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Patient safety

Greater vigilance needed to combat ureteroscope contamination

A new study by Ofstead & Associates (St Paul, Minnesota) is the latest to raise concerns about infections associated with endoscopic procedures.

The study, which focused on ureteroscopes, found that the techniques used to clean and sterilize or high-level disinfect flexible ureteroscopes are not sufficient and leave behind contamination including debris, residue, and bacteria.

"Our study provides evidence that contaminated ureteroscopes are being used, with unknown implications for patients," lead researcher Cori L. Ofstead, MSPH, told OR Manager. Ofstead, an epidemiologist, has published numerous studies on endoscope reprocessing and contamination. This study adds ureteroscopes to the list of devices that threaten patient safety.

Reprocessing introduces contamination

Cori L. Ofstead, MSPH

Ofstead and colleagues conducted this prospective study at two large multispecialty healthcare facilities in the Midwest. The researchers performed microbial culturing, biochemical testing, and visual inspections of 16 ureteroscopes after they were cleaned and sterilized with hydrogen peroxide gas, and they found contamination on all of them:

- 100% had substantial protein
- 63% had detectable hemoglobin
- 44% had higher adenosine triphosphate (ATP) levels than anticipated
- 12% had microbial growth.

"Our team was quite surprised to find that two of the ureteroscopes, one at each site, had viable bacteria on them because sterilization should be eliminating all microbial life," says Ofstead.

Visual inspections identified debris protruding into channels, oily deposits, residual fluid discoloration, and a white foamy residue. The residue, says Ofstead, was an abnormality the researchers had never seen before (photos at right).

"The residue could be coming from other devices cleaned in the same area, or it could be reprocessing chemicals that came out of the channel and became hardened onto surfaces during the sterilization cycle," says Ofstead. "Whatever it is," she adds, "the technicians aren't seeing this white, foamy, crunchy material on the outside of the ureteroscope when they put it into the tray to be sterilized, but after sterilization it's there. The material is near the instrument port, which suggests that the vacuum of the sterilizer may be sucking something out of the inside of the ureteroscope and depositing it on the outside."

The researchers also tested two new ureteroscopes and found that hemoglobin and protein levels increased after initial processing—before they were ever used.

One of the new ureteroscopes had an ATP level of 338 and a protein level of 20, which are much higher than the benchmark for a clean gastrointestinal (GI) endoscope. Ofstead notes that for the study, they had to use benchmarks for manually cleaned GI endoscopes, even though the level of residual contamination on sterilized ureteroscopes should be far lower, because there are no reprocessing standards or benchmarks for permissible levels of residue specific to ureteroscopes.

The second new ureteroscope was first tested right out of the box and was found to have a low level of ATP, a protein level of 2, and an undetectable level of hemoglobin. After it was subjected to manual cleaning, automated cleaning and high-level disinfection (HLD), and sterilization, the researchers found hemoglobin on the ureteroscope, and the protein level had increased 10-fold.

"It definitely suggests that the reprocessing was introducing contamination," says Ofstead.

Closer examination also showed a foamy white residue on the external surface of both new ureteroscopes after the initial reprocessing and before they were ever used on any patients.

"This could put your mind at ease," notes Ofstead, "because that meant we weren't seeing residual tissue or patient secretions that had dried on the outside of the scope."

However, she says, if there are residual reprocessing chemicals or adhesive, or if the ureteroscope is degrading, that could be worse because the ureteroscopes are going into a patient's kidneys, and could deposit residual reprocessing chemicals or adhesives inside the urinary system and other places where there is access to the vascular system.

Fragile, high-risk devices

As an epidemiologist, Ofstead says she considers the flexible ureteroscope a high-risk type of endoscope because it:

- is more fragile than GI endoscopes
- can be easily damaged by frequent passage of instruments and lasers
- is exposed to blood, bodily fluids, and kidney stones that have bacteria in them
- has the potential for transmission of bacteria and debris directly into the bloodstream.

"We know these scopes have a high frequency of damage and repairs, which may be a 'canary in a coal mine' about the problems occurring in them even before they are identified as needing repair," she says.

Contaminated ureteroscopes also may pose patient safety and public health risks because of routine use of prophylactic antimicrobials, Ofstead adds.

Urologists almost always prescribe antimicrobials for ureteroscopy patients, but even so, studies have shown that up to 25% of patients get postoperative urinary tract infections (UTIs), and between 1% and 3% end up with sepsis.

"If patients are getting UTIs in some cases because the ureteroscopes are contaminated, eliminating that might drive down the rates of infection and sepsis," she says. "This, in turn, could allow us to use fewer antimicrobials and reduce our risk of developing resistance to these agents."

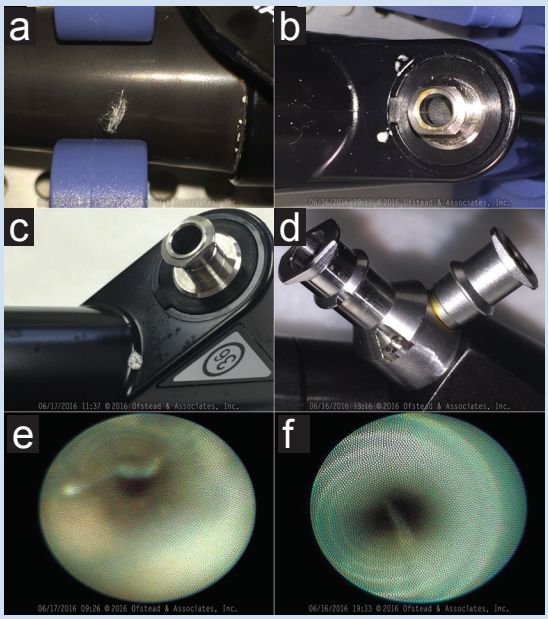
Frequency, cost of repairs

"We know from studies that ureteroscopes have a high frequency of failures during procedures that require them to be sent out for repairs," says Ofstead. The maximum number of uses for a brand new ureteroscope is about 60, but it can go as low as five, and after the initial repair, hospitals get fewer uses (from four to 11) before more repairs are needed. "The average number of uses between repairs in our ureteroscope study was 19," notes Ofstead, "and then they would fail leak tests or have functional problems requiring repair."

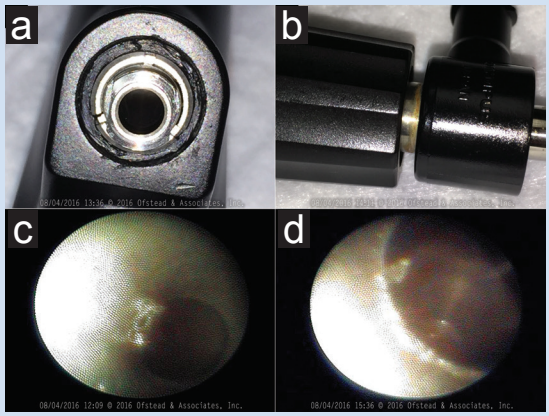
Those repairs come at a very high cost. "The cost per ureteroscope per year is somewhere between $4,000 and $11,000," she says.

If a ureteroscope has a functional failure during a procedure, it is disruptive, which is why instructions for use (IFU) for flexible ureteroscopes say two should be available for each case. However, many institutions don't have two available for every case, which is something OR managers should think about, Ofstead says.

Additionally, ureteroscope failure is frustrating not only to physicians, who must in-



Irregularities found at site A. (A) White fibrous debris on control handle and rusty discoloration and white residue near junction. (B) White residue near port and yellow discoloration on port. (C) White foamy residue and oily deposits. (D) Yellow discoloration on port. (E and F) Filamentous debris in channel.



Irregularities found at site B. (A) Dents and scratches around port. (B) Discoloration and buildup on valve. (C) Filaments of debris inside channel. (D) Flaky debris near channel-port junction.

Photos reprinted from the American Journal of Infection Control, 45/8, Ofstead C L, Heymann O L, Quick M R, et al, The effectiveness of sterilization for flexible ureteroscopes: A real-world study, 888-895, © 2017, with permission from the Association for Professionals in Infection Control and Epidemiology, Inc. Published by Elsevier.

terrupt the procedure, but also to reprocessing technicians, who must interrupt their workflow when the device fails the leak test and needs to be sent for repair.

Findings and recommendations

Ofstead notes that when they reviewed the methods used for reprocessing at the two sites for the study, they found that the OR staff were doing no bedside precleaning. There were also occasional reprocessing delays, which meant the ureteroscopes were not being delivered to the sterile processing department in a timely fashion.

In the sterile processing unit, the researchers identified some substandard drying of the ureteroscopes before they were sterilized. The researchers also noted that there was no preprocedural visual inspection by the OR staff.

This finding is important, says Ofstead, because the sterile processing department staff don't open a tray and check an instrument before it goes to the OR. They leave the trays sealed. Therefore, it is the responsibility of the OR staff to inspect instruments before use. Yet, no one at either study site noticed that there was visible residue on the outside of virtually all ureteroscopes.

Reprocessing staff at one site (Site A) also did not adhere to the IFU or guidelines for manual cleaning, which they explained in part was because they were using an automatic endoscope reprocessor (AER) that had a cleaning cycle and was doing HLD before sterilization.

Staff at the other site (Site B) exceeded the IFU and guidelines for manual cleaning and were doing cleaning verification tests, but there was still contamination on the ureteroscopes.

At the end of the study, Ofstead and colleagues summarized their findings and made recommendations to improve practice. The findings include:

- Contamination levels in the ureteroscopes at both sites exceeded the benchmarks for clean GI scopes, even though the ureteroscopes were sterilized.
- The microbial samples taken from the ureteroscopes had to incubate more than 48 hours before microbial growth could be identified. Microbial growth may be caused by suboptimal reprocessing, use of damaged ureteroscopes, or reprocessing practices that introduced contamination.
- Active monitoring is needed to ensure that ureteroscopes are sterile and safe for patient use. Monitoring may include unannounced evaluations of reprocessing practices, cleaning verification tests to ensure cleaning effectiveness, visual inspections of patient-ready ureteroscopes, and more frequent assessment and repair.

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Included in the recommendations are:

- Move toward sterilization of ureteroscopes. A lot of sites are still using HLD, which Ofstead says she does not believe is sufficient. "To do anything less than sterilization makes no sense," she cautioned.
- Review the IFU and ask manufacturers for guidance about how to approach reprocessing and to help train all staff who have responsibility for endoscope reprocessing.
- Make sure every step is done correctly, every time, and do cleaning verification tests to ensure that is happening. "Our study shows that technicians need to do cleaning verification tests. They would have never known that cleaning wasn't working if we hadn't tested the scopes," Ofstead notes.
- Perform routine visual inspections and send damaged ureteroscopes out for repair. "OR personnel have to take the responsibility to do visual inspections of the instruments they are using. They can't just assume that something in a sterile tray is okay to use," she says. "If you are using a scope that's damaged or dirty, sterilization isn't going to work. You have to make sure your instruments are in good repair, and make absolutely certain they get cleaned—for sterilization to work, those two things have to be in place," she says.
- Conduct unannounced audits to observe practices and to proactively find out if there are problems and correct them.
- Consider using single-use endoscopes and accessories, such as valves and buttons, which are on the market today.
- Have a strategy for managing quality issues and breaches. "It is important to know how you are going to respond when breaches happen so you can rapidly improve your quality," Ofstead notes.

What OR managers can do

"One of the most important things OR managers can do now to remove risk and improve the quality of reprocessing is read the new recommendations published between 2015 and 2016 by the Society of Gastroenterology Nurses and Associates (SGNA), Association for the Advancement of Medical Instrumentation/American National Standards Institute (AAMI/ANSI), and AORN," says Ofstead.

Among the new recommendations (sidebar, p 4):

- **Training.** All three organizations recommend training. Training should be done for new employees, and retraining should be done regularly and when there is new equipment. There should be competency testing by a qualified individual.
- **Bedside precleaning.** AORN says precleaning should be done at the point of care and should include wiping exterior surfaces, flushing the channels, and purging, and that precleaning should be done as soon as possible after the procedure is completed. Evidence shows that gram-negative bacteria replicate approximately every 20 minutes.
- **Visual inspection.** AORN clearly states that inspections should be done for every endoscope every time it's used. All three organizations are recommending the use of lighted magnification to see whether there is damage or debris.
- **Cleaning verification.** All three organizations recommend that tests be done to verify that cleaning worked because sterilization will not work if the ureteroscope is not clean. AORN specifies that these tests should be done after each use or daily.

"The bottom line is that when the new guidelines are followed, endoscope reprocessing takes more time and costs more," Ofstead says.

In a cost study she did last year with the International Association of Healthcare Central Service Materiel Management, she found that the hands-on time to reprocess one endoscope was 76 minutes, and the cost was between $100 and $300 to process one endoscope properly and in accordance with the new guidelines.

OR managers must give technicians enough time to do reprocessing properly and have enough ureteroscopes on hand so there is no pressure to go fast.

"If you are pressuring them to go faster, they are going to skip steps, and we are going to have the breaches we are seeing now," she says.

—Judith M. Mathias, MA, RN

Table 1: Overview of recommendations included in new reprocessing standards issued by SGNA, AORN, and ANSI/AAMI, compiled by Ofstead & Associates, Inc. Checkmarks indicate which organizations recommended each step, and new recommendations appear in **red**.

Step	Recommendations	Organization		
		SGNA 2015*	AORN 2016	AAMI 2015
PPE	Wear fluid-resistant face masks, eye protection (e.g., face shields), impermeable gowns, shoe covers, head covers, and gloves when reprocessing endoscopes	✔	✔	✔
	Wear clean gloves to handle reprocessed endoscopes		✔	✔
Bedside pre-cleaning	Begin immediately after the procedure ends	✓	✓	✓
	Inspect visually for damage	✓	✓	✓
	Wipe exterior and flush solution through all channels	✓	✓	✓
	Transport to reprocessing area in closed container	✓	✓	✓
Leak testing	Pressurize endoscope to recommended pressure	✓	✓	✓
	Maintain pressure for time specified in IFU (30+ seconds)	✓	✓	✓
	Manipulate all moving parts	✓	✓	✓
	Watch for a drop in pressure or bubbles indicating a leak	✓	✓	✓
Manual cleaning	Prepare detergent solution and soak endoscope	✓	✓	✓
	Scrub exterior surfaces	✓	✓	✓
	Clean removable parts and accessories	✓	✓	✓
	Brush channels multiple times using correct-size brushes	✔	✔	✓
	Flush channels with detergent and rinse with water	✔	✔	✔
	Reprocess reusable brushes after each use	✓	✓	✓
	Clean and disinfect transport containers after each use		✔	✔
	Perform biochemical cleaning-verification tests	✔	✔	✔
Visual inspection	Inspect endoscope visually *after every use*	✓	✓	✓
	Use lighted magnification for visual inspection	✔	✔	✔
HLD using an AER	Complete manual cleaning before loading AER (even when the AER has a cleaning cycle)	✓		✓
	Perform MEC test of disinfectant *before each use*	✔	✔	✔
	Attach channels, initiate cycle, and ensure completion	✓	✓	✓
	Unload AER promptly after cycle completion	✔		✔
Drying	Completely dry the endoscope *before* storage	✔		✔
	Flush alcohol through channels	✓		✓
	Dry channels using pressurized, filtered air	✓	✓	✓
	Dry exterior using a lint-free towel or wipe	✔	✔	
	Dry all accessories (valves, caps)	✔	✔	✔
	Transport to storage using a clean container		✔	✔
Storage	Store endoscope in a clean, well-ventilated area	✔	✔	✔
	Store accessories with their assigned endoscope	✔	✔	✔
	Use a positive pressure cabinet that circulates filtered air		✔	
Documentation	Use biohazard labels on dirty transport containers	✓	✓	✓
	Use a system (tag or label) to verify reprocessing occurred	✔	✔	✔
	Maintain records linking patient to endoscope	✓	✓	✓

Items marked as "new" reflect recommendations made in the 2015 SGNA standards, the 2016 AORN guidelines, and/or the 2015 ANSI/AAMI ST91 that did not appear in the 2011 Multisociety guidelines. *SGNA 2015 reflects two different sets of guidelines.

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