Reprocessing Standards for Medical Devices and Equipment in Otolaryngology

Safe Practices for Scopes, Speculums, and Single-Use Devices

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KEYWORDS

• Sterilization • Disinfection • Patient safety • Reprocessing • Quality improvement • Endoscope • Speculum • Medical devices

KEY POINTS

- Reprocessing standards for devices are primarily driven by assessed risk level to the patient: high-risk devices require sterilization, semicritical devices require high-level disinfection, and noncritical devices require intermediate to low-level disinfection.
- Flexible endoscopes used in otolaryngology are semicritical devices. Disinfection procedures depend on scope type and technique, with implications for adequacy, efficiency, and cost.
- Improperly disinfected or contaminated endoscopes can lead to disease transmission or even disease outbreaks. Individual packaging of speculums and related devices remains debated.
- Reprocessing of single-use devices is a highly regulated process requiring approval by the Food and Drug Administration.
- A nuanced understanding of disinfection/sterilization requirements and rationale ensure delivery of safe, ethical, and quality patient care.

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INTRODUCTION

In the wake of high-profile incidents of patient harm from inadequate disinfection or contamination of medical instruments, reprocessing procedures have come under increasing public scrutiny, with a rapid increase in regulatory oversight. It has, therefore, never been more important for otolaryngologists to be knowledgeable and proactive regarding how medical devices and equipment are prepared for use in clinical practice. A variety of sterilization or disinfection methods are available, with the appropriate selection of procedure relating to type of device and its potential risk for infection to the patient. Adhering to approved and effective methods for reprocessing can ensure efficiency and mitigate liability risk associated with reprocessing. The delivery of safe, ethical, and high-quality patient care is predicated on a detailed understanding of medical device and equipment reprocessing procedures and their rationale.

GUIDANCE ON DISINFECTION AND STERILIZATION

Modern standards for disinfection and sterilization have largely evolved from the classification scheme introduced by Earle Spaulding in 1957.[1] Spaulding proposed the minimum levels of disinfection required of a device based on infection risk to the patient. Risk levels include critical (highest risk), semicritical (intermediate risk), and noncritical (lowest risk). Each risk level requires a different stringency of antimicrobial security—from simple disinfection to sterilization—that should be considered in when reprocessing such devices (**Table 1**).[2,3]

Critical devices, such as surgical instruments and implants, enter or encounter normally sterile regions of the body and are sterilized before use. The preferred sterilization processes include high-pressure steam for optimal inactivation of bacteria (including endospores), viruses, and fungi. For heat-sensitive devices, alternative methods include treatment with ethylene oxide gas and hydrogen peroxide-based gas methods. Liquid chemicals are a less attractive alternative, because chemically sterilized devices need to be rinsed and packaged in a manner not synchronous with actual sterilization, because the liquid sterilant must absent from packaging.

Semicritical devices contact mucous membranes or nonintact (broken) skin. Many rigid and flexible endoscopes used in outpatient otolaryngology clinics are semicritical items and thus candidates for high-level disinfection. Chemicals approved by the US Food and Drug Administration (FDA) for this purpose include glutaraldehyde, hydrogen peroxide, ortho-phthalaldehyde, peracetic acid with hydrogen peroxide, and chlorine (via electrochemical activation).[4] Rapid chemical reprocessing is practical for expensive, regularly used devices such as flexible endoscopes and inactivates most pathogenic microorganisms (viruses, bacteria, mycobacteria, and fungi); however, some bacterial spores may not be destroyed without longer exposure times.

Noncritical devices present the lowest risk to patients, because they only contact intact skin. Examples include blood pressure cuffs, patient seating and furniture, stethoscopes, and ear speculums. Intermediate-level disinfection is tuberculocidal, virucidal, fungicidal, and bactericidal but not sporicidal. Low-level disinfection is virucidal, fungicidal, and bactericidal, but neither tuberculocidal nor sporicidal. Intermediate-level disinfectants also provide efficacy against a broader group of viruses (enveloped and nonenveloped) and some mycobacteria. Examples include 70% isopropyl alcohol, iodophor and phenolic compounds, and quaternary ammonium compounds and are regulated by the Environmental Protection Agency.[5]

Table 1
Classification scheme for medical instruments

Spaulding Scheme	Otolaryngic Examples	Reprocessing Requirement	Bacteria			Fungi	Viruses	
			Sporicidal	Tuberculocidal	Bactericidal		Enveloped	Nonenveloped
Critical instruments Penetrate sterile tissue, enter the vasculature, or contact bone or blood	Surgical instruments, implants	Sterilization Steam Ethylene oxide gas Hydrogen peroxide gases	✓	✓	✓	✓	✓	✓
Semicritical instruments Contact mucous membranes or nonintact skin	Diagnostic flexible endoscopes, rigid scopes	High-level disinfection Glutaraldehyde Peracetic acid	Limited	✓	✓	✓	✓	✓
Noncritical instruments Do not directly contact the patient or only contact intact skin	Stethoscopes, patient furniture	Intermediate-level disinfection 70% isopropyl alcohol Iodophor and phenolic compounds Concentrated quaternary ammonium compounds		✓	✓	✓	✓	✓
	Floors	Low-level disinfection Diluted quaternary ammonium compounds			✓	✓	✓	

Data from Rutala WA, Weber DJ, HICPAC. Guideline for disinfection and sterilization in healthcare facilities, 2008. Atlanta (GA): Centers for Disease Control and Prevention; 2008. Available at: http://www.cdc.gov/hicpac/pdf/guidelines/ Disinfection_Nov_2008.pdf. Accessed May 19, 2018; and U.S. Department of Health and Human Services Food and Drug Administration Center for Devices and Radiological Health. Guidance for Manufacturers Seeking Marketing Clearance of Ear, Nose, and Throat Endoscope Sheaths Used as Protective Barriers: Guidance for Industry. 2000. Available at: https://www.fda.gov/RegulatoryInformation/Guidances/ucm073746.htm. Accessed May 19, 2018.

OTOLARYNGIC ISSUES IN DISINFECTION AND STERILIZATION

Reprocessing of Flexible Nasopharyngoscopes

Most flexible nasopharyngoscopes are semicritical devices and should be cleaned thoroughly and at a minimum undergo high-level disinfection. Recommended reprocessing, detailed in **Box 1**, is a multistep sequence requiring attention to timely precleaning, leak testing, cleaning, disinfection/sterilization, rinsing, drying, and ventilated storage.[6,7]

Recent attention to sterilization procedures relates to infectious disease outbreaks traced to contaminated duodenoscopes, gastroscopes, cystoscopes, ureteroscopes, and bronchoscopes.[8] These scopes carry an increased risk if they encounter sterile cavities or have channels and ports that make cleaning and disinfection more challenging. In contrast, most scopes used in outpatient otolaryngology clinics have neither lumens nor contact with sterile areas. Nonetheless, some otolaryngology scopes used for sensory testing, laser treatments, and biopsy have lumens that may require more rigorous cleaning and disinfection processes. Channels should be flushed during the cleaning, disinfection, final rinse, and drying (with 70% alcohol and forced air) stages.

It is difficult to determine the risk of disease transmission from nonlumen nasopharygoscopes. Epidemiologic investigations are limited, because the detection of infection and linkage to the performance of an endoscopic examination is rare. No cases of human immunodeficiency virus, hepatitis B virus, or hepatitis C virus transmission associated with contaminated flexible nasopharyngoscopes have been reported in the literature. In a study where 1304 patients underwent flexible nasopharyngoscopy with improperly disinfected scopes, viral genetic testing was performed on 92% of these patients and no strong evidence of viral transmission was found.[9]

Endoscope reprocessing can be done by performing the steps manually or using automated systems. Manual approaches are susceptible to several pitfalls—human error, time pressure, disinfection liquid inconsistencies (inadequate monitoring of temperature, germicidal efficacy, and days of use), physical and chemical damage to scopes, and an inability to closely track. Automated systems cleanse, disinfect, and dry without human intervention, standardizing reprocessing and facilitating tracking. Damage to endoscopes is not entirely mitigated with automated reprocessors,

Box 1
Recommended reprocessing of flexible nasopharyngoscopes

1. Preclean the scope immediately after the procedure to remove bulk biocontaminants and prevent drying/hardening of debris.
2. Leak test the scope to confirm structural integrity.
3. Clean entire the scope with enzymatic detergent to remove debris and reduce microbial load.
4. Perform high-level disinfection or sterilization of the entire scope, including the handle.
5. Perform final rinse with sterile water or potable water.
6. Dry the scope fully.
7. Store by hanging scope vertically in a clean, dry, well-ventilated, dust-free area or cabinet.

Data from Muscarella LF. Prevention of disease transmission during flexible laryngoscopy. Am J Infect Control 2007;35(8):536–44; and Cavaliere M, Iemma M. Guidelines for reprocessing nonlumened heat-sensitive ear/nose/throat endoscopes. Laryngoscope 2012;122(8):1708–18.

because moving the process away from the clinic carries risks of damage induced by transportation and handling.[10] Additional disadvantages include the equipment and maintenance expenses, space required, cycling time, and volume limitations. Simpler systems automate only the disinfection step.

The use of sterile disposable sheaths has been described as an alternative to conventional flexible scope reprocessing. Sheaths cover the flexible tip and the portion of the scope that can contact a patient's mucous membranes, providing a contamination barrier between the scope and the patient. The FDA requires sheath manufacturers to instruct users to follow the cleaning procedure recommended by the endoscope manufacturer followed by intermediate-level disinfection such as wiping with a 70% isopropyl alcohol soaked gauze pad.[11] Studies have shown negative cultures on scope insertion tips after this procedure. Nonetheless, the use of sheaths would not prevent cross-contamination arising from a contaminated scope body or handle, from inappropriate technique in removal of the soiled sheath, or from soiling of a scope by a leaky sheath.[12] Because intermediate-level disinfection may be ineffective against endospore-forming bacteria such as *Clostridium difficile*, some investigators have advocated for high-level disinfection, even after sheath use.[4]

Storage and Packaging of Clinic Instruments

Traditionally, clinic instrumentation used in otolaryngology—nasal speculums, ear speculums, suctions, cerumen curettes, forceps—are stored comingled in an instrument cabinet. According to the Spaulding criteria, many of these instruments could be classified as noncritical, but some straddle the line between noncritical and semicritical. Short nasal speculums will only touch squamous lined vestibular skin at the nostril entrance; but, if inserted more deeply, speculums may touch intact mucosa, making the instruments' risk classification semicritical. Frazier suctions and forceps used during intranasal examinations routinely traverse mucosal borders and the devices are often used in nonintact mucosa as in nasal debridement procedures. Storage requirements for nonsterile but highly disinfected instruments may depend on the environment in which they are stored and accessed, because this influences the risk of cross-contamination.

A variety of potential sources of contamination are possible, although data on infection from office-based equipment are lacking. One possible source of contamination is medical staff, including the practitioner and support staff, when reaching into cart drawers with contaminated hands or gloves during a patient visit or between patients. Contamination may also arise from unattended patients rummaging through unsecured equipment cabinets. These concerns could be mitigated if instruments are stored away from patient access or contact. The Centers for Disease Control and Prevention guidance for packaging and storage of instruments is most explicit for instruments that must maintain sterility.[2] Approved packaging includes rigid containers, peel-open pouches, roll stock or reels, and sterilization wraps. Storage of semicritical instruments can be inferred from recommendations for endoscopes, which the Centers for Disease Control and Prevention simply states should be dried and stored in a manner that protects them from recontamination. Other recommendations suggest that the area should be dust free.

The Joint Commission has made a statement regarding storage of laryngoscope blades and handles used by the anesthesiologist during intubation, which may have bearing on otolaryngology practice.[13] The blades are treated as semicritical instruments requiring at least high-level disinfection. The manual goes further to state that the blades and handles should be wrapped individually and stored in a way that would prevent contamination. Examples include, but are not limited to, a peel

packaging or containment within a closed plastic bag. Examples of noncompliant storage would include unwrapped blades in an anesthesia drawer, as well as unwrapped blades on top of or within a code cart.

Storage requirements for otolaryngology clinic instruments are evolving. Taking a cue from The Joint Commission requirements for laryngoscope blades and handles, some hospital organizations and accrediting inspectors now require individual packaging—including sterile peel packaging—of all instruments stored in instrument cabinets. Proponents suggest such practices decrease the risk for cross-contamination and allow for easy confirmation that instruments have been appropriately reprocessed and are ready for use. Detractors cite the lack of evidence demonstrating comingling and cross-contamination to be a clinically observed problem as well as the increased storage burden and inability to rapidly retrieve multiple variations of a desired instrument in an emergency. A recent study showed no greater culture growth from comingled instruments than peel-packed instruments at the end of a clinic day.[14] Again, it was noted that loss of efficiencies resulting from decreased storage room and increased difficulty in finding the correct instruments are also relevant considerations. This area awaits further investigation and data, but regulatory procedures suggest a growing trend toward increasingly stringent practices for individual packaging of office-based instruments in our specialty despite the lack of strong evidence to support this rigor. The American Academy of Otolaryngology-Head and Neck Surgery has had recent discussions with The Joint Commission to clarify this position. While still in evolution at the time of this manuscript's submission, The Joint Commission agreed that peel-packaging non-critical instruments is neither required nor expected. It was also agreed that such instruments may acceptably be stored co-mingled in clean cabinet drawers (personal communication). While we should pursue everything possible to secure the safety of our patients, it should be done to maximize societal good with responsible management of finite resources.

Reprocessing Single-Use Devices

Whereas most medical equipment was traditionally built for long-term use, the medical equipment industry and medical centers have come to embrace a wide range of disposable equipment. Disposable items do not need to be cleaned for reuse, reducing labor costs. Furthermore, high-profile reports of contaminated equipment and outbreaks of infection further fueled trends toward disposable equipment and supplies. Responding to market forces and incentives to minimize regulatory burden, manufacturers and health care centers have evolved toward a heavy reliance on SUDs.

Original equipment manufacturers (OEMs) decide whether to pursue single use or reusable classification for devices, but the standards are significantly more stringent for reusable medical devices. The OEM may label a device as single use when insufficient data has been found (or pursued) to ensure reusability. Because single-use devices (SUDs) do not need to meet these requirements, the cost of developing and producing SUDs is significantly lower than their reusable counterparts. Decreased production costs of SUDs and increased profitability of disposable devices thus create incentives toward single use labeling.

The proliferation of SUDs has tended to promote a throw-away culture in health care and an attendant increase in health care spending. Initially, the extra expense was passed on as a cost to third-party payers; however, this transfer of cost has become more difficult in recent years. As a result, the recurring cost of disposable equipment became a significant concern for medical entities. Faced with ever-tighter budgets, some hospitals had made their own foray into SUD reprocessing; this was relatively

short lived, however, for a myriad of obvious reasons. The combination of liability concerns as well as the growing intricacy of reprocessing complex devices led to the development of companies specializing in reprocessing services. The use of SUDs not reprocessed in an FDA-approved manner violate sanctioned usage recommendations, which may violate public health laws and reimbursement allowances.

Regulation

The FDA is the primary arbiter of reprocessing standards. In response to growing concerns regarding the lack of SUD reprocessing oversight, in 2000 the FDA set forth policies and standards,[15] which were further fortified under the Medical Device User Fee and Modernization Act of 2002. SUD reprocessing companies are held to the same statutory and regulatory requirements of original equipment manufacturers. These requirements include device registration, quality reporting, and labeling. In addition to meeting all standards required of OEMs, reprocessors are required to submit a 510(k) marketing application, which provides data on the cleaning, sterilization, and performance of the reprocessed device. In addition, the device must retain reasonable quality to be substantially equivalent to the original after the maximum permitted number of reprocessing cycles.

The FDA categorizes medical devices according to a Code of Federal Regulations risk classification. It is this classification—which is distinct from the previously described Spaulding criteria—that dictates the specific requirements for reprocessing of a given device. Nasal cannulas, tongue depressors, and blood pressure cuffs are in the lowest risk category (class I). A variety of surgical devices used in otolaryngology are intermediate risk (class II). Examples include sinus microdebriders, harmonic scalpels, blades, bits, burs, syringes, masks, and some laser fibers. The highest risk devices (class III), such as coronary stents, heart valves, and implantable neuromuscular stimulators, are seldom reprocessed, although all are eligible for reprocessing. Although many class I and class II devices have received approval (**Box 2**), no class III devices have yet met the requirements for reprocessing.

Safety

The FDA stance is that reprocessed SUDs currently in use do not pose a safety threat. In the period spanning 2000 to 2006, there were 65 reports filed relating to reprocessed SUD, in comparison with 320,000 reports for devices overall. The adverse events involving reprocessed SUD were similar to those for new devices, but a comparative rate of device failure in reprocessed versus original products is unknown. The FDA concluded in 2006 that reprocessed SUDs were safe and effective options for clinical use.[16]

The scientific literature on the safety and efficacy of reprocessed SUDs is limited, with some studies suggesting decreased efficacy of devices or increased risk of contamination, whereas others show outcomes equivalent to new devices.[17–24] The variation within these reports may reflect variation in device complexity, design, and materials. Although some studies report on actual clinical experience, other literature involves experimental models. Given this paucity of data, clinicians who chose to use reprocessed devices in their practices should be conversant with FDA guidance on reprocessing and be mindful of the sterility and performance considerations of these devices.

Financial implications

The Centers for Medicare and Medicaid Services (CMS) and most commercial payers reimbursing for device costs do not distinguish between original SUDs and reprocessed SUDs. Because both are identified as single use, both are eligible for pass-

Box 2
Examples of commonly reprocessed single-use devices

Otolaryngology
- Coblators®
- Colorado microdissection needles™
- Adenoid blades
- Xomed shavers
- Harmonic focus®
- Ent shavers

General/gyn/urology
- Harmonic® scalpels
- Laparoscopic trocars and cannulas
- Scissor tips

Multi-department
- Pulse oximeter sensors
- Open/unused/expired items
- Somanetics®
- Neptune® manifolds

Orthopedic surgery
- Ablation wands
- Arthroscopic shavers and abraders
- Carpal tunnel release blades
- Athroscopic trocars and cannulas
- Drill bits and burs
- Anterior cruciate ligament blades
- Saw blades
- Rasps
- Tourniquets
- Reamers
- Scorpion needles
- ExpressSew™ needles
- Suture lassos, graspers, passers, and retrievers
- Countersinks

Ophthalmology
- Phaco tips

through payments, provided the reprocessing procedures conform to FDA standards.[25] CMS reimbursement generally provides payment for full procedures—not itemizing the individual devices—so there is the potential for significant cost savings. Similar considerations pertain to procedures in office setting or surgical centers, where the cost of devices is bundled into the facility expense component of relative value units for a procedure.

Reprocessed SUDs cost approximately one-half as much as original SUDs. Interestingly, the SUD reprocessing industry can put downward pressures on prices for original SUDs by creating competition in the health care marketplace. The Association of Medical Device Reprocessors reports cases in which OEMs have decreased their "rack rate" for new SUDs by up to 50% to compete for contracts.[26] As the business of reprocessing SUDs has grown, some OEMs have acquired the infrastructure to become reprocessors of their own products.[27]

Ethics

The subject of reprocessed SUDs has relevance to ethical principles of transparency, fairness, autonomy, and trust. 1 one perspective, the use of reprocessed SUDs is not

off-label when issued by an FDA-approved third-party processor. The decision to use a reprocessed SUD with equivalent safety and performance profile to an original SUD might thereby be considered analogous to the decision to use any comparable instrument. Provided the FDA standard of "substantial equivalence" for reprocessed SUDs is consistently upheld, the decision to participate in a SUD reprocessing program is left to individual institutions. Informed consent does not typically involve conversations about the make or model of devices that a surgeon plans to use during a surgical procedure and it may suffice for surgeons to be knowledgeable and helpful in responding to patient queries on use of reprocessed SUDs.

One ethical consideration relates to potential asymmetric risk and benefit, wherein the patient primarily bears risk if a reprocessed SUD has impaired fidelity or residual contamination, whereas the medical facility enjoys the benefit of improved profit margin from cost saving on device and waste disposal. Respect for ethical principles is integral to the patient–physician covenant and delivery of high-quality care. The broad benefits of a greener health delivery system and reducing the overall costs of US health care can benefit patients, and revenue recovery from SUD reprocessing may allow hospitals to better fund quality and safety efforts or ensure adequate staffing. Nonetheless, these notions do not remove the need for transparency and careful reflection on this area. Any benefit to the environment or otherwise by adopting a "greener" approach is difficult to apportion to the patient, facility, or provider.

SUMMARY

Meticulous sterilization and disinfection procedures are necessary to ensure the safe and effective reprocessing of medical devices and equipment. Otolaryngologists should adhere to approved practices for endoscopes and other reusable devices. Practices continue to evolve regarding packaging and storage office based devices, with regulatory pressure increasingly driving individual packaging of nasal speculums and other contents of instrument cabinets without evidence to support these assertions. A rigorous, FDA-approved procedure also allows for responsible recycling of a variety of SUDs. Otolaryngologists' knowledge of best practice and transparency with patients regarding such practices ensure high-level care in the complexity of care we provide from various levels of devices. Future guidance should be refined to account for nuances in practice environment as well as the immune characteristics of the anatomic site where devices are being used.

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