Office of Evidence Based Practice – Specific Care Question: Endoscope Disinfection

Specific Care Question: Is automated endoscope reprocessing (AER) safer than manually cleaning.

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Evidence Summary from the Office of Evidence Based Practice:

Three guidelines (Petersen, Chennat, & Cohen, 2011; Society of Gastroenterology Nurses and Associates [SGNA], 2012; Rutala & Weber, 2008), one report from The Food and Drug Administration (FDA) (FDA, 2009) and one observational study (Ofstead, Wetzler, Doyle, Rocco, Visrodia, Baron & Tosh, 2015) were reviewed for this question. The FDA and all three guidelines recommend the use of both manual cleaning and automated endoscope reprocessing (AER) (FDA, 2009; Petersen & Cohen, 2011; SGNA, 2012; Rutala & Weber, 2008). Petersen et al. (2011) released a multisociety (The American Society for Gastrointestinal Endoscopy [ASGE] and The Society for Healthcare Epidemiology of America [SHEA]) guideline that reported pathogen transmission can effectively be prevented when both manual and AER are used**. It is critical to point out; failure to adhere to reprocessing endoscope guidelines is a major factor in pathogen transmission (Petersen, 2011). Although, Ofstead et al. (2015) reported that despite reprocessing performed in accordance with guidelines viable microbes and biologic debris can persist on gastrointestinal endoscopes.** Ofestead et al. (2015) suggest that the current guidelines may not be enough.

Ofstead et al. (2015) looked at the rate of persistent contamination of viable microbes and biologic debris on colonoscopes and gastroscopes detected by biologic cultures despite reprocessing in accordance with the ASGE and SHEA guidelines. Samples from 13 endoscopes during 60 encounters were obtained. Rapid indicator tests detected contamination (ATP, protein, or hemoglobin) above benchmarks on four different types of endoscopes: (a) bedside-cleaning (13 of 13 samples; 100%), (b) manually cleaned (12 of 13 samples; 92%), (c) high-level disinfected (9 of 12 samples; 75%), and (d) stored (9 of 11 samples; 82%). After high level disinfectant (HLD) and storage, all organisms were of low pathogenicity and in low concentration; these findings were unlikely to result in patient harm (Ofstead, 2015). However, methods should be considered to ensure effectiveness of reprocessing practices that include routine monitoring with rapid indicators and microbiologic cultures.

Manual cleaning and AERs offer advantages over manual cleaning alone that includes the reduced risk of skipped steps in cleaning process CDC (2008). The four steps identified by the CDC for general endoscope disinfection and sterilization with liquid chemical sterilants are:

1. Clean: Mechanically clean internal and external surfaces, including brushing internal channels and flushing each internal channel with water and detergent or enzymatic cleansers.
2. Disinfect: Immerse endoscope in high-level disinfectant (or chemical sterilant) and perfuse disinfectant into all accessible channels (eliminate air pockets and ensure contact of the germicide into internal channels), such as the suction/biopsy channel and air/water channel and expose for the time recommended by the specific disinfecting product(s).
3. Rinse: rinse the endoscope and all channels with sterile water, filtered water (commonly used with AERs), or tap water (such as high-quality potable water that meets federal clean water standards at the point of use).
4. Dry: rinse the insertion tube and inner channels with alcohol, and dry with forced air after disinfection and before storage.

The topic of reprocessing of endoscopes and surgical instruments is important. Inadequate reprocessing of endoscopes and surgical instruments is reported as a *Top 10 Health Technology Hazard for 2015* (ECRI, 2014). The FDA (2009) recommends the following program to identify breaches in endoscope reprocessing.

1. Establish an institutional program for endoscope processing, along with written procedures for monitoring adherence to the program and a chain of accountability. Ensure that those responsible for endoscope processing understand the importance of this job and that they maintain proficiency in performing it for each type of endoscope they handle.
2. Train employees to set-up, clean, disinfect or sterilize, and store endoscopy equipment properly. Periodically retrain and assess employee competence. Endoscopy is a constantly evolving technology, so it is essential to stay up to date with the specifics of each device your institution uses.
3. Instruct staff to read and follow the endoscope manufacturer's instructions for use. Staff responsible for reprocessing endoscopes must have the manufacturer's instructions available for each endoscope and its accessories, because various endoscopes and their accessories have different processing steps (for example most flexible endoscopic equipment cannot tolerate steam sterilization).
4. Be sure staff members understand that the cleaning and disinfecting of endoscopes are two separate processes. Thorough cleaning of the endoscope must be done first, in order to remove gross contamination and debris. Without this step, the endoscope cannot be effectively disinfected or sterilized. Cleaning should begin immediately after use by thoroughly flushing the channels and rinsing/wiping the outside of the endoscope. The initial cleaning must be followed by a very thorough cleaning with brushes, concentrating especially on the channels. Only then is the endoscope ready for high level disinfection, which can be done manually or in an automatic endoscope reprocessor (AER). During disinfection, the high level disinfectant must contact every contaminated surface/channel for the time recommended by the disinfectant manufacturer.
5. Be sure that the AER or sterilizer is compatible with the endoscope. Before using an AER, confirm that it properly fits the endoscope. Adhere to the AER or sterilizer instructions that specify which endoscope makes and models the AER can process. Assure that the instructions for endoscopes, AERs, and germicides do not contradict one another. If you become aware that instructions are contradictory, inform the endoscope and AER manufacturers as well as the FDA.
6. Be sure that endoscopes or accessories that contact tissue are sterilized before each use, and that endoscopes that contact intact mucous membranes (such as the respiratory and gastrointestinal tracts) undergo at least high-level disinfection before each use.

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Ofstead 2015

Methods	Observational Study
Participants	**Setting:** Conducted at Mayo Clinic; Rochester, Minnesota **Participants:** 30,000 endoscopic procedures performed annually; **Number randomized:** not randomized, but included: **Inclusion criteria:** 60 endoscope encounters which occurred between November 4-8 2013. Clinically used colonoscopes (n = 7) and EGDs (n = 6) were sampled. Endoscopes were assessed after bedside cleaning (13 encounters), manual cleaning (13 encounters), HLD (11 encounters), and overnight storage (11 encounters). 10 additional post re-cleaning encounters occurred. Samples also obtained from 2 control endoscopes, and one new colonoscope that had never been used tested immediately after removal from its packaging to ensure rapid indicators were not producing false positives. **Number Complete:** Tests included a total of 332 surface ATP tests conducted on distal ends (n=60), control handles (n = 60), biopsy ports (n = 60), biopsy caps (n = 42) suction buttons (n = 42), air and water buttons (n = 40), and AUX ports (n = 28). Surface protein (75 tests) was assessed on control handles (57 tests) and suction and air and water (18 tests) ports. Researchers tested effluent samples from SB (n = 60) and AUX (n = 28) channels for carbohydrate (n = 88), protein (n = 88, hemoglobin (n = 85), and ATP (n = 88). Aerobic cultures were also performed with effluent form SB (240 samples) and AUX (112 samples) channels. **Power analysis:** cohort-- not needed.
Interventions	Reprocessing consisted of several steps: bedside cleaning in the procedure room by a technician who flushed the enzymatic solution through suction/biopsy (SB) and auxiliary water (AUX) channels and used disposable wipes to clean exterior components. Followed by leak testing and manual cleaning in dedicated reprocessing rooms. --Manual cleaning involved wiping external surfaces, brushing channels and components and using irrigation system to flush detergent and water through channels. An automated endoscope reprocessor was used for HLD. The disinfectant's temperature and minimum effective concentration were verified before cycle irrigation. Disinfected endoscopes were stored vertically after drying with isopropyl alcohol and forced air. --Endoscopy testing performed in dedicated room adjacent to the procedure room which allowed rapid sampling and testing. Barrier separation between procedural, reprocessing, data collection and testing activities minimized potential for environmental cross-contamination. Extensive measures to ensure aseptic environmental conditions during data collection included use of disinfectant wipes on surfaces, use of absorbent pads, and restricting room access. --Researchers wore gloves, impervious gowns, face mask with splash protection, hair nets and shoe covers. --Gloves were changed between sampling, and gowns were changed between endoscope encounters. --Each instance where samples were obtained from an endoscope was considered an encounter. --Samples were collected during a minimum of 4 encounters with each clinically used study endoscope. --Endoscope encounters occurred sequentially after each processing step and after overnight storage to assess contamination levels throughout reprocessing.

	--After post HLD sampling, another cycle of HLD was performed before storage. --Components sampled at each encounter included handles, suction and air and water valves, biopsy ports and caps, distal ends, SB channels, and AUX channels and ports. --Tests were conducted to detect protein, carbohydrate, hemoglobin, ATP and viable microbes. --Visual inspection was performed on all external endoscope components and channel effluent and sampling instruments. --External surfaces were individually sampled with sterile swabs. --Interior channels were assessed by testing effluent samples obtained via the flush-brush-flush method with 20 mL of sterile water and a 6-mm brush. --The effluent was divided into 3 sterile collection tubes for microbiologic culturing and rapid indicator testing.
Outcomes	**Primary Outcome:** --Interim analysis on a 2 day of data collection determined that contamination levels on multiple endoscopes exceeded post-cleaning protocol-established benchmarks. A new protocol was added, amended, to permit additional cleanings to reduce contamination levels, rather than quarantining endoscopes. --Visible residue was never apparent to technicians after manual cleaning and researchers verified that the endoscopes appeared to be clean. --Researchers occasionally observed residue when inspecting effluent and while taking samples with white swabs. --After bedside cleaning, rapid indictors detected ATP, protein or hemoglobin on 13 of the 13 (100%) endoscopes. --Aerobic cultures showed 92% of bedside-cleaned endoscopes harbored viable microbes. After manual cleaning, 12 of the 13 (92%) endoscopes had protein or ATP levels exceeding benchmarks. Surface protein was detected on 9 of 12 (75%) endoscopes, and ATP levels were above on 9 of 13 (69%) endoscopes or associated buttons or caps. --6 endoscopes were sent back for additional cleaning and disinfection because of high ATP levels. Viable microbes were removed from 3 endoscopes after re-cleaning and disinfection. --6 endoscopes (46%) had at least 1 positive culture plate after 1 round of manual cleaning. --After HLD, rapid indicators were positive for contamination exceeding manual benchmarks for 8 of the 11 (73%) endoscopes. Surface protein was detected on 55% of control handles. --Viable microbes were found in samples representing 64% of endoscopes. --All colonoscopes that received only 1 round of manual cleaning (n =5) harbored viable microbes after HLD. --After overnight storage, 9 of 11 (82%) endoscopes had positive rapid indicators. Protein tests from 7 of 9 (78%) endoscopes were positive. --Microbes were removed from the SB channel of 1 of 11 (9%), endoscopes. **Secondary analysis:** --Relative risk of endoscope having 1 of the 3 highest ATP results after HLD was 2.1 times higher (95% confidence interval), if it was also 1 of 3 with the highest ATP results after bedside cleaning (P = .01). --All 11 endoscopes tested after HLD had control handle ATP measures; 6 were positive for protein on the control

	handle. --After storage, 8 of 9 had control level handle ATP levels; but 7 of 9 positive for protein (P = .031). --Viable microbes were recovered after all steps of reprocessing. Small colonies were identified after HLD and storage.
Notes	**Results:** High levels of contamination were found on endoscopes reprocessed during the study. GI endoscopes were highly contaminated during clinical use and residual organic materials including viable organisms persisted despite reprocessing in accordance with cleaning/disinfecting guidelines. Cleaning process is laborious and time consuming and need objective verification that the cleaning process is complete and process may need further improvement