

Properly sterilizing scopes still a challenge, experts say

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Maybe you're getting a gallstone removed or maybe your doctor says there's a new way to remove a painful kidney stone. There's a medical device to pluck them out, but how clean is it?

Years after rising concerns about infections caused by hard-to-clean reusable endoscopes, infection-control experts say it's an ongoing effort to properly sterilize the flexible lighted tubes used by doctors to look and work inside patients' bodies.

Two studies published this year found contamination even after cleaning in gastroscopes, used for upper GI procedures; endoscopes used for colonoscopies; and ureteroscopes, used to find and remove kidney stones.

Infection outbreaks have been linked to contaminated duodenoscopes (which pass into the small intestine), gastroscopes (stomach), bronchoscopes (airways) and cystoscopes (bladder).

Because they are usually reused in other patients, the scopes require extensive cleaning to prevent harmful germs from being passed from one patient to another.

"Some scopes are more difficult to clean and sterilize than other scopes," said Raymond Pontzer, director of infection prevention at UPMC. "As they get more intricate ... (there's) more difficulty."

A key concern is the transmission of drug-resistant microbes, he said.

Fewer than 10 years ago infections started to show up in patients after they had undergone the procedure known as endoscopic retrograde cholangiopancreatography, or ERCP. It's used to diagnose and treat problems in the bile and pancreatic ducts, primarily the removal of gallstones, Pontzer said.

A flexible lighted scope is inserted through the mouth, down the esophagus, the stomach and to the point where the ducts from the pancreas and gallbladder drain into the duodenum. X-rays are then taken. During the test, the doctor can insert small tools through the scope to take a sample of tissue for a biopsy, remove a gallstone from a bile duct or open a narrowed [bile duct](#) by inserting a small stent.

After an outbreak of antibiotic-resistant infections in 2012 in patients who had the procedure, UPMC investigated the disinfecting process for the scopes. The cleaning didn't eliminate all the bacteria, so UPMC switched to a sterilization process, which is the basis of current recommendations from the U.S. Food and Drug Administration. In the U.S., the FDA reports, duodenoscopes are used in more than 500,000 ERCP procedures each year.

They've caused issues around the world, Pontzer said. "We go to great lengths (to solve and prevent problems). In 2012 UPMC was the first to recognize a problem. We changed procedures and have had no issue since."

In 2015, the FDA released new guidelines for reprocessing reusable medical devices that addressed the risk of drug-resistant infection from contaminated duodenoscopes. It listed criteria to be included in manufacturer's instructions for reprocessing and recommended that scope makers consider the cleaning challenges early in device design and

test the cleaning method to prove its effectiveness. The FDA maintains the risk of infection is relatively low, but it continues to collect reports of adverse events linked to the devices (accessible at www.fda.gov).

Despite the advance, the latest research found risks. A team led by Cori Ofstead, head of Ofstead & Associates of St. Paul, Minn., found reprocessing procedures still don't do the job. Ten years after her first study found endoscopes resistant to cleaning, in January Ofstead reported on a study of 20 endoscopes over a seven-month period. There were visual inspections, microbial cultures and biochemical tests to detect organic matter. The research team found all scopes had irregularities (fluid, discoloration and debris), and 12 had microbial growth after cleaning. Signs of organic residue were at higher levels in the gastroscopes compared to the endoscopes used for colonoscopy.

In a recent interview, Ofstead said the research supports recent cleaning guidelines from national nursing organizations.

"The assertion is you should be inspecting visually with lighted magnification to see if there is a defect or contamination (on the scope)," she said. "We can't expect the sterilization to work if we're not absolutely certain the cleaning is working."

The diameter of the channels within scopes vary. Large scopes like that for ECRP have an instrument channel of 4 millimeters. The ureteroscope channel is far narrower at 1 millimeter.

In June's *American Journal of Infection Control*, Ofstead reported the results of her study of sterilization for flexible ureteroscopes at two large multispecialty health care facilities in the Midwest. Despite reprocessing, all 16 ureteroscopes had visible irregularities and contamination with microbial growth, hemoglobin, protein or a chemical indicating the presence of living cells. The study concluded that there should be regular

checks of reprocessing practices, routine cleaning verification tests and visual inspections according to the accepted guidelines.

"I believe this is a highly complex task that should be done by highly trained (specialists)," she said. "There may be factors that go beyond the human factors. Scopes may not be as durable as we thought."

Pontzer said ureteroscopes require a special touch: "They're small, flexible and have lasers in them. They are delicate and take some careful cleaning without damaging. As soon as they are used, they are manually cleaned, then go through disinfection, then the sterilization process."

UPMC has had no outbreaks of infection from scopes since the ERCP experience, and he's confident new endoscope practices are working.

He explained UPMC has found it's best to clean the channels of each scope immediately after use. No bedside precleaning was done in the two locations in the Ofstead ureteroscope study.

"After they have been reprocessed, before they are used again, we make a visual exam."

That step is important, he said. "Sometimes (there is something) overlooked."

In situations like the ureteroscope study, where contamination is detected, Pontzer said, "(The scopes) may not be looked at quickly enough. ... When they're done being processed, they are hung out to dry. They have to be hung correctly, dried correctly. Before using (a scope), the standard process is to look at it. ... They're supposed to inspect it before they utilize it."

Although more costly, disposable single-use scopes can be used in some

cases, Pontzer said.

Because bronchoscopes are inserted into a person's airways, a disposable scope helps reduce the risk of transmitting bacterial or fungal organisms from one patient to another, Pontzer said. In particular, tuberculosis and related organisms might be resistant to treatment and especially risky.

As new devices are introduced, technicians and nurses are trained specifically to use them.

"These scopes are a godsend to these patients. ... The benefit far outweighs the risks," Pontzer said. "We use them hundreds of times a day."

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