level disinfection

or sterilization. In lieu of adoption of the recommendation to intermediate-level disinfect a flexible endoscope after removal of the sheath, it is recommended that the instrument be cleaned after removal of the sheath, followed instead by HLD. This alternative recommendation is based on the Spaulding classification scheme (Tables 1 and 2) and provides an arguably more appropriate and safe standard of care.

CONCLUSION

This review of the medical literature found that current reprocessing practices for flexible laryngoscopes are at a times inadequate and inconsistent.^{3,5,6,12,13} Although few published reports document disease transmission associated with flexible laryngoscopes, failure to reprocess properly these instruments violates the standard of care established for other types of flexible endoscopes and *semicritical* instruments, posing an increased risk of disease transmission and nosocomial infection. Like other types of *semicritical* instruments, flexible laryngoscopes require HLD to prevent disease transmission. As displayed in Fig 1 and Tables 1 and 2, reprocessing flexible laryngoscopes (or another *semicritical* instrument) using 70% isopropyl alcohol, quaternary ammonium compounds, or another biocidal agent that is not sporicidal and is limited to ILD or LLD is contraindicated. Adoption and implementation of the formal and detailed set of step-by-step guidelines provided in Table 3 (or a comparable set of guidelines) are recommended to promote compliance, standardize patient care, improve reprocessing practices, and prevent nosocomial infection during flexible laryngoscopy.^{5,6,31} Proper care, handling, and maintenance of the laryngoscope are also important to prevent nosocomial infection and instrument damage. The use of disposable sheaths to cover, and prevent the contamination of, flexible laryngoscopes during patient contact may further reduce the risk of disease transmission, but it does not eliminate reprocessing. It is recommended that guidelines be revised and clarified to recommend HLD (at a minimum) of flexible laryngoscopes (and other types of *semicritical* devices), whether or not a sheath is used during flexible laryngoscopy.

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