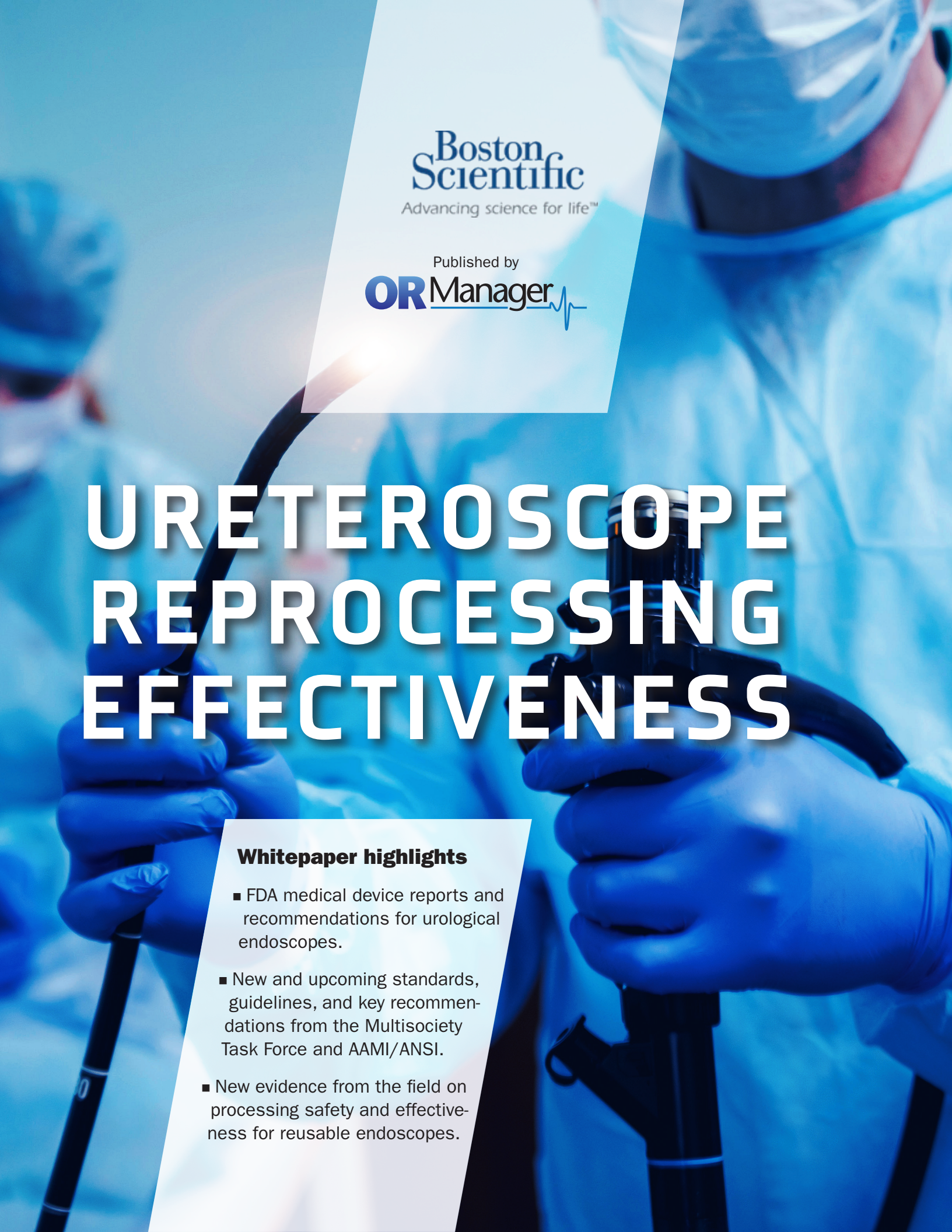

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URETEROSCOPE REPROCESSING EFFECTIVENESS

Whitepaper highlights

- FDA medical device reports and recommendations for urological endoscopes.
- New and upcoming standards, guidelines, and key recommendations from the Multisociety Task Force and AAMI/ANSI.
- New evidence from the field on processing safety and effectiveness for reusable endoscopes.

INTRODUCTION

Each year, there are more studies raising concerns about infections associated with endoscopic procedures and the techniques used to clean and sterilize or high-level disinfect (HLD) endoscopic devices.

In this whitepaper, sponsored by Boston Scientific, epidemiologist Cori L. Ofstead, MSPH, President and CEO of Ofstead & Associates, St Paul, Minnesota, presents a real-world view of ureteroscope reprocessing effectiveness and what has happened since the Food and Drug Administration's (FDA's) letter to healthcare providers in April 2021.

The FDA, in its letter, says it wants to raise awareness among health care providers about the risk of infections associated with reprocessed urological endoscopes, including cystoscopes and ureteroscopes.

The agency also says it has received and is investigating numerous Medical Device Reports (MDRs) that describe post-procedure patient infections or other possible contamination issues associated with reprocessing.

The FDA emphasizes the importance of following the manufacturer's labeling and reprocessing instructions for use (IFU) for these devices and their accessory components.

EVIDENCE/CONTRIBUTING FACTORS

Evidence cited by the FDA in its April 2021 letter includes receiving more than 450 MDRs on urological endoscopes since 2017 that resulted in:

- patient infections
- three deaths
- microbial contamination.

Factors the FDA says may have contributed to the adverse events include:

- inadequate endoscope reprocessing
- maintenance issues
- device design
- reprocessing instructions.

"It's sounding a lot like the situation with duodenoscopes, except, urological endoscopes don't have the complex elevator mechanisms the scopes used for ERCP [endoscopic retrograde cholangiopancreatography] have," notes Ofstead.

She and her team researched the FDA's database because they wanted to know if the problems that led the agency to release the letter were mostly associated with cystoscopes or with ureteroscopes.

They found that from October 2020 through March of 2021, the FDA was receiving more than 20 reports every month that were related just to ureteroscopes (sidebar, Evidence behind the FDA's health care provider letter).

"This stacks up to a lot of problems with flexible ureteroscopes," Ofstead says.

RECOMMENDATIONS

Also in its April 2021 letter, the FDA lists a number of recommendations for reprocessing urological endoscopes that organizations could use while it was determining the root causes of the problems.

The recommendations include:

- carefully following reprocessing IFU for precleaning at the point of care, leak testing, cleaning, and sterilization or

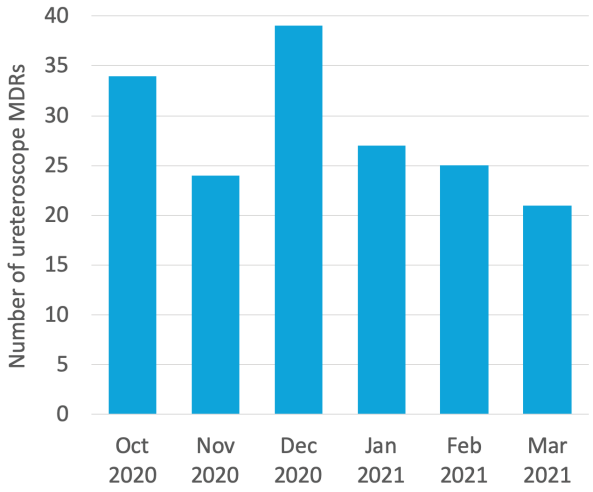
Evidence behind the FDA's health care provider letter (April 1, 2021)

FDA received >450 medical device reports (MDRs) on urology scopes since 2017:

- Patient infections
- 3 deaths linked to urology scopes
- Microbial contamination

Factors that may be contributing:

- Inadequate endoscope reprocessing
- Maintenance issues
- Device design
- Reprocessing instructions



HLD plus drying

- increasing awareness of reprocessing instructions for reusable accessories
- stopping the use of damaged devices because they can harm patients
- developing schedules for inspection and maintenance
- informing patients of risks associated with reprocessed urological endoscopes
- submitting MDRs for any adverse events experienced with urological endoscopes to MedWatch (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home).

Ofstead says the recommendation to inform patients of risks associated with reprocessed urological endoscopes was somewhat of a surprise, and that it raised some questions for her:

- "Does your informed consent process currently tell patients they are at risk of infection or injury related to the endoscope?"
- "If it doesn't, how is it going to impact your patient intake process and procedural efficiency if you start explaining the findings and risks to your patients?"
- "How do you think they are going to respond?"

NEW STANDARDS/GUIDELINES

Lane Jacobs, an expert in global product solutions for Boston Scientific, Marlborough, Massachusetts, notes that the evidence and recommendations from the FDA are "sobering at least," and asks Ofstead what changes she has observed.

A notable development is the strengthening of guidelines and standards for reprocessing endoscopes, she says.

A new "Multisociety guideline on reprocessing flexible GI [gastrointestinal] endoscopes and accessories" was published last winter, and an update of the Association for the Advancement of Medical Instrumentation (AAMI)/American National Standards Institute (ANSI) standard (ST) 91—"AAMI/ANSI ST 91"—is coming soon.

Even though the Multisociety guideline pertains to GI endoscopes, it spells out practices that healthcare workers need to be aware of when reprocessing all endoscopes, says Ofstead. In addition, AORN has signed onto this guideline.

Key recommendations in the Multisociety guideline focus on three areas:

All personnel

- should receive model-specific training and competency testing—this is no small task, says Ofstead, because most institutions have many different kinds of endoscopes, and they come with different reprocessing instructions
- must comply with infection prevention/control recommendations
- should wear gloves whenever handling endoscopes—there is good compliance with glove-wearing in the OR, she says, but personnel in some outpatient departments are handling fully reprocessed endoscopes with their bare hands. This is no longer permissible in the new guideline.

Reprocessing suite layout and equipment

- there has to be a dedicated reprocessing space with separation of dirty and clean areas—this means endoscopes cannot be cleaned or disinfected in patient care areas, and soaking endoscopes in a basin of disinfectant in patient care rooms or anywhere else is no longer acceptable, Ofstead says. The only time personnel can use manual soaking in disinfectant is when the automated endoscope reprocessor (AER) is broken or when there is an emergency situation
- HLD should be done in an AER.

Reprocessing practices

- initiate manual cleaning within 60 minutes after a procedure or follow IFU for delayed reprocessing—this involves extended soaking and extra cleaning steps
- use model-specific cleaning devices (brushes)—personnel cannot use one brush for every endoscope or every channel
- perform visual inspection with lighted magnification—this applies to every endoscope, every time
- sterilize all devices classified as Critical according to Spaulding—Ofstead notes that urological endoscopes, in particular ureteroscopes, should be classified as Critical because they are coming into contact with the kidney, which is sterile tissue. As such, they should be sterilized, not just disinfected
- completely dry endoscopes using 10 minutes or more of pressure-regulated forced air between uses—this should be done before they go into the sterilizer or before they go into storage, whether or not they are going to be used again that day, she says.

"There are some new things in this updated guideline," notes Ofstead, "and it's stronger than we have seen before in the field."

FDA REPORTS SINCE APRIL LETTER

With the FDA letter raising awareness of issues and the new Multisociety guideline in place, Jacobs asks, have things gotten better in the field?

Ofstead answers that from her perspective, things have not improved.

Her team reviewed new reports of adverse events related just to ureteroscopes released by the FDA since April. There were 20 to 25 reports a month until August and October, when they increased to more than 35 reports, and that uptick continued through the fall (sidebar, FDA reports released since the April 1 letter to healthcare providers).

"This indicates that either the problems haven't gone away or that more people are filing reports since they heard about the risks," she says.

Between April and October, the FDA's Manufacturer and User Facility Device Experience (MAUDE) database had 177 new MDRs, and 105 were for reusable flexible ureteroscopes, including:

- five patient injuries or exposures
- 11 reprocessing breaches
- 18 ureteroscopes with residual contamination in spite of reprocessing
- 72 damaged ureteroscopes.

The FDA also reported six new MDRs on semi-rigid or rigid reusable ureteroscopes, including:

- two reports of infections (one report had multiple patients becoming infected)
- four damaged ureteroscopes (one with a patient exposure).

The MDRs were associated with various brands and models.

Q&A: Ofstead and Jacobs queried a group of OR Managers about their familiarity with the FDA's MAUDE database and found out that 35% were familiar with it, and 58% wanted to hear more about it (sidebar, Familiarity with the FDA MAUDE database).

NEW FDA SAFETY COMMUNICATION FOR REPROCESSING BRONCHOSCOPES

On June 25, 2021, the FDA posted a new Safety Communication on "Flexible bronchoscopes and updated recommendations for reprocessing" that was similar to the April letter for urological endoscopes.

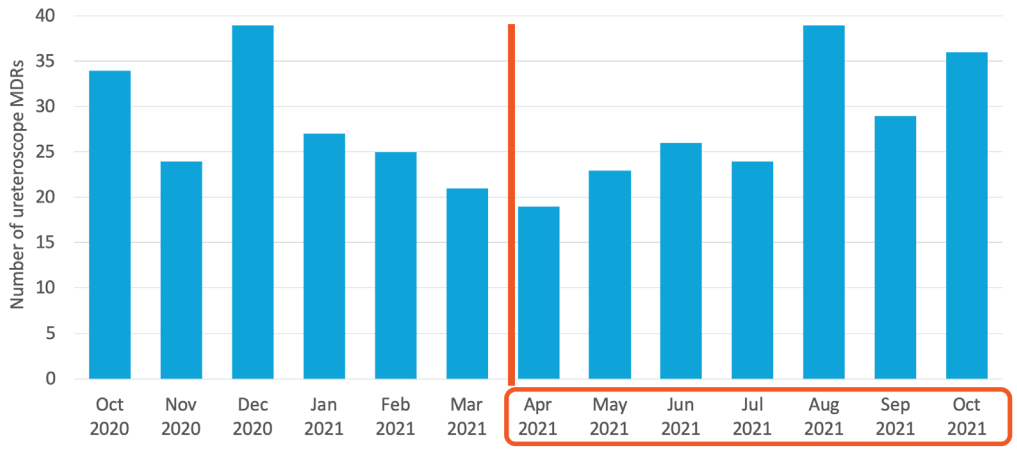
Between July 2015 and January 2021, the FDA received 867 new MDRs, and there were seven deaths related to infections or device contamination associated with reusable flexible bronchoscopes.

In the Safety Communication, the FDA recommends the following:

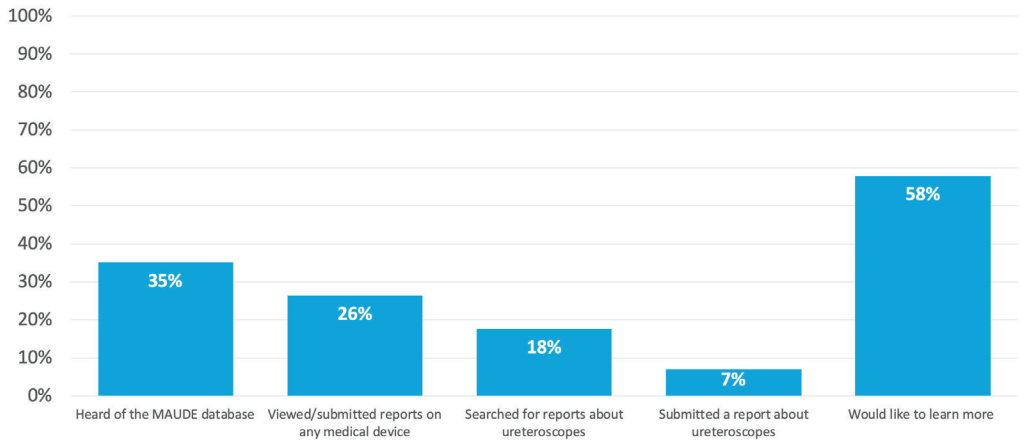
- consider sterilization rather than HLD—Ofstead notes that OR managers and OR personnel need to know that the FDA is now calling for sterilization rather than HLD for bronchoscopes
- follow manufacturer IFU
- perform routine inspections and maintenance
- do not use damaged devices
- discuss risks with patients
- consider single-use bronchoscopes in high-risk situations.

Ofstead adds that she is not sure how the FDA defines high-risk situations, but in her view it's high risk anytime an endoscope is inserted into a sterile area like a lung or a kidney.

FDA reports released since the April 1 letter



Familiarity with the FDA MAUDE database indicated by the first 200 webinar registrants



NEW EVIDENCE FROM THE FIELD ON ENDOSCOPE REPROCESSING

There is new evidence from the field showing the problems associated with reprocessing safety and effectiveness for reusable endoscopes, says Ofstead.

Breaches have been documented by several federal agencies, including the FDA, Centers for Medicare and Medicaid Services (CMS), and the Office of Inspector General (OIG) for the Veterans Administration healthcare system.

Among the breaches noted were:

- no precleaning of endoscopes after procedures
- no flushing of endoscope channels with detergent and water as recommended in the IFU
- lack of instrument maintenance and inspection
- improper storage of fully reprocessed endoscopes
- inadequate infection control, insufficient training, and lack of adherence to the dirty-to-clean workflow
- no reference manuals available
- no hand sanitizer or hand-wash stations available for reprocessing personnel
- personal protective equipment (PPE) breaches and PPE that wasn't convenient to personnel.

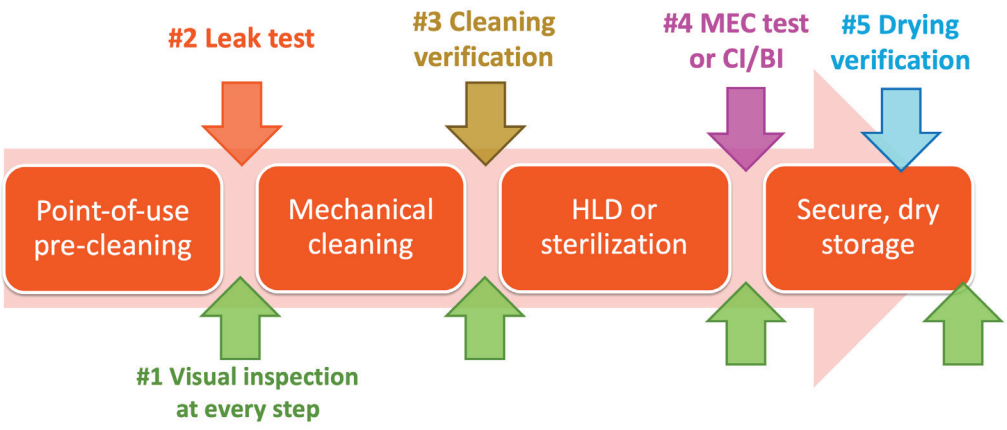
There is also new evidence showing the benefits of single-use flexible ureteroscopes, including that they:

- eliminate risk of cross-contamination
- are clinically equivalent to reusable ureteroscopes in procedural outcomes and complication rates
- reduce repair costs for reusable ureteroscopes when used occasionally
- have comparable environmental impact.

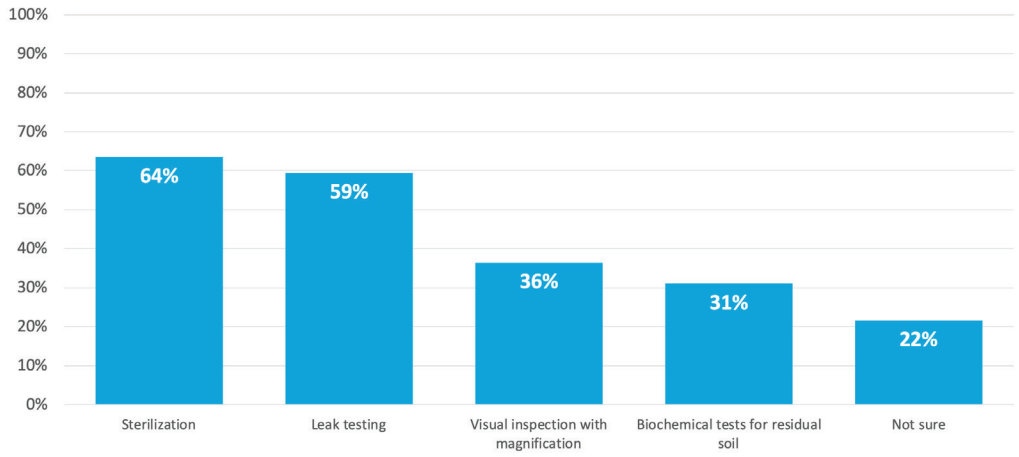
OVERVIEW OF URETEROSCOPE REPROCESSING EFFECTIVENESS

"Let's start by assuming that the ureteroscope is entirely free of soil and microbes before a procedure," says Ofstead. During the procedure it gets coated with blood, soil, and bioburden. At the end of the procedure, the nurse or technologist performs bedside pretreatment or

Reprocessing one endoscope takes >100 steps



Ureteroscope reprocessing practices indicated by the first 200 webinar registrants



precleaning at the point of care. This is followed by a thorough manual cleaning that should get rid of all the soil and most of the microbes. "We know that a few germs can remain on the surface after manual cleaning, so we use high-level disinfectants or sterilants to eliminate those," she says. If everything works correctly, the endoscope surface will again be free of soil and microbes and ready to use on the next procedure.

In reality though, precleaning at the bedside is often skipped, and manual cleaning isn't done right away, which allows biofilm to form and attach to the surfaces, she says. This creates a physical barrier between the HLD or sterilants and the surface of the endoscope, which allows some microbes to remain and create a risk for the patient.

Ofstead explains that reprocessing one endoscope is very complex and takes more than 100 steps. These steps fall into four main categories and five quality assurance checkpoints or pillars that are considered the foundation of patient safety (sidebar, Reprocessing one endoscope takes >100 steps).

The four main categories are:

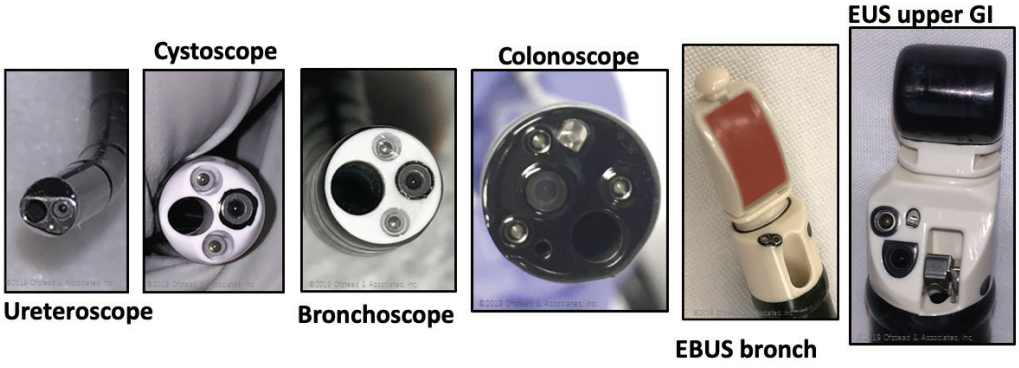
- point-of-use precleaning
- manual cleaning
- HLD or sterilization
- drying/storage.

The five quality checkpoints are:

- visual inspection at every step with lighted magnification
- leak testing to identify tiny leaks that could impact reprocessing effectiveness or allow fluid to get inside and damage the endoscope
- cleaning verification test to see if there's still soil on the endoscope after manual cleaning
- MEC (minimum effectiveness concentration) test or CI/BI (chemical and biological indicators) testing to make sure the disinfectant or sterilant is strong enough to kill any microbes that remain
- drying verification to ensure the endoscope is completely dry before attempting to sterilize it or putting it into storage.

"The new Multisociety guideline that says all personnel should receive model-specific training and competency

Distal ends of various commonly used endoscopes



Reprocessing quality and microbial growth detected at study sites

Successful reprocessing steps	Hospital	
	1	2
Bedside pre-cleaning	-	-
Leak test	-	✓
Manual cleaning	-	✓
Visual inspection (magnification)	-	-
Cleaning verification tests	-	✓
HLD and/or sterilization	-	✓
Drying	-	-
Storage and handling	✓	✓
Microbes in "sterilized" scopes	**8%**	**25%**

testing for all endoscopes really comes into play with ureteroscopes," says Ofstead, "because they are so tiny compared to other endoscopes, and it's hard to see the components on the distal end." This also is why ureteroscopes have to be inspected with a magnifying glass each time they are processed (sidebar, Distal ends of various commonly used endoscopes).

In addition, the ureteroscope is very fragile, and tiny brushes have to be used to clean the channels, and the brushes have to be inserted slowly and carefully or they can tear up the ureteroscope's channel, she says. "This is what happens if the technologists or nurses are hurrying. They need to know the steps, and they need to be given the time to do it properly," she says.

"Just remember," says Ofstead, "all endoscopes are not created equal. They're really different, and that's why nurses and technologists are supposed to have training and competency testing on each and every model."

Q&A: Ofstead and Jacobs queried a group of OR Managers on their reprocessing practices—64% said sterilization and 22% said they weren't sure (sidebar, Ureteroscope reprocessing practices)

REPROCESSING QUALITY AND OUTCOMES

Ofstead notes that she and her team performed reprocessing audits as part of a study on ureteroscopes at two hospitals, and they found room for improvement at both (sidebar, Reprocessing quality and microbial growth detected at study sites).

Personnel at Hospital 2 did most of the steps correctly, she says, however they did not do bedside precleaning, and they did not use a magnifying glass for visual inspection or dry the ureteroscopes.

At Hospital 1, personnel were not only skipping bedside precleaning, but they were making errors at almost every step.

Both of these hospitals sterilized their ureteroscopes, but because they were skipping the precleaning step, biofilm had formed that was protecting live microbes.

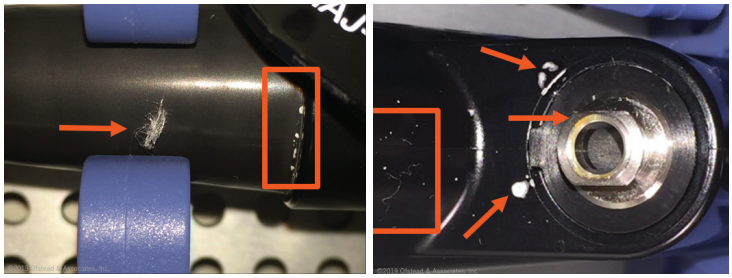
In addition, Ofstead says, when she and her team tested the sterilized ureteroscopes at the two hospitals, they found:

- 44% had adenosine triphosphate (ATP), which indicates there is some kind of cellular structure still on the ureteroscope
- 63% had hemoglobin, which means manual cleaning didn't work
- 100% had protein, which is probably due to poor manual cleaning, lack of precleaning, and delays in reprocessing
- 100% had visible defects.

When Ofstead's team took the lid off a tray holding a sterilized ureteroscope, they found fibers sitting on the control handle and a white substance in a crease of the control handle. There also was a white substance around the instrument port (sidebar, Debris and residue found on a sterilized ureteroscope).

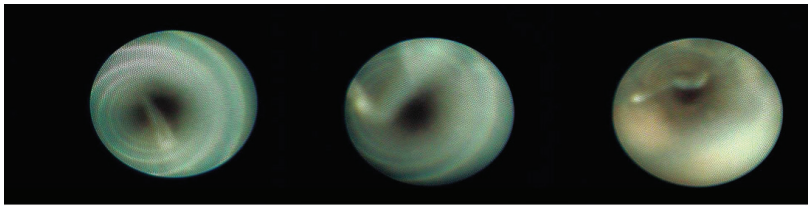
In addition there was debris and scratches inside the channel of the ureteroscope (sidebar, Filamentous debris inside ureteroscopes).

Debris and residue found on a sterilized ureteroscope



Filamentous debris inside ureteroscopes

Photographed with 0.8mm borescope



Ofstead says sterile processing personnel don't take the lids off sterile instrument trays to inspect them, so unfortunately, they would have no way of knowing about the debris on the ureteroscope. Therefore, it is really the responsibility of the OR staff to look for visible debris and defects when they open the sterile tray, and then let sterile processing know about it.

It is also important to note that some people believe sterilization kills microbes and eradicates everything from endoscopes, she says, but that is not true. "The cooked protein may not cause an infection, but it can cause inflammation."

URETEROSCOPE REPROCESSING EFFECTIVENESS STUDIES

Jacobs asks if there are any studies that show whether the soil and bioburden left on ureteroscopes actually cause problems for patients.

Ofstead notes that before the FDA released its April 2021 letter, two other research groups had published findings on ureteroscopes.

A 2019 European study by Legemate and colleagues examined 20 brand new, HLD ureteroscopes.

Of 389 samples collected after HLD:

- 40.6% had detectable microbes
- 12.1% had high levels of microbial growth
- 2.3% had uropathogens.

"These findings show that HLD utterly failed," says Ofstead.

Urinary tract infections (UTI) were reported after 25 (6.4%) procedures, and this happened even though the patients had all received prophylactic antibiotics.

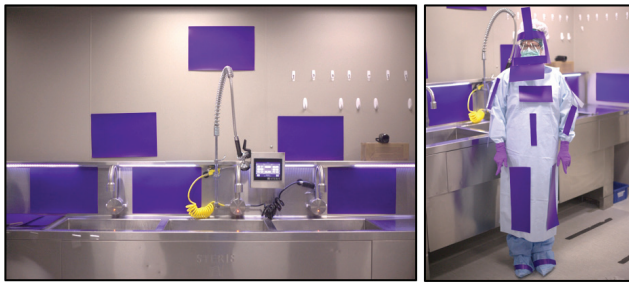
The authors concluded that the contamination levels they found implied that flaws in reprocessing were occurring and that they needed to strengthen their audit system to ensure that reprocessing was done correctly.

A study from King's College Hospital in London reported a multidrug-resistant *Pseudomonas* outbreak that resulted from two dirty ureteroscopes. Of 40 patients who had procedures with the ureteroscopes, 13 of them became infected with multidrug-resistant *Pseudomonas aeruginosa*, an attack rate of 32%. Again, all of these patients received prophylactic gentamicin, but they became infected anyway.

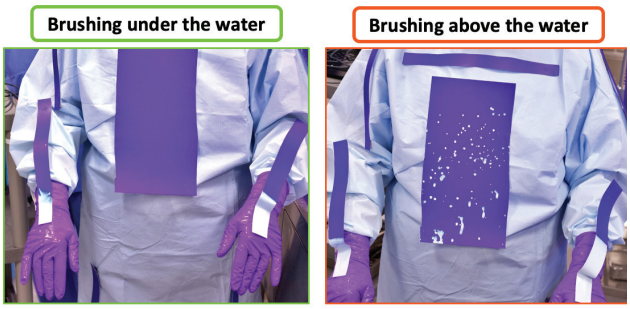
An audit of the ureteroscopes found exterior cuts that were visible, and the channels were damaged. They also found that the OR staff were not doing any bedside precleaning, and there were delays in completing reprocessing, which they blamed on insufficient staffing.

"The bottom line is that it doesn't make a difference if prophylactic antimicrobials are given or not. It doesn't reduce the infection rate, and it opens the door for superbug development," says Ofstead.

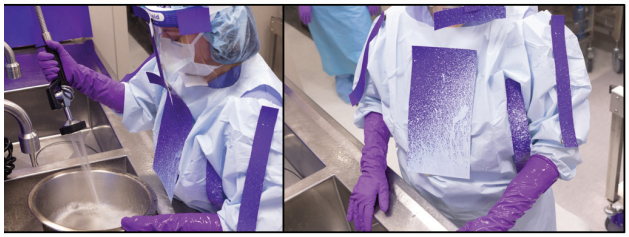
Splash pilot project: Seeing where droplets go in decontam



PPE exposure to cleaning solution



PPE exposure when power-washing a basin



PPE exposure when power-washing a basin

SPLASHING DURING REPROCESSING

During the COVID-19 pandemic, much attention has been focused on the potential for personal exposure of OR staff to viral particles during aerosol-generating surgical procedures. However, personnel in endoscopy and sterile processing also get splashed often.

Ofstead and her team did a pilot project in a decontamination area of a sterile processing department in the spring of 2021 to determine:

- which activities generate splashes
- where the droplets go
- whether scrubbing instruments under the water surface makes a difference
- how well PPE prevents exposure to splashing during reprocessing.

Their study methods included:

- direct observation by the research team
- use of blue moisture detection paper that turns white when splashed by water
- photographs and videos of droplets that were generated during various activities.

The research team stuck sheets of the blue water detection paper to the walls and backsplash areas as well as to PPE worn by the reprocessing technologists. Then they observed, photographed, and videoed where the splashes landed as the technologists went through reprocessing steps of various instruments, including ureteroscopes (sidebar, Splash pilot project: Seeing where droplets go in decontam)

They compared the splashing generated when brushing the channel of a flexible ureteroscope under and above the surface of the water. When the technologists held the ureteroscope under the surface of the water their hands and arms got splashed and there were numerous tiny droplets on their arms and chest areas. Holding the ureteroscope above the surface of the water resulted in the front of their gowns getting heavily splashed (sidebar, PPE exposure to cleaning solution; brushing under and above water).

After instruments are cleaned, the sink and instrument basin have to be cleaned, which is commonly done with a power sprayer. This resulted in the technologists getting splashed from head to toe (sidebar, PPE exposure when power-washing a basin; chest and below). Splashes also were detected under their chins, on their necks, and on their masks (sidebar, PPE exposure when power-washing a basin; head and neck).

“At the end of the day,” says Ofstead, “we found that instrument reprocessing has a high potential for environmental cross-contamination and personnel exposure because the splashes can travel up to 5 feet away.”

The PPE did not adequately protect the sterile processing personnel. Needed are engineering controls, administrative controls, better PPE, and more training for personnel, she says.

REDUCING RISKS

To reduce the risks to patients and personnel, the use of sterile single-use ureteroscopes should be considered in some circumstances, particularly for overnights and weekends when delayed reprocessing might be an issue, says Ofstead.

Facilities also should be moving to sterilization rather than HLD, and personnel should be noticing and repairing damage to ureteroscopes before they harm patients.

Organizations also have to provide personnel with reprocessing training and competency testing for every single model of endoscope, she says, and ensure that “proper steps are done for every endoscope, every time, no exceptions.”

JUDITH M. MATHIAS, MA, RN

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