High-Level Disinfection of Otorhinolaryngology Clinical Instruments: An Evaluation of the Efficacy and Cost-effectiveness of Instrument Storage

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Sponsorships or competing interests that may be relevant to content are disclosed at the end of this article.

Abstract
Objectives. Despite increasing interest in individual instrument storage, risk of bacterial cross-contamination of otorhinolaryngology clinic instruments has not been assessed. This study is the first to determine the clinical efficacy and cost-effectiveness of standard high-level disinfection and clinic instrument storage.

Methods. To assess for cross-contamination, surveillance cultures of otorhinolaryngology clinic instruments subject to standard high-level disinfection and storage were obtained at the start and end of the outpatient clinical workday. Rate of microorganism recovery was compared with cultures of instruments stored in individual peel packs and control cultures of contaminated instruments. Based on historical clinic data, the direct allocation method of cost accounting was used to determine aggregate raw material cost and additional labor hours required to process and restock peel-packed instruments.

Results. Among 150 cultures of standard high-level disinfected and co-located clinic instruments, 3 positive bacterial cultures occurred; 100% of control cultures were positive for bacterial species (P < .001). There was no statistical difference between surveillance cultures obtained before and after the clinic day. While there was also no significant difference in rate of contamination between peel-packed and co-located instruments, peel packing all instruments requires 6250 additional labor hours, and conservative analyses place the cost of individual semicritical instrument storage at $97,852.50 per year.

Discussion. With in vitro inoculation of >200 otolarynology clinic instruments, this study demonstrates that standard high-level disinfection and storage are equally efficacious to more time-consuming and expensive individual instrument storage protocols, such as peel packing, with regard to bacterial contamination.

Implications for Practice. Standard high-level disinfection and storage are equally effective to labor-intensive and costly individual instrument storage protocols.

Keywords
high-level disinfection, PS/QI, clinic instrument, peel pack, health care–associated infections, nosocomial, sterilants, disinfectants, germicides

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A number of clinic instruments are used per patient visit in the outpatient otolaryngology setting. With in vitro inoculation of flexible fiberoptic laryngoscopes (FFLs), recent studies have demonstrated that efficient, cost-effective practices of high-level disinfection (HLD) are equally efficacious to more time-consuming, expensive techniques, such as sterilization, with regard to bacterial contamination.¹ However, the risk of bacterial contamination of other clinic instruments over the course of daily clinical practice has yet to be evaluated. Although instruments such as suction tips and nasal speculum generally have a lower level of bioburden accumulation, there have been suggestions of possible cross-contamination of...
other co-located instruments during routine clinical use by practitioners.

Current disinfection protocols are based on the 2008 Centers for Disease Control and Prevention’s recommendations for disinfection and sterilization in health care facilities, which sought to reduce rates of health care–associated infections through appropriate use of disinfection and sterilization.2 According to the Spaulding classification, semicritical devices or those that contact intact mucosal surfaces during use should undergo HLD after each use. HLD with disinfectants such as glutaraldehyde, hydrogen peroxide, ortho-phthalaldehyde, peracetic acid with hydrogen peroxide, and chlorine for approximately 40 minutes at 20°C to 25°C has been shown to inactivate pathogenic organisms, such as viruses, mycobacteria, fungi, and fungal spores.3,4

At our institution, cleaning, disinfection, and sterilization of patient care devices occur in a central processing area. Clinic instruments are cleaned with water and enzymatic cleaners to remove visible organic and inorganic residues prior to HLD. Instruments are stored in a well-ventilated area that provides protection against dust, moisture, and temperature extremes. After HLD, instruments are rinsed with sterile water, followed by an alcohol rinse. All instruments are additionally autoclaved for 30 minutes, and sterilizer challenge packs are used with each autoclave session to ensure efficacy.

No recommendations or studies have been performed into storage of cleaned instruments and equipment in separate packaging, such as peel packs, and the risk of cross-contamination via provider hands of instruments stored together. This study aims to determine the efficacy of current disinfection protocols of ear, nose, and throat clinic instruments over the course of daily standard practice and the additional cost of individual instrument storage, in terms of labor hours and cost of the sterilization and storage process.

Methods

To provide more clinically oriented data regarding the efficacy of standard disinfection protocols, clinic instruments were assessed via microorganism culture prior to the start of the outpatient clinic day in a tertiary academic medical center. Standard clinic instruments included Luc’s forceps, nasal speculum, suction tips, and Jobson’s aural probes. These instrument cultures were compared with those obtained from clean instruments at the end of an 8-hour clinic day to assess for cross-contamination and appropriate storage of clean instruments during routine clinical use. This study was repeated over several days at 3 outpatient clinics within the same academic institution.

The study arms were as follows: instruments after routine use (positive control), peel-pack stored clean instruments (negative control), co-located clean instruments at the start of the outpatient clinic day, and co-located clean instruments at the end of the outpatient clinic day. Standard clean instrument storage is shown in Figure 1.

Instruments were swabbed with a sterile cotton swab with an applicator stick and plated onto LB agar and chocolate agar. Plates were incubated at 35°C for 48 hours. After incubation, the plates were scored as positive or negative for growth, and positive cultures were speciated by the hospital pathology department (MALDI Biotyper; Bruker, Billerica, Massachusetts). In addition, the remaining negative plates were incubated at 35°C for an additional 48 hours to ensure that no contaminant was present.

Descriptive statistics were performed, and Fisher exact test was used to determine significance. Cost estimates are
based on historical data obtained from the clinic purchasing department.

Results
When the efficacy of the disinfection on bacterial growth was examined, all of the positive control clinic instruments after routine use were positive for bacterial growth, confirming that used instruments were contaminated with upper aerodigestive tract bacteria. Of 150 co-located clean instruments evaluated over multiple days of standard clinical practice, 3 cultures were positive. Speciation revealed coagulase-negative Staphylococcus, specifically Staphylococcus warneri, a common commensal organism found as part of the skin flora. There was no significant difference in rate of contamination among clean instruments tested prior to the clinic day and those tested after it ($P = 1.00$). Table 1 shows rates of bacterial cross-contamination for clinic instruments.

Of the clean instruments stored in peel packs ($n = 75$), 2 cultures were positive. Speciation again revealed coagulase-negative Staphylococcus, likely S warneri. There was no significant difference in rate of contamination of individually stored peel-pack instruments and co-located clinic instruments ($P = .64$). Table 1 outlines the cumulative culture results.

Discussion
Cross-contamination of co-located clinic instruments with body fluids and debris, such as mucous and even pathogenic organisms, is a theoretical risk in daily clinical practice, so effective disinfection and storage must be determined. Practices vary widely for clinic instrument disinfection and storage, and while effective protocols for FFL disinfection in clinical practice have been studied, there are few data on effective disinfection and storage of semicritical instruments, such as standard instruments in the ear, nose, and throat clinic. Our study sought to determine the efficacy and cost-effectiveness of current disinfection and storage practices of clinic instruments.

With in vitro inoculation of $>200$ otorhinolaryngology clinic instruments subject to HLD, this study demonstrates that standard HLD and storage are equally efficacious to more time-consuming and expensive individual instrument storage protocols, such as that with peel packs. Specifically, there was no significant difference in rates of contamination over the course of an 8-hour clinic day, making cross-contamination of co-located equipment with pathogenic organisms unlikely. In addition, there was no significant difference in rates of contamination of individually stored or peel-packed instruments and clean instruments, questioning the need for this costly and time-intensive practice for standard clinic instruments, such as a nasal speculums and suction tips. Speciation of contaminated plates revealed normal skin flora that is rarely pathogenic, specifically S warneri.

A consideration in the design of this study was the cost and additional labor hours of storage practices, such as applying individual peel packs for each instrument. Over the course of a year, peel packs for standard clinic instruments, such as suction tips and Jobson’s aural probes, would cost an additional $7852.50. More significant, each peel pack requires an additional 5 minutes of tagging, documentation, and restocking for each disinfection cycle such that over the course of a year, peel packing all clinic instruments would require 6250 additional labor hours or approximately 3 more full-time staff members. Conservative estimates therefore place the cost of individual semicritical instrument storage at $97,852.50 per year, without offering an improvement in practice and patient outcomes.

While it is important to consider the efficacy of disinfection protocols on viral and fungal transference, this analysis was beyond the scope of this study. Prior studies have reported that HLD with chemicals such as orthophthaldehyde is virucidal against hepatitis B virus and hepatitis C virus. Chang et al also showed, in a study of protocols of effective FFL disinfection techniques, complete disinfection of Candida-inoculated FFLs with standard HLD. Further investigation could be performed to determine virucidal and fungal disinfection of semicritical clinic instruments.

Implications for Practice
Ultimately, strict adherence to disinfection and sterilization guidelines is critical to prevent exposure to infection agents. Semicritical devices, such as otorhinolaryngology clinic instruments, can be co-located with other clean clinic instruments without a significantly increased risk of bacterial cross-contamination, precluding the need for costly individual instrument storage practices such as peel packs, which require additional full-time staff.

Further research exploring the risk of virucidal contamination of clean, stored instruments by the handling of co-located instruments in drawers would be helpful. Having instruments that will likely be used for each patient visit laid out on the top of the cart would further lower any risk of introducing contaminants into the instrument drawers. If these simple measures are followed, we believe that HLD is adequate for clinic instruments while being cost-effective and safe.

Author Contributions
Pratyusha Yalamanchi, design, data acquisition and analysis, drafting, revision; Jason Yu, data acquisition and analysis,

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<thead>
<tr>
<th>Table 1. Rates of Bacterial Cross-contamination of Semicritical Clinic Instruments.</th>
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<tr>
<td><strong>Study Arm</strong></td>
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<tr>
<td>Instruments after routine use</td>
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<tr>
<td>Clean instruments</td>
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<tr>
<td>Individually stored (peel pack)</td>
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<tr>
<td>Cultured before clinic day</td>
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<td>Cultured after clinic day</td>
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*Values indicate the number of positive samples per the total number of samples analyzed. P values are based on comparisons with positive controls.
revised; Laura Chandler, data acquisition, revised; Natasha Mirza, design, drafting, revised.

Disclosures

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References