

The Q-Net™ Monthly

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What's News

An article entitled "Infection control and its application to the administration of intravenous medications during gastrointestinal endoscopy" appears in the August (2004) issue of *The American Journal of Infection Control*.

A second article entitled "The importance of bronchoscope reprocessing guidelines: raising the standard of care" appears in the September (2004) issue of *Chest*. Both articles were written by this newsletter's editor (LFM).

Editor-in-Chief

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What is 'Q-Net'?

Q-Net is a technology-assessment network of questions and answers. Its newsletter is *The Q-Net™ Monthly*.

The mail goal of **Q-Net** is to encourage the infection control and endoscopy communities to not only ask good questions but to also demand well referenced responses.

Q-Net addresses the needs of both the health care provider whose goal is to provide the best care possible, and the patient who deserves affordable quality health care.

Rigid Laryngoscope Reprocessing

QUESTION: "Are the **blades and handles** of rigid laryngoscopes classified as 'semicritical' items that require cleaning and high level disinfection (or sterilization)?"

~ **Third in a series of articles** ~

Recommended is a change to the common practice of merely wiping down the laryngoscope handle between uses with 70% alcohol or a surface disinfectant. Cleaning and high-level disinfection (or sterilization) of the rigid laryngoscope's blade and handle are recommended.

Background and answer: Published in the *March-April 2004* issue of this newsletter (Vol. 10, No. 3, 4), the first article in this series responded to a question about whether it is a safe and acceptable practice to use quaternary ammonium products to clean and disinfect flexible and rigid laryngoscopes. Laryngoscopes, which along with several other types of rigid and flexible endoscopes are sometimes referred to as ENT (or "ear-nose-throat") endoscopes, require proper reprocessing, care, and handling, to prevent cross-infection and instrument damage.

Background information that included the following topics was discussed in this previously published newsletter: (1) the three categories into which medical devices are classified, based on the risk of infection associated with their use—*critical*, *semicritical*, and *noncritical*; (2) the definitions, characteristics,

and relative effectiveness of *sterilization* and the three "levels" of disinfection—*high-level disinfection*, *intermediate-level disinfection*, *low-level disinfection*; (3) the relative resistance of different types of microorganisms to sterilization and to each of the three levels of disinfection; and (4) the claims and effectiveness of quaternary ammonium products labeled for cleaning and disinfecting certain types of instruments and surfaces.

Flexible and rigid laryngoscopes, as well as other types of ENT endoscopes and anesthesia equipment, are classified as *semicritical* devices that require *high-level disinfection* (or *sterilization*).¹⁻⁶ High-level disinfection is a rigorous process that, in addition to destroying mycobacteria, viruses, fungal spores, and vegetative bacteria, is sporicidal (during long exposure times).

Depending on their concentrations, however, quaternary ammonium products are generally classified and labeled as *intermediate-level* or *low-level disinfection*.

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tants, both of which are less effective than high-level disinfection and neither of which is sporicidal (*refer to the March-April 2004 issue of this newsletter*). In accordance with published guidelines, the first article in this series concluded, therefore, that the use of quaternary ammonium products to reprocess flexible and rigid laryngoscopes (and other semicritical devices) is contraindicated, potentially unsafe, and violates the standard of care.

Nevertheless, although not labeled to achieve high-level disinfection (or sterilization), quaternary ammonium products may instead be used to clean, deodorize, and low-level disinfect noncritical items, such as blood pressure cuffs, and hard, non-porous environmental surfaces, such as sink tops. Depending on their instructions and whether their labeling includes a tuberculocidal claim, some quaternary ammonium products may also be used to achieve intermediate-level disinfection of these noncritical items and environmental surfaces.

Flexible laryngoscopes: Despite their importance to the prevention of disease transmission during laryngoscopy and to the standardization of patient care, published guidelines for reprocessing flexible laryngoscopes (as well as rigid laryngoscopes, bronchoscopes, and cystoscopes) are lacking.⁷ A step-by-step set of guidelines for reprocessing flexible laryngoscopes, therefore, was provided in the second article in this series (*refer to the May-June 2004 issue of this newsletter*).

Rigid laryngoscopes—the blade and handle: This current article is the third in this series and addresses in more detail the reprocessing of rigid laryngoscopes—both their blades and handles. Similar to a flashlight, rigid laryngoscopes provide the requisite light for examination and diagnosis of the physiological and pathological states of the larynx, vocal cords, and other laryngeal structures. These portable instruments, which are routinely used in anesthesia and resuscitation to facilitate endotracheal intubation, feature a detachable, folding blade that connects to a handle. The blade is placed into the patient's mouth and passed down into the throat during rigid laryngoscopy. The handle, which does not ordinarily enter the patient's mouth, holds small disposable or rechargeable batteries that power the light source. Both conventional and fiber optic rigid laryngoscopes are available. The former use for illumination a conventional bulb contained in the blade, whereas the latter use fiber optic technology to transmit light to the blade from a bulb (or lamp) that is contained in the handle (along with the batteries).

Laryngoscope blades are available in several different sizes (eg, infant, child, adult) and styles (eg, straight, curved). Both reusable and single-use, disposable (non-sterile) blades are also available. These blades may be sold individually or in a carrying case as part of a kit, which may include several different sizes and styles of blades, with or without one or more standard reusable handles. In general, most laryngoscope handles, which also are available in different sizes, are designed to attach to and be compatible with several different sizes and styles of blades, both reusable and disposable. Due primarily

to convenience, confusion regarding the reprocessing of handles (*see below*), the relatively low cost of blades, and the purchase of blades as part of a kit, several laryngoscope blades are often stocked for immediate clinical use, whereas only a few laryngoscope handles may be available. It is important to have available a sufficient number of reprocessed and ready-for-use blades and handles to meet patient demand, compensate for instrument downtime during reprocessing, and provide the same high standard of care for each patient.

Contamination, infections linked to rigid laryngoscopes: Improperly reprocessed rigid laryngoscopes have been associated with nosocomial infection and identified as potential vectors for transmission of methicillin-resistant *Staphylococcus aureus* (MRSA) and other virulent microorganisms.^{3,5,8-12} One report identified inadequate cleaning of the blades as the cause of an outbreak of *Pseudomonas aeruginosa* in a pediatric intensive care unit.⁸ A similar report isolated an outbreak strain of *Serratia marcescens* from the surface of a blade in a neonatal intensive care unit.¹⁰ Although the handle is not ordinarily inserted into the patient's mouth, another report microbiologically sampled 20 handles after clinical use (i.e., before reprocessing) and found all 20 to be contaminated with *Staphylococcus epidermidis* and other types of bacteria, some strains of which were resistant to antibiotics.⁹

Calling into question the reliability of visual determinations of "cleanliness," a study reported that, although none of 65 laryngoscopes appeared under visual examination to be soiled with blood, a significant number of reprocessed and ready-for-use blades (20%) and handles (40%) were, in fact, contaminated with blood as determined using a sensitive blood indicator assay technique.⁵ The presence of blood on any medical instrument poses an infection risk.^{5,9} These reports underscore the importance of proper reprocessing of both the rigid laryngoscope's blade and handle between uses, to prevent cross-infection. Proper care, handling, and maintenance of the blade and handle are also important to prevent nosocomial infection as well as instrument damage.

Disposable blades, sheaths: Disposable, single-use (non-sterile) blades may be used during rigid laryngoscopy.¹³ In addition to reducing the emphasis on reprocessing, disposable blades may reduce the risk of disease transmission compared to reusable blades, especially when the risk of contamination of the blade with prions is of concern. Prions are thought to be infectious proteins responsible for CJD, or Creutzfeldt-Jakob disease (*refer to the October 2000 issue of this newsletter*), and other human transmissible spongiform encephalopathies.^{14,15} Whether prions can reside in tonsillar and other lymphoid tissues of the head, throat, and neck of infected patients and be transmitted to other patients via a contaminated laryngoscope is unclear.^{11,16} Also unclear is whether the use of single-use, disposable blades compared to properly reprocessed reusable blades reduces the risk of transmission of prions and other infectious agents. Although some reports encourage the use of disposable blades,^{3,17} others suggest that

their performance may be inferior to reusable blades, especially during difficult intubations.^{16,18}

Disposable, single-use (sterile) sheaths designed to cover the laryngoscope's reusable blade (and handle) are also available.³ Offering some of the same potential advantages as disposable laryngoscope blades and other disposable instruments, some reports encourage the use of these disposable sheaths during laryngoscopy,^{7,9,19} to reduce the downtime associated with instrument reprocessing and potentially to reduce the risk of instrument contamination and cross-infection. Concerns that these disposable sheaths may provide a false level of safety, however, have been expressed.^{4,20,21}

Although these sheaths may reduce the risk of instrument contamination, this risk is not eliminated.^{4,20} Not only might they tear during clinical use resulting in contamination of the laryngoscope, but these sheaths also cannot prevent contamination of the laryngoscope by soiled hands or gloves during handling of the unprotected laryngoscope after removal of the sheath. Some published guidelines therefore recommend reprocessing the laryngoscope's blade (and handle) after removal of the sheath,²¹ the potential reduction in the risk of cross-infection achieved using the sheath notwithstanding. According to the US Food and Drug Administration (FDA), reprocessing of the laryngoscope is necessary after removal of the used sheath.⁴

Current reprocessing practices: Several surveys have been conducted to determine and evaluate current practices for reprocessing rigid laryngoscopes. Some of these surveys have reported that the majority of responding health care facilities do not have on file a written policy or procedure for reprocessing either the laryngoscope's blade or handle.^{12,20} Moreover, surveys have revealed that reprocessing practices for the blade and handle are often inadequate and vary significantly from one health care facility to another (as well as within the same facility).^{7,13,20,22}

For example, whereas some healthcare facilities steam sterilize or high-level disinfect the laryngoscope's blade between uses, others only clean the blade using a detergent, or wipe the blade using an intermediate-level disinfectant, such as 70% alcohol or a quaternary ammonium product (refer to March-April 2004 issue of this newsletter).^{13,17,20} One survey reported that only 5% of 239 responding health care facilities routinely steam sterilized the handle between uses, while one third failed to even wash the handle using a detergent.²⁰ This survey also reported that some responding health care facilities reprocessed and reused single-use, disposable laryngoscope blades,²⁰ despite this practice being contraindicated by published guidelines.²

Discussion and conclusion: Several surveys report that current practices for reprocessing the laryngoscope's blade and handle vary significantly from one healthcare facility to another.^{7,13,20} These results raise concern because variations in, and unfamiliarity with, reprocessing requirements for

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"For the Record"

A bacterial outbreak at a New York hospital that was caused by imipenem-resistant *Pseudomonas aeruginosa* (IRPA) was discussed in an article published in the July 2002 issue of *Infection Control and Hospital Epidemiology* (Muscarella LF. 23[7]:358-60). Expressing concern that there were insufficient data to conclude the outbreak's mode of transmission was *patient-to-patient*, this article raised the possibility that the source of this outbreak's IRPA could have been the environment—a scenario not considered by this outbreak's investigators, which included the FDA.

This article noted that during this (or any) outbreak investigation, it was essential to have microbiologically sampled all relevant environmental surfaces—including sinks, wash basins, and tap water—to evaluate the potential role of each in the transmission of the IRPA. Failure to have considered the environment as a potential source of the IRPA could have resulted in misleading conclusions about the true source and cause of this outbreak.

Also, this article recommended that the FDA consider requiring the labeling of flexible endoscopes and automated endoscope reprocessors (AERs) to instruct users to dry the endoscope after terminal water rinsing (ie, water rinsing that follows chemical immersion), to prevent bacterial transmission (refer to the January-February 2004 issue of this newsletter). Several reports document wet or inadequately dried flexible GI endoscopes and bronchoscopes as sources of nosocomial infections, pseudo-infections, and patient deaths.

A reply to this article was published in the same issue of *Infection Control and Hospital Epidemiology* (p. 360). Refuting this article's conclusions, the author of this reply retorts: "Dr. Muscarella fails to recognize an important infection control principle regarding antibiotic-resistant *P. aeruginosa* (IRPA). It is widely recognized that such antibiotic-resistant organisms are not found in the general water supply... IRPA is an organism exclusively associated with the presence of nosocomial infection or colonization... (Muscarella) needs to substantiate scientifically his implication that IRPA may be found in the general water supply."

To substantiate scientifically his conclusions and respond to this reply's instruction, Muscarella wrote another article entitled "Contribution of tap water and environmental surfaces to nosocomial transmission of antibiotic-resistant *P aeruginosa*" (Muscarella LF. *Infect Control Hosp Epidemiol* 2004 Apr;25[4]:342-5). This article discussed several peer-reviewed published studies that identified tap water and rinse water, as well as AERs, endoscopes, sinks, and other environmental surfaces, as sources of IRPA and other strains of antibiotic-resistant *P aeruginosa*. ■

laryngoscopes can result in inconsistencies in the standard of care, ineffective reprocessing, and an increase in the risk of cross-infection.^{5,11,13,23,24}

Several factors may be responsible for these reported significant variations in reprocessing practices for laryngoscopes. First, although the reprocessing of the blade of the laryngoscope is commonly practiced to prevent patient-to-patient disease transmission, surveys and reports indicate that the risk of cross-infection via a contaminated handle is not as well recognized and, therefore, its reprocessing may at times be overlooked.^{9,13,20,23} One plausible explanation for a health care facility to fail to reprocess the laryngoscope's handle may be its misperception that the handle is classified as a non-critical device that poses a low risk of contamination and cross-infection, because the handle does not ordinarily come into direct contact with the patient's mucous membranes during laryngoscopy. This misperception would explain why the handle at some health care facilities receive little more than cleaning between uses.²⁰

To be clear, however, the handle, like the blade, is classified by several organizations as a semicritical—not a noncritical—device.^{2,3,25} According to the Centers for Disease Control and Prevention (CDC), devices that directly or indirectly contact mucous membranes, like the laryngoscope's handle, are classified as semicritical.¹ Although it is not ordinarily inserted into the patient's mouth during laryngoscopy, the handle, like the blade, can become contaminated and transmit disease from one patient to another.^{2,3,5,8-12,20,23} Contamination of the handle with patient secretions and microorganisms can occur through direct contact with the patient during laryngoscopy, or when a used blade is folded onto the handle after intubation.^{9,20,23} The handle can also become contaminated through indirect contact with the patient's mucous membranes or the used blade via the physician's or anesthetist's soiled hands or gloves during or after laryngoscopy.²³

According to the *American Association of Nurse Anesthetists (AANA)* and other organizations, the rigid laryngoscope is a semicritical device.^{2,3,6,25} Both its blade and handle, therefore, require cleaning and high-level disinfection (or sterilization) between uses.^{2,3,9}

Second, although the published guidelines of AANA and some other organizations recommend reprocessing the laryngoscope's blade *as well as* its handle to prevent nosocomial infection,^{2,3} other published guidelines, while also recommending reprocessing of the blade, do not recommend or make any reference to reprocessing the handle.^{1,9,21,23,26} Failure of a guideline to recommend reprocessing the handle can be confusing, result in significant variations in reprocessing practices,⁹ and leave the misconception for some health care facilities that only the blade—and not the handle—requires reprocessing between uses, to prevent patient-to-patient disease transmission via a contaminated laryngoscope.

The third and possibly most important factor responsible for significant variations in the reprocessing practices of rigid

laryngoscopes is the lack of a published and universally-accepted set of step-by-step guidelines for reprocessing these instruments (and other types of ENT endoscopes). No doubt, failure of a health care facility to have access to detailed instructions for reprocessing the rigid laryngoscope's blade and handle can result in ineffective reprocessing and an increase in the risk of cross-infection. Although some published guidelines recommend that laryngoscopes, like all semicritical instruments, be cleaned and high-level disinfected (or sterilized),^{2,3,25} virtually none provides any specific step-by-step instructions for reprocessing the blade and handle.

Furthermore, some of the reprocessing instructions provided by manufacturers of rigid laryngoscopes not only are incomplete and do not include all of the required steps for reprocessing the handle and the blade, but they also often vary from one manufacturer to another. In contrast, several step-by-step guidelines for reprocessing gastrointestinal (GI) endoscopes have been published.²⁷ For the most part, these guidelines are consistent (except with regard to endoscope drying; refer to the *January-February 2004 issue of this newsletter*), and their contribution to the prevention of disease transmission during GI endoscopy has been clearly established. The importance of the development and publication of detailed guidelines for reprocessing both the laryngoscope's handle and blade is recommended. Establishment of a quality assurance program that trains, certifies, supervises, and monitors reprocessing personnel to ensure their practices are in strict compliance with these guidelines is also recommended. ○

To be continued next month ...

Next month: A detailed set of step-by-step guidelines for reprocessing the blades and handles of rigid laryngoscopes. Also, the references for this current article are provided in next month's newsletter.

Thank you for your interest in this newsletter. *I have addressed each issue to the best of my ability. Respectfully, the Publisher: Lawrence F. Muscarella, Ph.D.* Please direct all correspondence to:

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