
California APIC Coordinating Council
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Sutter Center, Sacramento, CA

Presenters:

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Learning Objectives

- Summarize recent articles related to the increased risk for endoscopy-associated infections.
- Learn why assumptions on the effectiveness of endoscopy reprocessing is currently being re-evaluated
- Discuss some strategies for strengthening quality improvement programs.

*All images are from Google images unless otherwise indicated*

More than 20 million GI endoscopic procedures are performed every year in the USA.

GI endoscopy is considered a very safe procedure. What is the incidence of pathogen transmission? Experts assume it is a rare event....

Are the assumptions valid
#4 ECRI Top Ten Healthcare Hazards for 2015, Up from #6 in 2014 and still top 10 from 2011, #3

“Although the incidence is likely very low, the consequences of reprocessing failures can be severe. Of the 13 immediate threat to life (ITL) discoveries from the Joint Commission surveys conducted in 2013, seven were directly related to the improper sterilization or high-level disinfection of equipment (Joint Commission 2014). This topic, which has appeared on our Top 10 Health Technology Hazards list in the past, retains a spot near the top because we continue to see media reports, receive problem reports, and investigate cases involving the use of potentially contaminated instruments on patients.”

HIGH PRIORITY HAZARD REPORT
ECRI Institute Recommends Culturing Duodenoscopes as a Key Step to Reducing CRE Infections

PROBLEM:

- Over the past seven years, at least seven hospitals have reported outbreaks of carbapenem-resistant Enterobacteriaceae (CRE) bacterial infections associated with duodenoscopes used for Endoscopic Retrograde Cholangiopancreatography (ERCP) procedures. ERCP procedures are used to treat and diagnose a variety of conditions of the gall bladder and pancreas, including ductal obstructions, stones, and malignancy.
- Investigations of earlier infection outbreaks among these hospitals identified the cause as either poor reprocessing technique or damaged scopes.
- Investigations of more recent outbreaks have determined that infections can still occur with undamaged scopes despite close adherence to recommended reprocessing procedures.

- We believe this is a generic hazard and that most, if not all, duodenoscope models in use are susceptible.
- Because CRE bacteria have become resistant to most available antibiotics including carbapenem (considered a last resort, “big guns” antibiotic), infected patients can be very challenging to treat.
- The CDC estimates that CRE contributes to the cause of death in up to 44% of infected patients.

ECRI Institute
The Discipline of Science, The Integrity of Independence.

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March 4, 2015

Updated Information for Healthcare Providers Regarding Duodenoscopes

- FDA has received inquiries from healthcare providers about whether they should cancel ERCP procedures, based on the fact that one specific model duodenscope manufactured by Olympus (the TJF-Q180V) does not currently have a 510(k) clearance. FDA is not recommending that healthcare providers cancel ERCP procedures for their patients who need them.

- FDA recommends the following:
  - Thoroughly clean and disinfect duodenoscopes, pursuant to the manufacturers’ instructions;
  - Have a comprehensive quality program in place for reprocessing duodenoscopes;
  - If you suspect that a duodenscope may be associated with a patient infection, take it out of service and meticulously clean and disinfect it until it is verified to be free of pathogens;
  - Inform patients of the benefits and risks associated with ERCP procedures, including the risk of possible infection;
  - Discuss with your patients what they should expect following the ERCP procedure and what symptoms (such as fever or chills, chest pain, severe abdominal pain, trouble swallowing or breathing, nausea and vomiting, or black or tarry stools) should prompt additional follow-up;
  - Submit a report to the manufacturer and to the FDA via MedWatch if you suspect problems have led to patient infections.

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March 26, 2015

URGENT SAFETY NOTIFICATION

IMPORTANT UPDATED LABELING INFORMATION:
NEW REPROCESSING INSTRUCTIONS FOR THE OLYMPUS TJF-Q180V DUODENOSCOPE.

ATTENTION: Endoscopy Department, Risk Management and Reprocessing Units

Dear Health Care Professional:

Olympus America Inc. (OAI) is writing to inform you that we are issuing validated, new reprocessing procedures for the Olympus TJF-Q180V duodenscope (“TJF-Q180V”), consisting of revised manual cleaning and high-level disinfection procedures.

These new reprocessing procedures should be implemented as soon as possible. The new cleaning procedure requires the use of a small brush cleaning brush (MAJ-1888) which Olympus anticipates shipping no later than May 8, 2015. Until your facility has received the brushes, you should continue to clean the TJF-Q180V duodenscope in accordance with the original cleaning instructions.

In addition to the new cleaning brush referenced above, the new TJF-Q180V reprocessing procedures require additional rinse steps during cleaning and manual cleaning, manual disinfection, endoscope rinsing and alcohol flushing. These new TJF-Q180V flushing steps for pre-cleaning and manual disinfection are provided in the Attachment to this Safety Notification. Updated reprocessing manuals containing these instructions will be distributed by Olympus.

Please note the key differences in the new reprocessing procedure:

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What are the assumptions?

- Reprocessing guidelines are effective and produce scopes that are clean and ready to use
- Endoscopy-associated infections are rare
- Reprocessing guidelines are being followed and lapses are rare

Assumptions and Risk Assessment Drives Behavior

- When are patients notified? What do we tell them?
- Do we report the lapse? Do we even know when one has occurred?
- What actions do we take when a lapse occurs?
“Flexible endoscope reprocessing has been shown to have a narrow margin of safety. Any slight deviation from the recommended reprocessing protocol can lead to the survival of microorganisms and an increased risk of infection.”


Assumption #1: Reprocessing guidelines are being followed and lapses are rare.

- “My people are following guidelines and are doing a good job, they aren’t making mistakes.”

- “These are good people who work hard and do their job well”

- “We are following SGNA guidelines to the letter.”
Assumption #1: Reprocessing guidelines are being followed and lapses are rare.

- Reprocessing lapses are rarely reported in medical journals leading to the false conclusion that reprocessing lapses are rare.
- A recently published study looked for reprocessing lapses in peer-reviewed literature, gov’t reports, state health depts, CDC, FDA, Dept of Veteran affairs and media reports. The study was limited to Jan. 2005 – June 2012.
  - They found that improper endoscope reprocessing is an ongoing and pervasive problem.
  - In Table 1, if you add up the number of estimated exposed patients you come up with over 30,500 people exposed and this is just the tip of the iceberg. > 99% of these cases were not found in peer-reviewed medical journals.
Reported gastrointestinal endoscope reprocessing lapses: The tip of the iceberg.


Why are flexible endoscopes difficult to reprocess?

• Complex design
• Multiple, long, narrow, channels that are difficult to clean
• Lack of consistent effective training
• Lack of time and resources for adequate reprocessing
• Visual inspection not adequate to monitor efficacy of reprocessing.
• > 120 step involved in reprocessing!!

30,577 Pts exposed through endoscopes, MRSA, K pneumonia (CRE), Hep B, HepC
Basic steps for Reprocessing Flexible Endoscopes

• Pre-cleaning – Bedside
• Transport to Reprocessing - <1 hour
• Manual Cleaning
• Rinsing
• High-level disinfection – Manual, Automated (AER)
• Drying (Alcohol flush, Air flush)
• Storage

Observed Activity    Steps Completed (%)  (n = 69)

- Leak test performed in clear water 77
- Disassemble endoscope completely 100
- Brush all endoscope channels and components 43
- Immerse endoscope completely in detergent 99
- Immerse components completely in detergent 99
- Flush endoscope with detergent 99
- Rinse endoscope with water 96
- Purge endoscope with air 84
- Load and complete automated cycle for high-level disinfection 100
- Flush endoscope with alcohol 86
- Use forced air to dry endoscope 45
- Wipe down external surfaces before hanging to dry 90

Guidelines were followed only 1.4% of the time (manual cleaning followed by automated high-level disinfection) vs 75.4% using ECR (automated cleaning and disinfection).

Multiple steps skipped 45% of the time.

Ofstead, Cori L., Wetzler, Harry, P., Alycea Snyder, Rebecca A. Horton
“The biggest problem is that we can’t see inside these scopes. To put it bluntly, we’re just taking a shot in the dark with reprocessing.”

- Nancy Chobin, RN, St. Barnabas Health Care System. Livingston, New Jersey
  - “Probing the Challenges of Endoscopes”
  - Biomedical Instrumentation & Technology  May/June 2011

**Assumption 2:** When guidelines are followed the result is an endoscope that is clean and safe
Looks can be deceiving. This scope only received pre-cleaning in the patient room after the procedure. The Relative Light Unit (RLU) reading for the exterior of the distal tip was 633 RLU’s.

**Assumption 2**
When guidelines are followed the result is an endoscope that is clean and safe.

“We are following the reprocessing guidelines so our scopes are clean and safe to use on our patients. Are you saying our scopes are not clean?”

*Even after proper reprocessing your scopes could still be dirty*
**Water Pressure and Connectors Do They Matter?**

Of course they do

- Low pressure purging outlets are used to irrigate the scope channels
- High pressure purging is designed to irrigate the smaller/hard to reprocess channels (e.g. Aux. water channel, Duodenoscope (ERCP) elevator wire channel)

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**Time & Water Temperature**

- Custom Ultrasonics AER recommends a H20 setting of 110 degrees F/43 degrees C
- Temperature should not exceed 115 F/46 C and should NOT drop below 105 F/40 C
- Immersion time requirements are based on the detergent, enzymatic and high level disinfection manufactures Instructions for Use (IFU)
- Questions to ask ourselves: Did the temperature meet its requirements? Has the scope been immersed long enough to meet the manufactures IFU? Have I ensured that all of the cycles were met?
Water Quality & Filters

- In the U.S. as we know water quality varies and thus could affect the outcome of a process.
- Potable water although containing a low number of water borne microorganisms can still pose a risk when reprocessing flexible endoscopes.
- Some questions to ask: Are water softeners needed? Do we need a filtration system? If so what type?
- Custom Ultrasonics uses two different filter in their Automated Endoscope Reprocessors (AER’s) that require routine changes.
  a. .5 micron filter for removing gross sediment from water
  b. 0.1 micron bacterial

All Scopes are NOT created equal

DUODENOSCOPE WITH ELEVATOR WIRE CHANNEL

DUODENOSCOPE WITHOUT ELEVATOR WIRE CHANNEL
Assumption 2
When guidelines are followed the result is an endoscope that is clean and safe

- **Issues addressed:** Assess the bioburden level in routinely reprocessed flexible GI endoscopes that were stored over a week-end and to define a realistic benchmark for residual microbial levels.
- **Findings:** 14.1% of scopes tested had detectable growth after reprocessing.
- **Conclusions and Recommendations:** A benchmark of < 100 cfu/mL is achievable.


- This abstract won the William A. Rutala Abstract Award—recognizes the best abstract on the subject of disinfection, sterilization, or antisepsis.
- **Summary, 3 scope styles, 5 hospital sites**
- **245 scopes tested** (duodenoscope/gastroscope/colonoscope)
- 3 out of 20 scopes used to examine GI tracts and colons were improperly cleaned
Reprocessing might not be enough to remove biofilm
American Society for Microbiology, Denver, CO, May 18-21, 2013

Transmission of multidrug-resistant organisms and other pathogens via contaminated endoscopes: Can buildup of biofilm be eliminated by routine cleaning and high-level disinfection?
Alexandra Dirlam Langley, Ph.D.<sup>2</sup>, Pritish Tosh, MD<sup>3</sup>, Michelle Alfa, Ph.D., Ph.D<sup>1,4</sup>, Harry P. Wetzler, MD, MSPH<sup>1</sup>, Cori L. Ofstead, MSPH<sup>1</sup><sup>1</sup> Ofstead and Associates, Inc., St Paul, MN. 2Mayo Clinic, Rochester, MN, 3 Diagnostic Services of Manitoba, Winnipeg, MB, Canada; 4 University of Manitoba, Department of Medical Microbiology, Winnipeg, MB, Canada.

Issues addressed:
To assess the effectiveness of current reprocessing methods at preventing biofilm formation or removing it from endoscope channels.

Findings/Conclusions/Further Research
• Biofilm (containing pathogens) can persist in fully-reprocessed endoscope channels,
• What is the biofilm role in pathogen transmission
• Reprocessing deficiencies due to complex endoscope design,
• Engineer in efficiency of cleaning and resistance to biofilm
• Recommended reprocessing may not eliminate clinically relevant biofilm.
• Define monitoring reprocessing and patient surveillance
Even if the scope is contaminated, the microbes are usually harmless and besides, the scope is being used in non-sterile sites of the body.

Examples of microbes found on endoscopes or in scope-related outbreaks

- Acinetobacter baumanii
- Aspergillus spp
- Burkholderia
- Candida glabrata
- Clostridium difficile
- Enterobacteriaceae
- Enterococcus spp
- E. coli
- Mycobacterium chelonae
- Mycobacterium fortuitum
- Ochrobacterum anthropi
- Proteus mirabilis
- Psuedomonas aeruginosa
- Salmonella spp
- Serratia spp
- Staphylococcus aureus (MRSA)
- Viruses: Hepatitis B & C, HIV, Condyloma
- Klebsiella pneumoniae (CRE)

Assumption 3: Endoscopy-associated infections (EAI) are rare and often inconsequential
Assumption 3:
Endoscopy-associated infections (EAI) are rare and often inconsequential

“The risk of EAI is extremely rare, 1 in 1.8 million procedures. Even if our patients were exposed we have not seen any problems.”

There is now compelling evidence that the current risk estimate is wrong and that pathogens are being transmitted at a much higher rate than originally thought.

The current risk estimates are wrong:
Cori Ofstead, MSPH and Associates/Mayo


- Issues addressed: Evaluate the origins and accuracy of the risk estimates after a single outbreak involved more cases of EAI that would be expected in 1 year nationwide.

- Findings:
  - Math was wrong: they got the wrong answer because they did the division wrong
  - Math was wrong: counting errors led to wrong numerator (28 instead of 145)
  - Flawed methods include
    - Population size unsubstantiated (unsupported denominator)
    - Incidence of infection not assessed among at risk population
    - Counted only cases of infection that were published in peer-reviewed literature
    - Counted only cases of infection that were reviewed in a single 1993 article

- Conclusion – No credible estimate of infection risk

- This paper is the only citation used by ASGE to come up with the current risk assessment (1 in 1.8 million).
- **What the Spach paper also said:**
  - “These recognized and reported cases, however, probably represent a minority of all infections transmitted by endoscopy….”
  - “Finally, from the practitioners perspective, the incentive for recognizing and reporting these infections is minimal.”
  - “Given the above limitations and lack of prospective endoscopy, the true incidence of infections transmitted by endoscopy is impossible to determine.’

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**Assumption 3: Endoscopy-associated infections (EAI) are rare and often inconsequential**

- **We are not finding pathogen transmission because we are not looking in the right places.**
  - Currently exposed patients are only screened for 3 viruses HIV and Hepatitis B & C. Should also be looking for bacteria that live in the GI tract (enterics).
  - There is now documentation that transmission rates of pathogens from improperly reprocessed duodenoscopes were as high as 42%.
  - CRE (Carbapenem Resistant Enterobacteriaceae), a family of bacteria is that is now on CDC’s list of most dangerous bacteria. CRE has shown to be transmitted by contaminated scopes. There is no treatment for CRE; mortality rate is around 47%.
Monitoring and Improving the Effectiveness of Cleaning Medical and Surgical Devices. M. Alfa. 2013. AJIC 41 S56-S59.

- Transmission rate is 41%
- KPAC is an MDRO which means any further antibiotic therapy will select for growth of this bug.
- Rate of transmission from contaminated scopes previously unknown and thought to be unimportant and insignificant
- Does bowel prep change the microbial flora predisposing the patient to colonization?
- What are the effects of colonization with no apparent symptoms?

<table>
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<th>Date of duodenoscopy</th>
<th>Specimen</th>
<th>Infection colonization</th>
<th>Outcome</th>
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<td>August 1</td>
<td>Rectal swab</td>
<td>Colonization</td>
<td>Inpatient care</td>
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<td>August 18</td>
<td>Rectal swab</td>
<td>Colonization</td>
<td>Alive</td>
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<tr>
<td>August 29</td>
<td>Blood</td>
<td>Infection</td>
<td>Death (unrelated to K pneumonia)</td>
</tr>
<tr>
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<td>Rectal swab</td>
<td>Colonization</td>
<td>Alive</td>
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<td>Rectal swab</td>
<td>Colonization</td>
<td>Death (unrelated to K pneumonia)</td>
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<tr>
<td>September 14</td>
<td>Blood</td>
<td>Infection</td>
<td>Death (unrelated to K pneumonia)</td>
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<td>Rectal swab</td>
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<td>September 28</td>
<td>Rectal swab</td>
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</tr>
</tbody>
</table>

Table 1

Note: Table adapted from data in Carbone et al 2016.72

Multidrug resistant organisms are being transmitted

Ofstead and Associates/ Mayo
American Society for Gastrointestinal Endoscopy/Digestive Disease Week.
Orlando, FLA. May 18-21, 2013

- Transmission of multidrug-resistant organisms via contaminated duodenoscopes.
- Link to poster: http://www.ofsteadinsights.com/?p=1855

- Issues addressed
  - Guidelines say that there is little to no risk of exogenous infection with endoscopy.
  - The association between post-ERCP infections and endoscope reprocessing lapses was examined.

- Findings
  - Reprocessing lapses resulting in duodenoscope contamination with pathogens, including MDROs and have led to serious ERCP-associated infections. Confirmed by genetic testing.
  - Infection rates among patients exposed to contaminated duodenoscopes ranged from 6-42%.

- Recommendations
  - Routine monitoring is recommended to detect reprocessing errors and endoscope contamination prior to patient exposure.
  - Guidelines should be revised to reflect high attack rates and the need for patient follow up when reprocessing lapses occur.
A carbapenem-resistant Klebsiella pneumoniae outbreak following bronchoscopy

The outbreak ended after both endoscopes were submitted to the manufacturer who observed defects of the internal channel surfaces in both instruments. After repair, the bronchoscopes were used again, but surveillance sampling of the endoscopes was performed in short time intervals after reprocessing of the instruments. Flushing solutions of bronchoscope A still showed bacterial contamination > 200 CFU/mL, but no CRKP was detected. Nevertheless, bronchoscope A was taken out of use. In addition, microbiologic testing of endoscopes, which was performed twice a year before the outbreak took place, is now conducted more frequently.

Janine Zweigner, MD et.al. Institute of Hygiene and Environmental Medicine-University Medicine, Berlin, Germany
Medical Device Reprocessing: Can We “Ban the Biofilm”?  
Michelle J. Alfa, PhD, FCCM (presentation October, 2014)

Research is always producing new data and sometimes, in light of that new data, we have to re-evaluate what we think is true.
What are the new assumptions based on current clinical data?

1. Endoscope reprocessing is often not performed according to standards and guidelines. Reprocessing lapses are common and often go undetected for prolonged periods of time. This has resulted in an increased risk of cross-contamination and infection.
2. Patients are being exposed to improperly cleaned and disinfected scopes resulting in serious infections with multi-drug resistant organisms.
3. The current risk estimate is inaccurate, outdated and based on flawed methodology. The current risk of EAI is unknown and likely much higher than originally thought.

What are some steps that we can take now?
How well do you know this area?

Implement better Quality Improvement Programs

Compare what is in place for Steam Sterilization processes to the high-level disinfection of flexible endoscopes.
Quality Control for Steam Sterilization of Surgical Instruments

Steps have documented QA (39%)

Reprocessing a Flexible Endoscope is a Complicated Process

Steps have documented QA (8%)
What can we do now?

Implement a monitoring program to assess:
✓ Contamination levels
✓ Compliance to protocols
✓ Document Training and Competency
✓ Provide feedback to improve performance
✓ Assess if current protocols are effective

Do you know what is going on?
✓ Infection Control practices (PPE, Hand Hygiene, Surface Decontamination)
✓ Bedside flush
✓ Storage and Transportation (Drying, clean storage cabinets)
✓ How do you investigate lapses in reprocessing?
### How clean is clean?

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<th>Post-Hand Wash Data</th>
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<td>Protein</td>
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### ATP (ADENOSINE TRIPHOSPHATE) Flexible Endoscope Storage Durability

- **Date:** 4/27/2015

**Table:**

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**Legend:**
- N/A: Data not available
- REDDY: Readiness status
- CABINET: Cabinet storage
- "These scopes have not been tested in an environment..."
### ATP (ADENOSINE TRIPHOSPHATE) FLEXIBLE ENDOSCOPE STORAGE DURABILITY

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<th>Test</th>
<th>Time</th>
<th>Result</th>
<th>Year</th>
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*All endoscopes were tested after being high level disinfected.*

---

### ATP (ADENOSINE TRIPHOSPHATE) FLEXIBLE ENDOSCOPE STORAGE DURABILITY

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*All endoscopes were tested after being high level disinfected.*
ATP results after manual cleaning

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Regulatory Bodies, Associations, Mfr

- AAMI/FDA – How Clean is Clean Summit (Sept. 2013)
- ASGE and SGNA – Meeting Fall of 2013 to address new clinical data
  - Revise standards to address the unknown risk estimates?
  - Centralized reporting for reprocessing lapses?
- Manufacturers need to revise IFU for cleaning and reprocessing that reflect current scientific evidence.
The future of Endoscopy procedures?
A safer, non-invasive approach.....