American Journal of Infection Control ■■ (2016) ■■-■■

Contents lists available at ScienceDirect

American Journal of Infection Control

journal homepage: www.ajicjournal.org

Original Research Article

Practical toolkit for monitoring endoscope reprocessing effectiveness: Identification of viable bacteria on gastroscopes, colonoscopes, and bronchoscopes

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Key Words:
High-level disinfection
Microbial cultures
Stenotrophomonas maltophilia

Background: Experts have recommended microbiologic surveillance by external reference laboratories for certain flexible endoscopes. There is currently insufficient evidence on the feasibility and utility of cultures. Researchers evaluated a preassembled toolkit for collecting and processing samples from endoscopes.
Methods: A pilot study was performed in a large academic medical center. A toolkit was used to aseptically sample biopsy ports and suction/biopsy channels of 5 gastroscopes, 5 colonoscopes, and 5 bronchoscopes after full reprocessing. Blinded specimens were packaged and transported on icepacks to a reference laboratory that used standard methodologies for microbial cultures.
Results: The laboratory detected bacteria in samples from 60% of patient-ready endoscopes, including gram-positive and gram-negative species. Viable microbes (<10 CFU) were recovered from 2 gastroscopes, 3 colonoscopes, and 4 bronchoscopes. *Stenotrophomonas maltophilia* and *Delftia acidovorans* were recovered from all 3 endoscope types. Subsequent environmental testing detected *S maltophilia* in the reprocessing rinse water.
Conclusions: A preassembled toolkit facilitated the aseptic collection of samples for culturing by a reference laboratory that detected viable microbes on fully reprocessed endoscopes. Speciation allowed identification of potential pathogens and a possible common contamination source, demonstrating that microbial cultures may have value even when colony counts are low.

Gastrointestinal endoscopes can harbor organic residue and viable microbes despite reprocessing in accordance with current guidelines.[1-4] Although the risk of infection associated with contaminated endoscopes is unknown,[5] high attack rates and patient deaths have been documented in recent endoscopy-associated outbreaks of multidrug-resistant organisms.[3,4,6]

In the wake of these outbreaks, the US Food and Drug Administration recommended that health care facilities perform routine microbial cultures on samples from duodenoscopes to mitigate pathogen transmission.[7] In March 2015, the US Centers for Disease Control and Prevention released interim guidance for conducting duodenoscope cultures.[8] The American Society for Microbiology has recommended that cultures be performed by external reference laboratories because they may be better equipped than internal clinical labs in health care facilities to successfully conduct cultures.[9]

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This work was supported in part by STERIS Corporation, which provided funding and materials to Ofstead & Associates, Inc, for this study. STERIS did not have access to the data and was not involved in the preparation of this manuscript. Additional research support was provided by University of Minnesota Health and Ofstead & Associates, Inc. No monetary compensation was received by the physicians or staff at University of Minnesota or their departments for participating in the research or writing of the manuscript.

Conflicts of Interest: CLO is employed by Ofstead & Associates, Inc, which has received research funding and speaking honoraria related to infection prevention from STERIS Corporation, 3M Company, Medivators, HealthMark Industries, Boston Scientific, invendo medical, and Advanced Sterilization Products. EMD, JEE, MRA, and HPW are employed by Ofstead & Associates, Inc.

0196-6553/
http://dx.doi.org/10.1016/j.ajic.2016.01.017

To support the implementation of these recommendations in the field, we evaluated the clinical feasibility and value of using a preassembled toolkit to aseptically collect samples from colonoscopes, gastroscopes, and bronchoscopes for microbial cultures conducted by an offsite reference laboratory.

METHODS

Setting

This study was conducted in the Endoscopy Department at the University of Minnesota Medical Center (Minneapolis, MN), where both gastrointestinal and respiratory endoscopes are reprocessed. The University of Minnesota Institutional Review Board granted a waiver for this study because it did not involve human subjects. During the study period, procedures in this institution were performed using Olympus gastroscopes (models GIFXP190N and GIFHQ190), colonoscopes (models CFHQ190L and PCFH190L), and bronchoscopes (models BF1TH190 and BFH190) (Olympus America, Center Valley, PA).

Reprocessing steps

Reprocessing began with bedside precleaning immediately after case completion. A trained technician used a precleaning kit (Compliance Endokit; EndoChoice Inc, Alpharetta, GA) to wipe the external surfaces of the endoscopes with disposable sponges and flush detergent through the suction/biopsy (SB) channels in the procedure room. The endoscopes were then transported to a dedicated reprocessing room for leak testing, cleaning, and high-level disinfection (HLD). The external surfaces were wiped and the channels were brushed before the endoscope was placed in an automated endoscope reprocessor (AER) (MEDIVATORS Advantage Plus Endoscope Reprocessing System; MEDIVATORS, Inc, Minneapolis, MN). The AER performed automated cleaning (Intercept Detergent; MEDIVATORS, Inc) and HLD with peracetic acid (Rapicide PA 30°C High-Level Disinfectant; MEDIVATORS, Inc, Minneapolis, MN). The high-level disinfectant's minimum effective concentration was verified at the end of each cycle in accordance with the AER manufacturer's instructions. Following HLD, the AER flushed 10 mL isopropyl alcohol through the channels and purged them with forced air to aid the drying process. Disinfected endoscopes were wiped down with a lint-free towel and stored vertically. Researchers observed reprocessing practices and used a checklist to document adherence with reprocessing policies.

Toolkit

A preassembled sampling toolkit was used with a detailed protocol for aseptic collection and packaging to assess contamination levels on patient-ready endoscopes. The contents of the sampling kit were selected by researchers in collaboration with personnel from the reference laboratory (Biotest Laboratories, Inc, Brooklyn Park, MN). Decisions about the sampling kits' contents were based on scientific literature and researchers' previous experience with sampling and conducting cultures (Table 1).[1,10-12] The sampling kits were assembled by the laboratory and each kit contained enough materials to collect samples from 3 endoscopes.

Aseptic technique

Samples were collected in a dedicated procedure room that had been thoroughly cleaned before study initiation. All surfaces used for endoscope sampling were disinfected using CaviWipes (Metrex Research LLC, Orange, CA) and draped with disposable pads. Sampling was performed by 2 researchers with prior experience as operating room nurses, with assistance from other members of the research team. Researchers wore impermeable gowns, face shields, masks, shoe covers, and hair covers. Sterile gloves were worn while handling endoscopes and collecting samples. After sampling each endoscope, environment surfaces were disinfected, disposable pads were changed, and researchers performed hand hygiene and personal protective changes.

Table 1
Sampling kit contents

Material	Quantity
120-mL bottle sterile water	1
Remel BactiSwab #1275*	3
60-mL sterile syringe	3
5-cm long × 0.8-0.9-cm diameter flexible connection tubing	3
120-mL sterile urine cup	3
Styrofoam transportation container	1
Cold packs	2
Paraffin film strips	3

*Remel Inc, Lenexa, KS.

Sampling

Reprocessing personnel identified a convenience sample of patient-ready endoscopes for this pilot study. Researchers sampled biopsy ports and SB channels on 5 gastroscopes, 5 colonoscopes, and 5 bronchoscopes reprocessed in the endoscopy unit. Positive and negative controls were used to verify the effectiveness of aseptic technique and the sensitivity of culturing methods. Sterile water and a swab of an autoclaved wire cutter served as negative controls. For the positive controls, channel effluent and a biopsy port swab were taken from a clinically used gastroscope before manual cleaning. To evaluate the potential influence of the toolkit on workflow and efficiency, each sampling event was timed with a stopwatch.

Biopsy ports were sampled for culturable microbes using a sterile sample collection and transport device (BactiSwab Gel Collection and Transport Systems; Remel Inc, Lenexa, KS), which consists of a rayon swab with a plastic shaft placed into a polypropylene tube containing a nonnutritive, charcoal-based media designed to maintain specimen viability during transport. Researchers swabbed inside the biopsy port for 30 seconds before inserting the swab into its tube and securing it in accordance with the manufacturer's instructions for use.

The SB channel was sampled using a flush-only method previously described by Alfa et al.[10] A sterile 60-mL syringe was used to draw up 30 mL sterile water, followed by 20 mL air. The syringe was connected to the biopsy port using the connection tubing. The sterile water was injected through the SB lumen, followed by an air flush, and collected in a sterile urine cup at the distal end. The urine cup was capped and sealed with a plastic paraffin film (Parafilm; Bemis Company, Inc, Oshkosh, WI). The samples were labeled using a predetermined blinding protocol and packaged in sealed biohazard bags, which were placed in transportation coolers containing cold packs. Coolers were delivered to the reference laboratory within 3 hours of sample collection.

Cultures

The reference laboratory extracted samples from the swabs in 100 mL sterile buffered water with 0.02% polysorbate 80, which was mechanically shaken for 30 minutes. The extract was filtered through 0.45 μm nitrocellulose filters. The filters were rinsed with an additional 100 mL sterile buffered water with 0.02% polysorbate 80 and plated on tryptic soy agar.