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Are your Endoscopes Clean?

You might be surprised
what lurks inside

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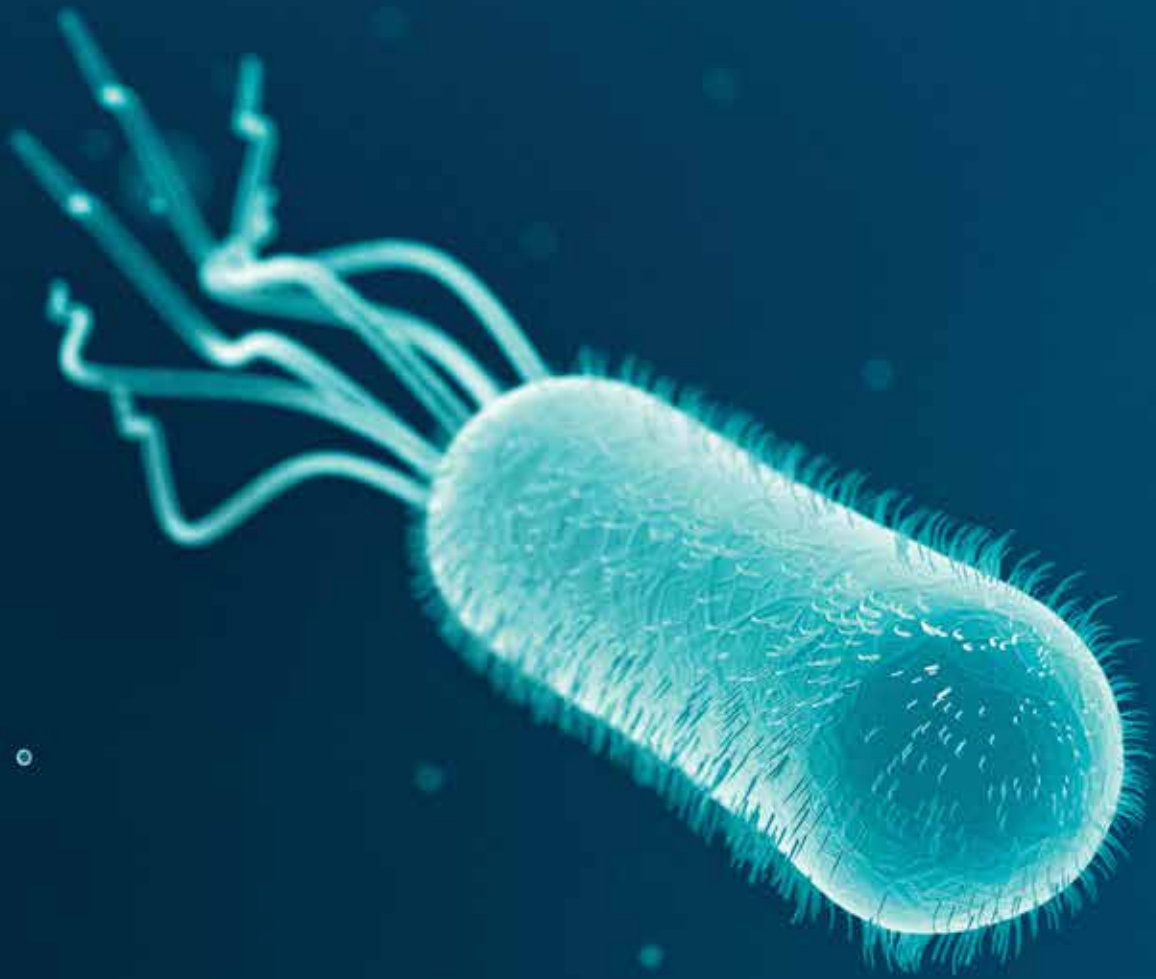
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ARE YOUR ENDOSCOPES CLEAN?

You might be surprised what lurks inside

As nearly any professional responsible for decontamination and disinfection, care and handling, and storage of flexible endoscopes can attest, these tasks are anything but easy. In fact, flexible endoscopes consistently rank at (or near) the very top of sterile processing professionals' lists of the most challenging, difficult-to-clean devices.

Just one glance at these complex, sophisticated instruments and their challenges become ever-apparent. Most notably, flexible endoscopes contain internal channels that are difficult to clean and can harbor bioburden. When bioburden remains in any of these channels, proper disinfection simply cannot occur and patients may become exposed to infectious microorganisms. Endoscopes are also delicate, so technicians must ensure that cleaning is performed effectively and meticulously, yet in a way that doesn't damage the instrument. Time pressures and sometimes limited endoscope inventories further exacerbate the problem, increasing the risk of staff rushing the process to meet case volumes and, at times, unrealistic physician demands.

More concerning, though, is that even when technicians follow proper cleaning practices – and don't deviate from standards, recommendations and Instructions for Use (IFU) – their endoscopes may still remain contaminated with pathogens. This was the eye-opening message shared by epidemiologist Cori Ofstead, MSPH, president and CEO of Ofstead & Associates Inc., during her May 5 IAHCSMM Annual Conference session, "The Real Dirt on Flexible Endoscopes."



Pointing to her own studies, as well as scientific data gathered from other well-published epidemiologists and microbiologists, Ofstead had a roomful of attendees taking a closer look at the risks that lurk in “patient-ready” endoscopes when inspections go beyond what can be seen by the naked eye. She also shared new evidence about the transmission of pathogens via dirty endoscopes, while offering practical advice for assessing the adequacy of scope reprocessing policies and practices, and promoting improved patient safety.

“Some common beliefs in the field are that guidelines and processes are adequate and ample, scopes are clean and ‘sterile’ [even though they can only be high-level disinfected], and infections associated with endoscopes are extremely rare,” said Ofstead. She further pointed out the belief by some that even if infections do occur, they are inconsequential and come from a patient’s own germs. A substantial amount of scientific data proves otherwise, however.

SHEDDING LIGHT ON THE TRUTH

The Centers for Disease Control and Prevention’s (CDC’s) 2008 guidelines for disinfection and sterilization indicate that roughly 5 million gastrointestinal procedures are performed annually, and the risk of endoscope-related infection is only one per 1.8 million procedures. Based on this CDC estimate, that amounts to just two or three cases in the U.S. annually. A 2013 report found these infection risk estimates are erroneous and based on flawed methods.¹

The CDC guidelines recommend removing visible organic residue, and, similarly, *ANSI/AAMI Standard ST58:2013, Chemical sterilization and high-level disinfection in health care facilities*, recommends cleaning until nothing is visible on the instrument. The Society of Gastroenterology Nurses and Associates



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(SGNA) recommends rinsing the brush in detergent solution after each pass and removing any visible debris before retracting and reinserting it back into the endoscope (repeating this brushing and rinsing process until there no visible debris remains on the brush).

“The problem is if you can’t see microbes, how do you know when an endoscope is clean enough?” asked Ofstead.

Process inconsistencies contribute to the problem. Although the guidelines point to a generic list of critical reprocessing steps (bedside cleaning; leakage testing; manual/auto cleaning; rinsing; high-level disinfecting; rinsing; drying; and storing), the reality is there are roughly 100 discreet steps involved in thorough endoscope processing. “Failure to perform any of those steps can result in disinfection failure,” she warned.

Ofstead’s CLEANR study², which involved five separate medical centers across five states, proved just how common those inconsistencies can be. The study consisted of direct observation and surveys of reprocessing staff and nurses, and interviews with management and infection control – and revealed that staff did not like performing all endoscope reprocessing steps. Roughly half of those

surveyed indicated that they didn’t like performing manual cleaning (brushing). What’s more, 36% didn’t like performing bedside wipe down/flushing and roughly that same percentage didn’t like flushing with alcohol because of the odor.

“Seventy-five percent felt pressure to work more quickly than what they thought was safe for the patient,” Ofstead added.

Results from the CLEANR study were alarming. During direct observation, only half of the 183 endoscopes were reprocessed properly. Even worse, manual cleaning was almost always inadequate. In fact, when scopes were reprocessed using manual cleaning, 99% of the time one or more steps was skipped or done incorrectly. Multiple steps were skipped 45% of the time, with failures most commonly seen in brushing all channels and components (57%) and drying with forced air (55%).

“These steps were skipped or performed incorrectly when we were right in the room watching,” explained Ofstead.

A WIDESPREAD PROBLEM

Of course, the missteps associated with endoscope cleaning weren’t limited just to facilities evaluated in the CLEANR study. To further underscore the challenges associated with endoscope reprocess-

ing, Ofstead and her Medical Director assigned their research staff and graduate students to research and explore other breaches associated with endoscope reprocessing.

“There were more than 500 lapses in [a six-year span] that were bad enough to appear in government documents, published papers, or media reports,” Ofstead noted, adding that by the time these cases came to light, hundreds and sometimes thousands of patients were exposed and placed at risk for serious, potentially life-threatening infections. More than 30,000 known patients have been notified of their exposure to contaminated scopes since 2005.

Although some of these incidents involved egregious reprocessing and handling mistakes, such as completely missed steps; use of old, incorrect or expired brushes; holding scopes in storage too long; inadequate staff training, etc., studies confirm that scopes can remain contaminated even after proper cleaning and adherence to published guidelines. One five-hospital study evaluating the effectiveness of manual flexible endoscope cleaning found evidence of cellular activity in endoscope channels after cleaning. Of the 275 endoscopes whose cleanliness was checked with adenosine triphosphate (ATP) tests, 30% of duodenoscopes, 24% of gastroscopes and 3% of colonoscopes had residual contamination.³ Other studies showed similar results. Microbiologist Michelle Alfa, Ph.D., conducted research at her own facility to assess residual contamination of endoscopes. Even though reprocessing staff did their best cleaning job on Friday, approximately 14% of scopes were growing viable bacteria or fungi when samples were taken on Monday mornings. Slightly more than 17% (17.4%) of colonoscopes had microbes, representing a one in five chance for contamination.⁴ Evaluation of reprocessing effectiveness by Of-

stead & Associates and their colleagues at Mayo Clinic lend further support of endoscope cleaning challenges. Recent studies involved 120 encounters with 37 endoscopes at two sites, and consisted of visual inspections, as well as sampling for protein, blood and carbohydrates. ATP testing was also conducted, along with culturing for aerobic bacteria.

“Our findings showed that cleaning according to guidelines doesn’t result in scopes that are free of contamination and viable microbes. This is deeply disturbing to us,” Ofstead said.

Despite the high incidence of residual contamination on colonoscopes, gastroscopes and duodenoscopes, the problem tends to be even worse for Endoscopic Retrograde Cholangiopancreatography (ERCP) scopes. Cultures taken from a reprocessed ERCP scope at an Illinois hospital following a New Delhi metallo- β -lactamase (NDM)-producing Carbapenem-resistant Enterobacteriaceae (CRE) outbreak in 2013 showed the scope grew NDM-producing *E. coli* and KPC-producing *k. pneumoniae*. Rectal swabs done on 50 patients found that 46% were colonized. Of the 243 patients exposed to a contaminated endoscope from January through September 2013, 114 were tested as of January 9, 2014, and 38 tested positive for CRE—far more than the 2 or 3 cases annually one would expect based on the CDC’s infection risk estimates. It’s important to note that CDC officials indicated no reprocessing breaches were found.⁵

“CRE outbreaks have up to a 50% mortality rate and CRE can transfer genetic material to other bacteria, rendering them resistant to antibiotics, as well,” Ofstead explained.

SLEUTHING FOR DIRTY SCOPES

Effective cleaning is essential for effective disinfection; however, as numerous incidents and studies confirm, even the



Endoscope Contamination

- Microbes enter body via non-sterile orifices
 - Mouth 200+ species
 - Large intestine 1,000 species)
- GI scopes contaminated with microbes during each use:
 - 1 million to 10 billion CFUs/mL
 - 1 billion to 100 billion bacteria in one gram of feces (1tablespoon holds about 14 grams of feces)

Citation: Ofstead, et al.





Microbes found on or in endoscope-related outbreaks since 2005

- *Acinetobacter baumannii*
- *Aspergillus spp.*
- *Burkholderia spp.*
- *Candida glabrata*
- *Clostridium difficile*
- Enterobacteriaceae (gen'l)
- *Enterococci spp.*
- *Escherichia coli*
- NDM-producing *E. coli*
- *Klebsiella pneumoniae and CRKP*
- *Mycobacterium*
 - *M. chelonae*
 - *M. fortuitum*
 - *M. immunogenum*
- *Ochrobactrum anthropic*
- *Proteus mirabilis*
- *Pseudomonas aeruginosa*
- *Pseudomonas picketti*
- *Salmonella spp.*
- *Serratia spp.*
- *Staphylococcus aureus and MRSA*
- *Stenotrophomonas maltophilia*
- Viruses
 - Condyloma
 - Hepatitis B and C
 - HIV
- Yeast

Citation: Ofstead, et al.



most diligent adherence to guidelines doesn't guarantee an endoscope will be free of microbial contamination. Fortunately, there are some useful tools and techniques available – some simple, some sophisticated – to help technicians rapidly determine if their endoscopes are clean.


For starters, Ofstead recommends developing internal auditing checklists for use by departmental supervisors. She also advocates announced and unannounced visits by someone else to help drive process accountability. Routine monitoring of endoscope surfaces and water samples from endoscope channels using rapid indicators for ATP, protein and hemoglobin/blood is also prudent. She also recommends culturing on a monthly or quarterly basis, or any time rapid indicators suggest substantial contamination on patient-ready scopes.

Reviewing guidelines; developing scope-specific internal policies; scheduling manufacturer-provided inservices to ensure all staff are trained how to properly clean, disinfect and store different endoscopes; conducting competency training and evaluations; directly observing practices; taking an active role in purchasing new endoscopy equipment and related materials; monitoring contamination levels; and implementing targeted quality improvement programs when contamination is detected can also go a long way toward reducing endoscope-related risks, according to Ofstead.

Equally important, she urges all staff members to pay attention to smells emanating from cabinets or even the endoscopes themselves. "If cabinets stink, if there's liquid dripping from the scopes, or if you smell alcohol after storage, something is wrong."

Keeping a keen eye on endoscopes, policies and practices is imperative, too. Are scopes stained? Are cleaning connectors discolored? Are scopes being stored vertically and is the cabinet bottom clean

and dry? Are clean scopes clearly labeled as such? Are up-to-date logs being maintained to document leak test results, HLD temperature, water filter changes, and minimum effective concentration (MEC) for HLD?

"Taking a good look around and keeping your eye out for these things will help," Ofstead assured. 

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