An Intensivist's Handbook

Preventing bronchoscope cross-contamination through proper care and cleaning
Cross-contamination linked to bronchoscopes is a problem on the rise. But anecdotal evidence suggests that while most intensivists agree that it exists, many also think it isn't an issue in their institutions.

In the past two years, two large endoscope-related outbreaks in major academic medical centers have brought new scrutiny from regulators and the general public.

In light of the recent endoscope outbreaks, is bronchoscope related cross-contamination a growing concern? Experts and institutions recommend that bronchoscope users should adhere to safety issues and act to implement best practices immediately.
A Review of Current Evidence on Bronchoscopy and Infection
A look at recent endoscope infection in general and specific cases of bronchoscope outbreaks and pseudo outbreaks

Biofilm: The Invisible Problem
A brief discussion of why biofilm is a particular problem for bronchoscopes

Three Experts’ Perspectives on Bronchoscopes and Cross-Contamination
Atul Mehta M.D., Jahan Azizi and Larry Muscarella, PhD, reveal the most important factors for physicians and hospital staff to consider in order to mitigate risk

No Shortage of Guidelines
Direct links to major institutional guidelines addressing the best practices for endoscope reprocessing

Institutional Thought on Cross-Contamination: A Sampling from the CMS, ECRI Institute, FDA, and AORN
Snapshots from a few of the major institutions on different dimensions of endoscope related cross-contamination

Preventing Bronchoscope-Associated Infection: Best Practices for Cleaning and Disinfecting the Bronchoscope
Short videos featuring Atul Mehta of the Cleveland Clinic discussing his key tips for bronchoscopy

Alternatives to Reusable Bronchoscopes: Disposable Sheaths and Bronchoscopes
A brief summary of two alternate solutions for bronchoscopy designed in part to mitigate cross-contamination risks
A Review of Current Evidence on Bronchoscopy and Infection

Approximately 500,000 bronchoscopy procedures are performed in the U.S. each year. While bronchoscopes must undergo reprocessing between procedures, if the meticulous process is not followed, the device can remain contaminated which could result in cross-contamination.

The Consensus Statement of the American College of Chest Physicians and American Association for Bronchology, published in 2005, cited four studies from 2003 on outbreaks caused by contaminated bronchoscopes (Kirschke, Srinivasan, Cetse and Singh) (1).

More recently (2015), the FDA issued a safety communication entitled, "Infections Associated with Reprocessed Flexible Bronchoscopes" (2)."

Endoscope related cross-contamination became national news last year with two cases involving carbapenem-resistant enterobacteriaceae (CRE) and New Delhi metallo-β-lactamase (NDM)–producing CRE. The former occurred at UCLA Medical Center in early 2015 and the latter at an unnamed Illinois medical center. The UCLA case made national news when it was reported on ABC Morning News, and the Illinois event was described at length in MMWR (The Mortality & Morbidity Weekly Report) in January 2014. Both cases are summarized here and are followed by brief summaries of similar cases.

CARBAPENEM-RESISTANT ENTEROBACTERIACEAE (CRE) AT UCLA MEDICAL CENTER

In 2015, one hundred sixty patients were exposed to carbapenem-resistant enterobacteriaceae (CRE), and seven were infected, at Ronald Reagan UCLA Medical Center (3). The hospital cited contaminated medical instruments as the cause (4).

The CRE was likely transmitted via contaminated medical scopes used in endoscopic procedures to diagnose and treat pancreatic and bile duct complications (5). The procedures had occurred between October 2014 and January 2015. A news release notes that the bacteria may have contributed to

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the deaths of two patients. Of seven total endoscopes, two were found to have been contaminated.

UCLA responded that it had sterilized the scopes according to manufacturer’s standards, but is now using a decontamination process that goes above and beyond those and national standards.

**NEW DELHI METALLO-β-LACTAMASE (NDM)–PRODUCING CRE IN ILLINOIS**

Nine Illinois patients who had undergone endoscopic retrograde cholangiopancreatography (ERCP) to diagnose and treat problems of the bile and pancreatic ducts, subsequently presented with New Delhi metallo-β-lactamase (NDM)–producing CRE in 2013.

This case was reported in detail by the CDC in January 2014 (5).

According to the CDC, infections with carbapenem-resistant Enterobacteriaceae (CRE) are increasing among patients in medical facilities and CRE that produce *Klebsiella pneumoniae* carbapenemase (KPC) have been responsible for much of this increase in the United States (5).

**How Contaminated Equipment Can Potentially Spread Infection**

<table>
<thead>
<tr>
<th>Scope is used on an infected patient.</th>
<th>Scope becomes contaminated.</th>
<th>Scope is disinfected but some contamination remains. Contaminant may also spread to the reprocessor.</th>
<th>Infection is spread to a subsequent patient via the original scope or another scope that has been cleaned in the contaminated reprocessor.</th>
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An Intensivist’s Handbook: Preventing bronchoscope cross-contamination through proper care and cleaning 2
New Delhi metallo-β-lactamase (NDM)-producing CRE have the potential to add to this burden. From the time it was first reported in 2009, through 2012, 27 patients with NDM-producing CRE have been confirmed by the CDC from isolates submitted by state laboratories. Since January 2013, a total of 69 patients with NDM-producing CRE have been identified in the United States (5). Of these, 44 were from northeastern Illinois.

BACTERIA SURVIVE HIGH-LEVEL DISINFECTION IN ENDOSCOPE REPROCESSOR

After manual cleaning and high-level disinfection in an automated endoscope reprocessor, cultures were obtained from the ERCP endoscope used on five of the case-patients. NDM-producing E. coli and KPC-producing K. pneumoniae were recovered from the device’s terminal section (the elevator channel). The E. coli isolate was highly related (>95%) to the outbreak strain

The CDC noted that the design of the ERCP endoscopes might pose a particular challenge for cleaning and disinfection.
[The CDC] suggest[s] that health-care facilities with CRE outbreaks consider the possibility of ERCP-related transmission.

a particular challenge for cleaning and disinfection (5).

Among 91 ERCP patients who were initially notified that they had potential exposure to a culture-positive endoscope, 50 returned for rectal surveillance cultures. NDM-producing E. coli were recovered from 23 (46%). An additional 12 patients with NDM-producing CRE have been identified in northeastern Illinois, bringing the total during January–December 2013 to 44. In September 2013, as a result of an investigation, hospital A changed ERCP endoscope reprocessing from automated high-level disinfection to gas sterilization with ethylene oxide; no new cases with exposure to a gas-sterilized ERCP endoscope have been identified.

The CDC concluded that this investigation highlights the potential for CRE transmission following ERCP. They suggest that health-care facilities with CRE outbreaks consider the possibility of ERCP-related transmission. If ERCP-related transmission of CRE is suspected, reprocessing and preventative maintenance procedures for ERCP endoscopes should be evaluated in consultation with the manufacturer of the endoscope and automated endoscope reprocessor, if used.

While national news coverage and even the Senate HELP committee have been focused on duodenoscopes, there is evidence that bronchoscopes—among other endoscope types—can be involved in spreading infections. Lawrence Muscarella, PhD, founder of LFM Healthcare Solutions, states, “While not well publicized, contaminated bronchoscopes, like duodenoscopes, are also prone to transmitting deadly superbug infections” (6). Dr. Muscarella also discusses a case of CRE being found on a bronchoscope after reprocessing the scope.

OTHER CASES: THE ENDOSCOPE AS A POTENTIAL DISEASE VECTOR

Patients exposed to bronchoscopes contaminated with Pseudomonas aeruginosa were at increased risk of pseudomonal infection in a 2015 study of 75 scopes. The study traced the problem to one endoscope washer-disinfector (7).

Japan

Bronchoscopes were also suspect in an outbreak of multi-drug resistant Pseudomonas aeruginosa (MDRP) in the ICU and ER of a Japanese hospital in 2007. The device was suspected because five patients had undergone
bronchoscopy. The hospital reexamined and adjusted its disinfection processes and disinfected the scopes appropriately, which ended the outbreak (8).

**Baltimore**
A pseudo-outbreak involving 12 patients, and including contamination with *P. putida, Pseudomonas aeruginosa,* and *Stenotrophomonas* at a large tertiary care hospital in Baltimore. The case highlighted the risks of ‘will-fit’ maintenance and using nonstandard bronchoscope repair parts from a third party vendor (9).

**Atlanta**
A damaged bronchoscope was also implicated in the infection of a cluster of patients, again with *Pseudomonas aeruginosa,* at a 1,000-bed teaching hospital in Atlanta (10).

**South Korea**
A bronchoscope was implicated in a pseudo-outbreak of *Stenotrophomonas maltophilia* at Chosun University Hospital in South Korea. Investigators traced the pseudo-outbreak to a bronchoscope which had been inadequately cleaned and disinfected (11).

**Legionnaire’s Disease from contaminated ice**
The bronchoscope's efficacy at transmitting disease is not limited to *P. aeruginosa.* Over an 8-month period, an unnamed hospital noticed a marked increase in the number of *Legionella Pneumophila* isolates recovered from bronchoalveolar lavage fluid specimens recovered during bronchoscopy (12).

This pseudo-outbreak was traced to a contaminated ice machine in a bronchoscopy suite, and to the practice of immersing uncapped syringes of sterile saline in contaminated ice baths. Cleaning the ice machine and its water filter ended the outbreak.

**Contaminated washer**
Another pseudo-outbreak, this one of *Mycobacterium chelonae,* in the bronchoalveolar lavage fluid of nine patients was traced to contamination of an automated bronchoscope washer. Molecular typing using PCR was useful in confirming these findings (13).

**Almost unlimited potential contaminants**
An analysis of microorganisms that could potentially contaminate a bronchoscope during examination was found to include all agents which would cause bronchitis or pneumonia in immunocompromised or otherwise healthy individuals...
Cases of Infection Related to Contaminated Equipment

- **Los Angeles, CA**
  - 160 patients at UCLA Medical Center exposed to carbapenem-resistant enterobacteriaceae (CRE), with seven infected, likely via contaminated medical scopes.

- **Illinois**
  - Nine Illinois patients presented with New Delhi metallo-β-lactamase (NDM)-producing CRE after undergoing ERCP in 2013. Since January 2013, 44 of 69 patients in the U.S. with NDM-producing CRE were from northeastern Illinois.

- **Atlanta, GA**
  - Damaged bronchoscope implicated in the infection of a cluster of patients with *Pseudomonas aeruginosa*.

- **Baltimore, MD**
  - Pseudo-outbreak involving 12 patients, including contamination with *P. putida, Pseudomonas aeruginosa*, and *Stenotrophomonas*.

- **South Korea**
  - Bronchoscope implicated in a pseudo-outbreak of *Stenotrophomonas maltophilia*.

- **Japan**
  - Bronchoscopes suspect in *Pseudomonas aeruginosa* (MDRP) outbreak.

- **Undisclosed Location #1**
  - Pseudo-outbreak of *Legionella Pneumophilia* traced to a contaminated ice machine in a bronchoscopy suite.

- **Undisclosed Location #2**
  - Pseudo-outbreak of *Mycobacterium chelonae* traced to contamination of an automated bronchoscope washer.
or pneumonia in immunocompromised or otherwise healthy individuals, according
to a study by Wendt and Kampf (14). The potential contaminants included
bacteria, mycobacteria, yeasts and moulds, enveloped and non-enveloped
viruses and rarely parasites. Since bronchoscopy can result in epithelial
injury with subsequent bleeding, all blood-borne pathogens including
HIV and HBV were also potential contaminants, the authors said. Wendt
and Kampf suggest that the disinfection process include chemical disinfectants
for bacteria, fungi and viruses. Sporicidal activity may only be warranted in specific
patient populations, say the authors, such as after bronchoscopy of suspected
anthrax patients, or before examination of the severely immunocompromised.

CONCLUSION
While outbreaks and pseudo-outbreaks of antibiotic “superbugs” have been
getting increased attention, whether or not best practices are being followed
by clinicians is perhaps the greater concern. According to the literature and
institutional evidence, it is relatively easy and quite common for diseases to
colonize the bronchoscope, making it a highly efficient vector. In addition,
reprocessors, washers, ice machines, and other areas are also susceptible to
spreading contamination.
Biofilm: The Invisible Problem

Of all the contaminants commonly found on bronchoscopes, biofilm may be the most pernicious. Its accumulation contributes to the failure of cleaning and decontamination.

An authoritative study by Pajkos, Vickery and Cossart describes biofilm as “multi-layered bacterial or fungal cell clusters embedded in an amorphous extracellular material composed of exopolysaccharides of bacterial origin (15).” The problem is that the extracellular material cements cells firmly to the surface and to each other and thereafter defies cleaning.

Fortunately, biofilm is not impenetrable, according to Pajkos et al. It can be removed by physical or chemical means.

“However, the air/water channels of many endoscopes are too small to be cleaned mechanically and require cleaning solely by chemical means, and the chemicals used for removal of biofilm in industry and incompatible with the materials used in endoscopes,” they say (15).

To find out whether biofilm develops on the internal channels of endoscopes during routine use, Pajkos et al. studied 13 biopsy channels and 12 air/water channels from 13 used gastrointestinal endoscopes from 13 different hospitals in Australia.

Electron microscopy of the biopsy control channels showed that all had surface defects in the form of microscopic cracks, grooves and pits, some covered by biofilm.
Cleaning did not remove the contagion from smaller air and water channels. Pajkos et al. found microorganisms entrapped in soil, in one case with extensive biofilm formation. Healthy bacterial cells were overlaid by exopolysaccharide and soil, shielding microorganisms from the damaging effects of disinfectants. Brushing removed a majority of the soil, but microscopic deposits were still seen in patches.

Pajkos et al. postulated that biofilm could prevent germicide from penetrating, and could inactivate disinfectants.

“Even rigorous cleaning with detergent and brushing, and disinfection with 2% glutaraldehyde followed by rinsing with 70% alcohol and forced-air drying left positive cultures in 18% of endoscopes tested (11 of 60 instruments).” Pajkos et al. concluded that current cleaning and disinfection processing of endoscopes are inadequate, and

Of all the contaminants commonly found on bronchoscopes, biofilm may be the most pernicious. Its accumulation contributes to the failure of cleaning and decontamination.
that damage to the lining by accessory instruments contributes significantly to soil accumulation. The authors also suggested that endoscopes be redesigned.

Pajkos et al. concluded that current cleaning and disinfection processing of endoscopes are inadequate...They suggested that endoscopes be redesigned. (15)

**Electron Micrograph Scans of Two Different Air/Water Channels with Biofilms**

- Low-power view showing a confluent layer of soil and biofilm.
- Multilayered biofilm consisting of healthy-looking cells surrounded and overlayed with amorphous-looking exopolysaccharides.
Three Experts’ Perspectives on Bronchoscopes and Cross-Contamination

A literature review does not yield reliable epidemiologic evidence of physician views on bronchoscope cross-contamination. We compromised by interviewing two leaders in the field. Additional thoughts are drawn from a forthcoming article by Lawrence F. Muscarella, PhD, on reconciling discrepancies between reprocessing instructions from endoscope manufacturers and automated endoscope reprocessor (AER) manufacturers.

**Q:** “We can’t imagine anyone not knowing about the potential for bronchoscope cross-contamination. Does everyone assume it just happens to the other guy?”

**DR. MEHTA:** “Actually, very few people know that bronchoscopes can spread infection. Only about 10% of physicians even know that every bronchoscope comes with a manual. And only half of that amount ever actually read the manual.” (He refers us to a paper entitled “The high price of bronchoscopy” [1]).

“But if you don’t read the manual, you don’t know the exact procedure of how to clean the bronchoscope.”

**Q:** “That’s alarming.”

**DR. MEHTA:** “If you were to make rounds with doctors in hospitals, you will quickly learn that they believe that cleaning the bronchoscope is the domain of nurses, assistants, respiratory therapists or bronchoscope technicians. Especially in community hospitals, the...
“Very few people know that bronchoscopes can spread infection. Only 10% of physicians even know that every bronchoscope comes with a manual.”

—Dr. Atul Mehta, MD

majority of doctors simply do not know how to clean the bronchoscope.

“In our teaching program, we train the fellows how to clean the bronchoscope in the first two weeks of the rotation. But in private institutions, there are no teaching programs.

“Physicians simply aren’t aware that there is the potential of causing cross-contamination with scopes. As a result, a doctor might use a scope, leave it on the table (without cleaning it) and in comes the next doctor who reuses it.”

[We notice two large charts in the bronchoscope cleaning area.]

DR. MEHTA: “If those posters are not there, the person cleaning the bronchoscope may not be performing all of the required steps. The only way the problem can really be solved is through education.”

Q: “And smaller institutions?”

DR. MEHTA: “When smaller hospitals cannot employ a full-time bronchoscopist, one will travel from institution to institution. If he or she continually puts the scope in the same bag, that’s the worst thing to do.”

Q: “Is biofilm a particular problem?”

DR. MEHTA (nods): “Sixty percent of all hospital infections are caused by biofilm. It’s less likely that biofilm will form in the endoscope if it is mechanically cleaned. But if you don’t actually brush the device and you just put the scope in the automatic processor, chances are the biofilm will still be there.”

Q: “Critical care doctors use endoscopes less frequently than bronchoscopists. Might they not think that contamination such as the recent case of CRE is an endoscopy issue, and not relevant to the ICU? And is it?”

DR. MEHTA: “Since CRE can occur anywhere, it isn’t just an ICU or endoscopy bug.”

[We asked for detail about how bronchoscopes spread disease.]

DR. MEHTA: “What is different about CRE is that the patient won’t show infection for eight days, at which point the bronchoscopy is forgotten. Very few labs actually take the time to follow-up on potential infections.

“Ideally, you would culture every scope once every month, but nobody does that.”
Q: “Is it true that some hospitals clean different scopes in the same processor?”

**DR. MEHTA:** “Yes, many smaller institutions typically clean bronchoscopes, endoscopes and colonoscopes in the same processor. However, there may not be a proper connector for every instrument, which leads to inadequate cleaning.”

Q: “CMS recently published a checklist for endoscopes. If there’s a conflict between what the scope manufacturer says to do, and what the reprocessor says to do, you’ll need to come up with a solution. Do you have any resources to solve that problem?”

**MEHTA:** “This is one of the bigger issues in proper scope care. There are typically two posters provided with cleaning instructions. However, if the posters are not hanging where I clean the scope, there is no way I know how to properly clean it. But the scope should be cleaned immediately after the procedure. Biofilm (presentation) is very subtle—it can, for example, even be hidden in the filter of an automatic processor.”

**JAHAN AZIZI, BS, CBET**

Jahan Azizi, BS, CBET, has over 28 years of experience in Biomedical Engineering. As the Clinical Engineer Consultant for the University of Michigan Health System Office of Clinical Safety until 2014, Jahan’s responsibilities included investigating and analyzing potential professional liability claims and incidents related to medical equipment; and advising and training medical staff in assessing, resolving and preventing incidents of risk to patient. He is currently the Director of Regulatory Affairs for Heart Sync Inc., a medical device manufacturer. Mr. Azizi has presented on patient safety and equipment issues to the Association for the Advancement of Medical Instrumentation (AAMI), the American Society for Testing of Materials (ASTM), and the FDA’s MedSun reporting group, and has published in AAMI Horizons and AORN Journal. Mr. Azizi talked with us about bronchoscopes and the challenges of disinfection.

Q: “So, why not just follow cleaning procedures?”

**MR. AZIZI:** “It’s a complicated issue. For example, small clinics often don’t have adequate space to clean scopes properly. Take the example of the sterilant glutaraldehyde. It is an effective cold sterilant, but can’t be used casually. To use it properly, you need negative pressure, at least 15 air exchanges per hour. A small clinic may have cleaning equipment tucked away in a little closet where they put the scopes in a bucket to soak. They are not really outfitted for 15 air exchanges.”
“The posters may be up, but nothing in them says how often you need to change glutaraldehyde-treated water. And glutaraldehyde is not potent all the time. So cleaning procedures have the potential for the human factor to cause problems.”

Q: “Is training ever an issue?”

MR. AZIZI: “Always. Does the staff have the same level of competence and training? I don’t think that’s happening at all of the institutions, or all the small clinics.”

Q: “How would you assess the risk of biofilm?”

MR. AZIZI: “Microbial and bacterial contamination can live underneath biofilm and become activated once the instrument is soaked and put to use. We found that as you hydrate those layers of biofilm, you loosen some of the bacteria that was living under the crust. If it’s not visible to the naked eye, and you don’t have a test mechanism, it’s difficult for the clinician to even know it exists.

“It’s not uncommon for clinicians to use a scope in the morning and not clean it until the end of the day, eight hours later. This is especially true if the clinician is responsible for the cleaning.

“But if a scope is not cleaned within two hours, bioburden is stuck in it—in a cannulated item. Now it has become impossible to clean.”

Q: “How would you solve that?”

MR. AZIZI: “I believe what should happen is to create an automated system for cleaning all these instruments. But that doesn’t exist. Most manufacturer’s instructions rely on manual cleaning, within X number of hours. That’s what has been validated. But that validation was not based on real-life scenarios. At least not real-life, worst-case scenarios.”

Q: “What’s an example of a real-life scenario?”

MR. AZIZI: “You have two different scopes, sometimes similar, from two different manufacturers. You may have two different sets of instruction for processing. You have to have two posters, because the protocols may be...”

“...But if a scope is not cleaned within two hours, bioburden is stuck in it...Now it has become impossible to clean.”

—Jahan Azizi, BS, CBET
different. All of this has the potential to create conflicts.

“A problem you see in large and small hospitals is varying approaches for cleaning the same instruments. This causes more headaches and complications. Or, alternately, you will see two or three different types of scope from different manufacturers being used in the same hospital. So then you have the requirement for two or three different types of cleaning. But once you’re under the mask and gloves, it’s really difficult to find the right procedure for each scope.

“This is a problem CMS should address; they should set guidelines for standardization.

“In a busy hospital, you can see that scope number one in the morning gets really clean, cleaner than scopes number four and five, which they need to turn around faster. You’re worried about volume and quantity throughput.”

Q: “Is there a solution?”

MR. AZIZI: “Automation, or going with a disposable product. If you’re a small place, you simply don’t have the means of cleaning your equipment properly. You don’t have the physical space, the 15 air exchanges, and you probably don’t have the manpower to do it properly in the appropriate time frame. So maybe you have to move away from that approach and go with something that you do not have to do the cleaning on.”

Q: “What is the most elusive problem?”

MR. AZIZI: “The areas that are not visible to the naked eye, the unaided eye. How can you really verify that you cleaned all the area of the lumens? If you have a scope, two, three, four or eight feet of length, you cannot really see all the nooks and crannies, all the channels, all the angles. So what do you need to do? You should come up with a process at least to be able to visually see them. And then moreover, try to check biochemically.

“Unfortunately, there are not really a lot of indicators in the market that you can just pick. Take a swab, look for biofilms, or look for other stuff that you didn't clean. Because if you really cannot clean it, you cannot high-level disinfect or sterilize it. Nobody out there said that if you put a dirty item in the autoclave it will get rid of all the bacteria.”
In discussing the extent of the reprocessing problem, Muscarella states, “Indeed, user confusion about which set of reprocessing instructions and reprocessing kits to follow and use—those provided and recommended by the AER’s manufacturer, or the endoscope’s manufacturer—has been linked to a number of bacterial outbreaks, with associated patient morbidity and mortality.

“An example of such a discrepancy would be a significant conflict between the endoscope’s reprocessing instructions and those of the automated endoscope reprocessor, or AER, with
each manufacturer recommending the use of its own unique and disparate set of reprocessing adaptors, fittings and caps, termed 'reprocessing accessories.'"

There are many publications that state the problem of these discrepancies...

“But, whereas each of these safety publications underscores the importance of the AER and endoscope manufacturer's reprocessing instructions being consistent, the specific advice they provide hospitals about how to resolve identified discrepancies is limited..."
No Shortage of Guidelines, But Which One to Follow?

Since 2000, there have been multiple authoritative bronchoscope disinfection and care guidelines published by professional societies:

- **AORN Guidelines 2016**
- **FDA 2015**
- **AAMI 2015**
- **CHEST Physicians Consensus Statement 2005**
- **British Thoracic Society 2001**
- **Association for Professionals in Infection Control 2000**

The 2005 Consensus Statement declared that a review of the available literature suggests that all episodes of cross-contamination are preventable (16).
Institutional Thought on Cross-Contamination: A Sampling from the CMS, ECRI Institute and the FDA

An audit of three major institutions’ stance on endoscope cross-contamination suggests that they are anything but laissez-faire. The following is a snapshot from each institution on one or more dimensions of the problem. Note, this section is not intended as a comprehensive summary of each institution’s position, but rather a sample.

FDA CAUTIONS FACILITIES ABOUT REPROCESSING
In a safety communication issued in September 2015 titled “Infections Associated with Reprocessed Flexible Bronchoscopes,” the FDA’s analysis of Medical Device Reports (MDRs) between 2010–2015 identified two recurring themes: failure to meticulously follow manufacturer reprocessing instructions and the continued use of devices despite integrity, maintenance and mechanical issues (2). As a result, the FDA recommended six precautions for facilities that reprocess flexible bronchoscopes ranging from strictly adhering to manufacturer’s reprocessing instructions to storing bronchoscopes so that the likelihood of contamination is minimized. The safety communication also referenced the 2005 American College of Chest Physicians and American Association for Bronchology Consensus Statement as the recommended guideline for bronchoscope reprocessing.

CMS AND DISCREPANCIES IN HIGH-LEVEL DISINFECTION INSTRUCTIONS
Muscarella’s article referenced above attempts to address a CMS checklist with requirements that must be adhered to in order to be accredited for payment by CMS. In section 3.A. the checklist states: “Hospital policies address steps to take when there are discrepancies between a device manufacturer’s instructions for completing high-level disinfection. To address this requirement, hospital staff must coordinate across departments on a variety of issues” (17).

ECRI INSTITUTE DISCUSSES THE CRUCIAL ROLE OF THE ENDOSCOPE IN RISK MANAGEMENT
The ECRI Institute has identified endoscope reprocessing failures as a top 10 health technology hazard for the last several years, including elevating it to the top of its most recent list for 2016 (18). ECRI Institute also pointed
out a simple and familiar paradox: if an organization is not currently experiencing patient infections as a result of endoscopic procedures, how is it to know that it has a flaw in its reprocessing process? Scott R. Lucas, PhD, a program manager at ECRI Institute, provided this answer: “It is often an increase in patient infection rates or a positive culture from a periodic microbiological sampling that triggers an investigation.” He suggests mitigating the risk of hospital-acquired infections related to endoscopy with a proactive approach.

The ECRI Institute has identified endoscope reprocessing failures as its top health technology hazard in its most recent list for 2016.
The problem's source can actually be elusive. Chris Lavanchy, ECRI Institute's engineering director, suggests for example that increases in workload can have an impact on effective endoscope reprocessing, a complex process. “A gradual increase in workload can lead to procedural deviations or shortcuts, particularly if the staff feel pressure to reprocess the scopes faster,” said Lavanchy.

THE FDA NOTES RISK OF CROSS-CONTAMINATION FROM ENDOSCOPE IRRIGATION CHANNELS
In new draft guidance issued January 20, 2015, the FDA warned that backflow in irrigation channels used with flexible gastrointestinal endoscopes can pose an infection risk to patients. The guidance, entitled “Mitigating the Risk of Cross-Contamination from Valves and Accessories Used for Irrigation through Flexible Gastrointestinal Endoscopes,” highlights the cross-contamination risks associated with specific types of irrigation valves and accessories when used with flexible gastrointestinal endoscopes (19). It also outlines strategies to mitigate the risk of cross-contamination between patients. Clinicians often use a water bottle to supply irrigation during colonoscopy or esophagogastroduodenoscopy, and typically use a single water bottle for multiple patients without reprocessing it between patients. The FDA says that this practice raises the risk of cross-contamination because, with some devices, the water bottle and associated tubing and connectors can become contaminated with blood or stool in a phenomenon referred to as “backflow.”

Other channels including air and biopsy channels can also present a potential source for cross-contamination. The FDA recommends that, in the absence of valves to prevent backflow, the water bottle and any associated tubing and connectors should be reprocessed or discarded after every patient use. For auxiliary water channels with external valves, any device that is directly connected to the auxiliary water inlet (up to and including the distal valve in the fluid pathway) should be considered contaminated and should be reprocessed or replaced after every patient use.

“A gradual increase in workload can lead to procedural deviations or shortcuts, particularly if the staff feel pressure to reprocess the scopes faster.”

—Chris Lavanchy, Engineering Director, ECRI
Preventing Bronchoscope-Associated Infection: 
Best Practices for Cleaning and Disinfecting the Bronchoscope

Are Bronchoscopes At Risk?

Best practice takeaways:

• Each sub-specialty must be trained properly in bronchoscope care
• Off-hours and weekend staff must properly clean all scopes

The Critical Steps to Bronchoscope Sterilization and Storage

Best practice takeaways:

• As scopes become smaller in diameter, cleaning is even more important
• Bronchoscopes should be cleaned immediately after use
Proper Care of Bronchoscopes Takes Teamwork and Logbook

Best practice takeaways:

- Every institution should have one head of bronchoscopy services and depending on size, perhaps two
- Every unit must maintain a proper log documenting the instrument used, patient's name and the results
- There should be great teamwork between bronchoscopy, the microbiology lab, and infection control in the event of an epidemic

Why Bronchoscope Cross-Contamination Is Under-Reported and Under-Recognized

Best practice takeaways:

- Cross-contamination is under-recognized and under-reported, but the problem is real
- It takes a high degree of suspicion to diagnose bronchoscopy-related infection
- A recommended standard of practice is to call patients within 24–48 hours about potential infection symptoms
Why Leak Tests Are Critical to Contamination Prevention

Best practice takeaways:

• Once a biofilm forms, it is almost impossible to eradicate

• Any breach either outside or inside a scope means that it must be repaired before being used

• A leak test should always be used to determine if a scope is damaged

Two Major Areas of Bronchoscope Failure and How to Prevent Them

Best practice takeaways:

• Bronchoscopy nurses or assistants often don’t know how to perform a leak test, especially in community hospitals

• Bronchoscopy units require a dedicated assistant

• Mechanical cleaning is vital, but often overlooked

• Repairs must be done by an authorized repair provider or by the manufacturer
Alternatives to Reusable Bronchoscopies: Disposable Sheaths and Bronchoscopes

SHEATHED ENDOSCOPES
To date, advances made to improve and streamline bronchoscope care and improve safety include two solutions: disposable sheaths (Cognetix Medical) and disposable or single-use bronchoscopes (Ambu).

The disposable sheath, commercially known as EndoSheath, contains a suction/working channel and therefore mitigates the risk of the reusable portion of the endoscope from becoming contaminated.

The sleeved endoscopes are marketed to the following specialties:
- Laryngoscopy
- Cystoscopy
- Sigmoidoscopy
- Colonoscopy
- Gastroscopy
- Bronchoscopy
- Esophagoscopy

The Cogentix Medical system of sleeves do not fit over standard bronchoscopes (such as Olympus and Karl Storz) but instead require the purchase of new bronchoscopes and video systems.

Process for Using Sheathed Scope Technology

1. Purchase proprietary scope
2. Prior to procedure, insert into proprietary sheath
3. After procedure, remove and dispose of sheath
4. Clean scope with simplified procedure

FOR ILLUSTRATIVE PURPOSES ONLY. NOT INTENDED TO REPRESENT SPECIFIC PRODUCTS.
DISPOSABLE BRONCHOSCOPIES
The disposable bronchoscope (Ambu) is primarily intended for bedside bronchoscopies in critical care settings as well as airway management in the OR and ED.

The aScope 3 system is for use in a hospital environment. The disposable scopes have been designed to be used with the aView monitor and can be used with endotherapy accessories and other ancillary equipment for endoscopy within the airways and tracheobronchial tree.

Disposable bronchoscopy come in three outer diameters—a 5.8 mm with a 2.8 mm channel (aScope™ 3 Large), a 5.0 mm with 2.2 mm channel (aScope™ 3) and 3.8 mm with a 1.2 mm channel (aScope™ 3 Slim).

Since the entire bronchoscope is disposed of after a procedure, the risk of handle contamination is mitigated.

Contamination of handles, particularly on laryngoscopes, has recently been studied and is a well-documented risk (20).

With the increasing risk of resistant bacterial strains, disposable scopes offer a unique opportunity to avoid the risk of cross-contamination. Additionally, the time and cost associated with reprocessing is also eliminated so valuable resources could potentially be used for other procedures.

Process for Using Disposable Scope Technology

Unwrap scope from sterile packaging

After procedure, dispose of entire scope
REFERENCES


19. Food and Drug Administration (FDA). Mitigating the risk of cross-contamination from valves and accessories used for irrigation through flexible gastrointestinal endoscopes. 20 Jan 2015.
