Outbreaks, Investigations and Evidence for Flexible Endoscope Reprocessing – Overcoming the Challenges
Learning Objectives

- Present overview of recent endoscope related outbreaks
- Discuss factors that have contributed to the use of contaminated flexible endoscopes
- Understand key recommendations in new endoscope reprocessing guidelines and standards
- Review quality control requirements
- Discuss practical aspects and rationale for using various methods to detect damaged or dirty endoscopes, including enhanced visual inspections, biochemical indicators, and microbial cultures
Janet Prust - Disclosure

Employee of 3M Health Care
Infection Prevention Division

Association for Advancement of Medical Instrumentation (AAMI)

Positions held:

AAMI Board of Directors – Director representing industry since 2015

Member:

- AAMI Finance committee
- Sterilization Standards Committee
- WG 61: Chemical sterilants hospital practices – co-chair
- WG 84: Endoscope reprocessing
- WG 40: Steam sterilization hospital practices
- WG 13: Washer disinfectors; TAG to ISO TC 198 WG 13
- WG 93: Cleaning of reusable devices
- Sterilization of endoscopes stakeholders group
- Task group – HVAC conditions in OR
The Outbreaks
Flexible Endoscope Remain Contaminated After Reprocessing – Alfa 2012

Report of contaminated endoscopes well before publicized outbreaks

- Gastroscope (N=29): 10%
- Colonoscope (N=69): 17%
- Duodenoscope (N=43): 12%
- Total (N=141): 14%

Citation: Alfa et al., AJIC 40(3): 233-236, 2012.
### Contamination and Outbreaks Occurring – Kovaleva 2013

#### Report of outbreaks occurring in published literature before media reporting

<table>
<thead>
<tr>
<th>Endoscope</th>
<th>Outbreaks</th>
<th>Primary organism</th>
<th>Patient contaminated</th>
<th>Patients infected</th>
<th>Root cause</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper GI</td>
<td>19</td>
<td><em>P. aeruginosa</em>, <em>H. pylori</em>, <em>Salmonella</em></td>
<td>169</td>
<td>56</td>
<td>Cleaning or disinfection gaps</td>
</tr>
<tr>
<td>Sigmoidoscopy/colonoscopy</td>
<td>5</td>
<td><em>Salmonella</em>, <em>HCV</em></td>
<td>14</td>
<td>6</td>
<td>Cleaning or disinfection gaps</td>
</tr>
<tr>
<td>ERCP</td>
<td>23</td>
<td><em>P. aeruginosa</em></td>
<td>152</td>
<td>89</td>
<td>C/D, water bottle, contaminated AER</td>
</tr>
<tr>
<td>Bronchoscopy</td>
<td>51</td>
<td><em>P. aeruginosa</em>, Mtg, Mycobacteria</td>
<td>778</td>
<td>98</td>
<td>C/D, AER, Water</td>
</tr>
<tr>
<td><strong>Totals</strong></td>
<td><strong>98</strong></td>
<td></td>
<td><strong>1,113</strong></td>
<td><strong>249</strong></td>
<td></td>
</tr>
</tbody>
</table>

- 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.
- 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

Reprocessing lapses are rarely reported in medical journals leading to the false conclusion that reprocessing lapses are rare.
First reports of duodenoscope CRE related outbreaks

US government action related to outbreaks occurring in published literature before media reporting

- 2012 outbreaks with multi-drug resistant organisms seen
- US CDC published alert January 2014
The Outbreaks: 2015 - In the news but not new.....

After a well documented history of outbreaks
High levels of Persistent Contamination on Patient Ready Endoscopes – Ofstead 2013, 2014, 2016

Citation: Ofstead et al. The effectiveness of reprocessing in accordance with current guidelines. SGNA Conference Poster. 2015.
# Published CRE Outbreaks – A Wake Up Call

<table>
<thead>
<tr>
<th>Primary Author</th>
<th>Multi-drug resistant organism</th>
<th>Number of patients impacted</th>
<th>Yr. of publication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbonne</td>
<td><em>K. Pneumoniae</em></td>
<td>13</td>
<td>2010</td>
</tr>
<tr>
<td>Smith</td>
<td><em>E. Coli</em></td>
<td>3</td>
<td>2015</td>
</tr>
<tr>
<td>Marsh</td>
<td><em>K. Pneumoniae</em></td>
<td>34</td>
<td>2015</td>
</tr>
<tr>
<td>Kim</td>
<td><em>K. Pneumoniae</em></td>
<td>15</td>
<td>2016</td>
</tr>
<tr>
<td>Epstein</td>
<td><em>E. Coli</em></td>
<td>39</td>
<td>2015</td>
</tr>
<tr>
<td>Kola</td>
<td><em>K. Pneumoniae</em></td>
<td>12</td>
<td>2015</td>
</tr>
<tr>
<td>Wendorf</td>
<td><em>E. Coli</em></td>
<td>35</td>
<td>2015</td>
</tr>
<tr>
<td>Vertaillie</td>
<td><em>P. Aeruginosa</em></td>
<td>22</td>
<td>2015</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td><strong>173</strong></td>
<td></td>
</tr>
</tbody>
</table>
Additional Cited Outbreaks:


Additional Evidence Detail

- Saliou, et al. 2016. **Persistent Contamination on Endoscopes** – Micro surveillance post processing with 8 day incubation
  - 34% exceeded target of <25 CFU of indicator organism

- England, et al. 2016. Transmission of MDRO from **gastroscope** – 5 patients with CRE (9 more exposed)
  - Superbug persisted through 12 reprocessing cycles

- **Duodenoscope** ERCP / CRE Outbreaks
  - Illinois 2013 – 156 patients exposed to CRE/ 39% transmission rate
  - Wisconsin 2014 – 3 deaths
  - California – 2014 - 2 deaths

  - 19 patient exposed, 12 infected, 2 deaths

- FDA MDRO Reports:
  - 2015. Contaminated **cystoscopes**. 4 patients infections

Outbreaks occurring with all types of flexible endoscopes and a variety of organisms
Flexible GI Endoscope are not the only risk....


FDA analysis to date has identified two recurrent themes:

- Failure to meticulously follow manufacturer instructions for reprocessing
- Continued use of devices despite integrity, maintenance and mechanical issues.”

FDA Recommendation: “Implement a comprehensive reprocessing quality control program. Your reprocessing program should include written procedures for monitoring, training and adherence to the program, and documentation of equipment tests, processes, and quality monitors used during the reprocessing procedure.”
Other reprocessing lapses and patient exposure to contaminated endoscopes

<table>
<thead>
<tr>
<th>US Location</th>
<th>Facility types</th>
<th>Errors in reprocessing</th>
<th>Patients impacted</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colorado</td>
<td>Medical center</td>
<td>Improper cleaning</td>
<td>71</td>
</tr>
<tr>
<td>Minnesota 1</td>
<td>ASC; Outpatient clinic; 5 hospitals</td>
<td>7 incidents reported: improper cleaning/HLD; reprocessing single use device; inadequate training</td>
<td>6 – 2000 per incident</td>
</tr>
<tr>
<td>North Carolina</td>
<td>Hospital</td>
<td>No cleaning/sterilization of one channel</td>
<td>10</td>
</tr>
<tr>
<td>New Jersey</td>
<td>ASCs</td>
<td>Improper reprocessing; unchanged water/cleaning solution</td>
<td>Not reported</td>
</tr>
<tr>
<td>Ontario, Canada</td>
<td>Clinic</td>
<td>Multiple cleaning/HLD breaches</td>
<td>6800</td>
</tr>
<tr>
<td>Louisiana</td>
<td>Medical center</td>
<td>Wrong HLD temperature</td>
<td>360</td>
</tr>
<tr>
<td>British Columbia, Canada</td>
<td>Hospital</td>
<td>Bioburden allowed to dry before cleaning</td>
<td>536</td>
</tr>
<tr>
<td>California</td>
<td>Hospital; surgery center</td>
<td>Improper HLD; expired disinfectant</td>
<td>3400</td>
</tr>
<tr>
<td>Minnesota 2</td>
<td>Medical center</td>
<td>No HLD of one channel</td>
<td>2600</td>
</tr>
<tr>
<td>Florida</td>
<td>Hospital; cancer treatment center</td>
<td>Improper cleaning of elevator channel</td>
<td>191</td>
</tr>
<tr>
<td>Georgia</td>
<td>Surgery center</td>
<td>Wrong HLD time</td>
<td>1300</td>
</tr>
</tbody>
</table>
Non-endoscopic Related Outbreaks

Poor Infection Control Practices:

- New York – improper handling of intravenous sedation tubing, multi-dose vials and reuse of needles.
- Las Vegas – Outbreak of Hepatitis C due to cross-contamination from syringes - ~40,000 patient exposed. No follow-up information.

Source: ASGE 2017
Outbreaks Related to Tubing, Water Bottles and other sources

- Hep C outbreak related to malfunctioning one-way valves contaminated water bottles (water and bottles not changed between patients)
- Biofilm formation on tubing
- Contamination of endoscope from hands of HC workers
- Failure to sterilize biopsy forceps

Source: ASGE 2017

143 gastroscope testing encounters (June-October)
The Outbreaks: The microbes are changing the game

- Carbapenem-resistant Enterobacteriaceae – CRE
- Limited or no treatment
- High transmission rate 6-46%
- High mortality rate ~ 50%

www.cdc.gov/drugresistance/threat-report-2013/
Guidelines
The complex design of duodenoscopes may impede proper reprocessing.

Meticulous manual cleaning should reduce risk of transmission of infection.

Implement a comprehensive Quality Control program.

Quarantine scopes suspected of association with patient infection until shown to be free of pathogens.

http://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm434871.htm
FDA seeking expert scientific and clinical opinion. 19 member advisory panel.

“Duodenoscopes and AERs do not provide a reasonable assurance safety and effectiveness”

“Manual Cleaning is a critical component.”

There is a need for “...development and validation of cleaning verification assays”

“ Majority of the panel also believes it is necessary to reclassify duodenoscopes from semi-critical to critical and support the move from high level disinfection to sterilization.”

http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm454766.htm

Enhanced measures include:

- Ethylene Oxide Sterilization.
- Multiple rounds of High-Level Disinfection
- Use of a liquid chemical sterilant processing system
- Microbial surveillance

Implementation of these additional measures may not be feasible

The limitations of each of these measures must be taken into consideration.

These measures are to be considered in addition to following manufacturer’s instructions for reprocessing, meticulous manual cleaning and the implementation of a comprehensive quality control program.
Between 2012 and spring 2015, closed-channel duodenoscopes were linked to at least 25 different incidents of antibiotic-resistant infections that sickened at least 250 patients worldwide.

Hospitals, FDA and mfr’s all failed in their responsibility to report, notify and act on knowledge that outbreaks were occurring.
New Guidelines Issued

SGNA (4): Society for Gastroenterology Nurses and Associates
AAMI: Association for Advancement of Medical Instrumentation
AORN: Association of periOperative Registered Nurses
APSIC: Asia Pacific Society of Infection Control
ASGE: American Society for Gastrointestinal Endoscopy/ Multisociety update
CDC/HICPAC: Healthcare Infection Control Practices Control Advisory Committee

To varying level of detail, guidelines agree on:

- Implement quality control program
- Follow manufacturer’s instructions for reprocessing
  - New, revalidated IFUs
- Pay special attention to manual cleaning
  - Meticulous cleaning required
  - Elevator mechanism needs special attention
- Implement comprehensive training with competency assessment by qualified personnel
- Periodic review of policies and procedures
- AORN, AAMI, APSIC and SGNA recommend use or assessment of cleaning verification
- ASGE, CDC recommends microbial surveillance
SGNA Guidelines

- Standards of Infection Prevention in Reprocessing Flexible Gastrointestinal Endoscopes 2015
- Standards in Infection Prevention in Gastroenterology Settings 2015
- Standards of Infection Prevention in Reprocessing Flexible Gastrointestinal Endoscopes 2016
- Guideline for Use of High-Level Disinfectants & Sterilants in the Gastroenterology Setting 2017

http://www.sgna.org/Portals/0/Standards
ANSI/AAMI ST91:2015 Flexible and semi-rigid endoscope reprocessing in health care facilities – currently under revision

- Design of the endoscope processing area, including work flow considerations
- Personnel issues such as training, hygiene, clothing, policies, and immunizations
- Processing steps and recommendations including sterilization
- Addresses other related topics including automated endoscope reprocessors (AER), sterile endoscope sheaths, and processing accessories
- Storage and transport
- Quality control
- Bibliography

CDC Interim Microbial Surveillance Protocol - March 2015

- Protocol suggested but not yet validated
- Sensitivity of this method is unknown
- Look for pathogens and elevated levels of non-pathogens
- Frequency of testing not defined
  - Weekly, monthly, every time, every 60 procedures
- Pay Special attention to
  - Inspection and Manual Cleaning
  - Drying

http://www.cdc.gov/hai/outbreaks/index.html
CDC Interim Protocol: The Jury is Still OUT……

“...Not sufficient in the current form to be implemented by healthcare facilities as best practice” FDA Panel on Gastroenterology and Urology, May 14-15, 2015

Sensitivity unknown  *CDC Interim Protocol for Duodenoscope Surveillance*

“...clinical microbiology labs should not perform routine cultures of reprocessed duodenoscopes due to lack of data on utility of such culturing” American Society for Microbiology statement on *CDC Interim Protocol*. 
Discussion - Outbreaks

1. Why are we seeing the increase level of outbreaks?
2. What has changed?
3. How can these be detected?
4. Any experiences in your facilities to share?
5. What is the level of awareness and concern by administration/management? Auditors?
Human Factors

(N = 69 GI endoscopes)

2 or more steps performed improperly nearly half of the time *while being observed*
Reprocessing staff comments

- 50% didn’t like performing manual cleaning
- 53% reported discomfort due to working with scopes
- 13% problems with lungs, sinuses, or breathing
- 27% bothered by odors or fumes
- 50% physical discomfort or bothersome symptoms
- 75% felt pressure to work quickly while reprocessing
- 37% observed procedural delays due to reprocessing

Citation: Ofstead et al., Gastroenterology Nursing, 2010
IAHCSMM Survey: 2017
Staff report of issues encountered during reprocessing. N = 67

Factors that contribute to patient risk related to flexible endoscopy procedures:

- Complicated reprocessing guidelines
- Lack of training by qualified instructors
- Non-adherence to guidelines
- Repeated exposure of endoscopes to organic debris and pathogens
- Inability to see pathogens and internal endoscope damage with the naked eye
- Resistance to testing for contamination
- Increasing pressure to do more, faster, with less resources
- Longstanding belief that there’s no risk – 1 in 1.8 million often cited by GI community
Flexible Endoscope Reprocessing – Basic Steps*:

- Bedside pre-cleaning and transport
- ☐ Leak testing
- ☐ Thorough manual cleaning
- ☐ Visual inspection and verification
- ☐ Rinsing
- ☐ High-level disinfection
- ☐ Rinsing
- ☐ Drying
- ☐ Storage

* This is an oversimplification. It is a very complex process with over 200 steps.
## Complicated Guidelines

<table>
<thead>
<tr>
<th>Guideline or Standard</th>
<th>Pages</th>
<th># reference to IFU</th>
</tr>
</thead>
<tbody>
<tr>
<td>AORN Guideline for processing flexible endoscopes (2016)</td>
<td>84</td>
<td>73</td>
</tr>
<tr>
<td>SGNA Standards of Infection Prevention in Reprocessing Flexible GI Endoscopes (2015)</td>
<td>31</td>
<td>66</td>
</tr>
<tr>
<td>SGNA Guideline for Use of High-Level Disinfectants &amp; Sterilants in Gastroenterology Setting (2017)</td>
<td>5</td>
<td>13</td>
</tr>
<tr>
<td>AAMI ST 91: Flexible and semi-rigid endoscope processing (2015)</td>
<td>70</td>
<td>149</td>
</tr>
<tr>
<td>APSIC</td>
<td>9</td>
<td>12</td>
</tr>
</tbody>
</table>
Clinical Use of products Containing Simethicone

Active ingredient: silicone ...

• In bowel prep formulations
• Lubricants/de-foaming agents sued in procedures, e.g. simethicone
  • Silicone is NOT WATER SOLUALBE
• Add substance to water bottle or injected into endoscopes using a syringe to reduce foam, bubbles, gas
• Sprayed on surfaces to facilitate procedure

• Other ingredients in products include thickeners, sweeteners, preservatives, and water

Citation: Ofstead et al., Simethicone residue, AJIC, 2016
Discussion – Human Factors

1. Describe your experience regarding staff or human factors issues?
2. What works well? What doesn’t.
3. What are the key factors that prevent effective reprocessing from a staff or management factors?
4. What Guidelines are available and followed?
5. How are staff trained and assessed?
Process Effectiveness and Quality Control
### How Fast do Microbes Multiply?

<table>
<thead>
<tr>
<th>Time</th>
<th># organisms</th>
</tr>
</thead>
<tbody>
<tr>
<td>After HLD reprocessing</td>
<td>1</td>
</tr>
<tr>
<td>20 minutes</td>
<td>2</td>
</tr>
<tr>
<td>40 minutes</td>
<td>4</td>
</tr>
<tr>
<td>1 hour</td>
<td>8</td>
</tr>
<tr>
<td>2 hours</td>
<td>64</td>
</tr>
<tr>
<td>3 hours</td>
<td>512</td>
</tr>
<tr>
<td>4 hours</td>
<td>4,096</td>
</tr>
<tr>
<td>5 hours</td>
<td>32,768</td>
</tr>
<tr>
<td>6 hours</td>
<td>262,144</td>
</tr>
<tr>
<td>7 hours</td>
<td>2,097,153</td>
</tr>
</tbody>
</table>

Prompt initiation of cleaning is critical to an effective cleaning process.

Current guidelines recommend documentation of time pre-clean was completed to determine if delayed reprocessing procedures are needed.

Implementation of a Quality Control (QC) Program

“Implement a comprehensive quality control program for reprocessing duodenoscopes. Your reprocessing program should include written procedures for monitoring training and adherence to the program, and documentation of equipment tests, processes, and quality monitors used during the reprocessing procedure.”

Design of Endoscopic Retrograde Cholangiopancreatography (ERCP) Duodenoscopes May Impede Effective Cleaning: FDA Safety Communication

What to consider? Quality Control through the implementation of rapid cleanliness indicators, ethylene oxide sterilization to replace HLD and appropriate use of microbial monitoring audits.
Endoscope Reprocessing
Quality System Requirements

- Training and routine competency assessments
  - Certification
- Visual inspection
- Cleaning Verification
- Disinfectant concentration testing
- Physical/mechanical monitoring
- Water quality testing to ensure no contamination
- Ensure AER / Washer Disinfection functioning and not contaminated
- Effective drying
- Storage and handling to prevent contamination
- Validation of equipment and processes*

* Required in some regions
Training and Competency

- **Complete and thorough training programs**
  - Standards
  - Manufacturer’s instructions for use
  - Certification through formal program recommended

- **Competency assessment**
  - Direct observation of competency
  - Routine assessment (e.g. quarterly)
  - Assessment performed by knowledgeable, experienced individual in endoscope reprocessing
Visual Inspection for gross soil and damage

SGNA
• “Due to recent issues with reprocessing, visual inspection warrants its own step. It may be considered a “time out” or safety stop to verify that the endoscope is at least visually clean before proceeding to HLD.”
• “Look for conditions that could impact HLD (corrosion, discoloration, cracks, and retained debris)

AORN
• “Lighted magnification should be used to inspect endoscopes and accessories for cleanliness and damage.”
• “An endoscope that appears clean may harbor debris that cannot be seen without magnification. Lighted magnification may increase the ability to identify residual soil or damage.”
• “Internal channels of flexible endoscopes may be inspected using an endoscopic camera or borescope.”
• “Defective endoscopes, accessories, and equipment should be removed from service and repaired or replaced”

Images: Ofstead AJIC poster 15, 16
Borescopes – a new approach to inspection

- Small fiberoptic camera to view inside channels
- Greatly magnified image
- Available for S/B channel size
- Can capture images
- Valuable for inspection of damage and gross debris
- Challenges:
  - No benchmark as acceptable wear and tear
  - Disinfection between uses
  - Sizes not available for all channels
- Guidelines referencing for inspection

Image: Courtesy of SP Concepts
Borescope images
What does everyone agree on?

Focus on Manual Cleaning

- It is a problem
- It is critical to success of HLD or Sterilization
- Lack of proper manual cleaning contributed to outbreaks
- It can be improved
- Use validated, real-time indicators of cleaning efficacy
  - Commercially available kits that test for ATP, protein, hemoglobin, carbohydrate
QC is critical to successful reprocessing

- All facilities should have a comprehensive QC program
  1. Product identification and traceability
  2. Documentation and record-keeping
  3. **Verification and monitoring of the cleaning process**
     - Technologies: ATP, protein, hemoglobin, carbohydrate, bioburden
     - Provides Pass/Fail threshold measuring effective soil removal
  4. Monitoring of high-level disinfection and sterilization processes
  5. Product recalls procedure
  6. Quality process improvement program
Cleaning Verification Recommendations

AORN:
“Manual cleaning of flexible endoscopes should be verified using cleaning verification tests when new endoscopes are purchased and at established intervals (eg, after each use, daily).”

AAMI:
“The frequency of testing the efficacy of the manual cleaning step should occur on a regular basis, weekly or preferably daily…”

SGNA:
If the test results for organic soil are positive, the endoscope should be re-cleaned before HLD

APSIC:
Cleaning verification should be performed at least daily and prefer every time the endoscope is manual cleaned.
Cleaning Verification Practices

Samples endoscope surfaces and channels after manual cleaning:

- Swab the insertion tube, distal end, and ports
- Flush sterile water through channels and collect effluent
- Run rapid biochemical cleaning verification tests for residual contamination
  - ATP
  - Protein (less sensitive)
  - Hemoglobin (only detects presence of blood)
- Re-clean whenever results exceed benchmarks for “clean”
- Re-test after re-cleaning
- Repeat until test passes or a decision is made to send it for repair
Duodenoscopes Have Added Complexity

- Elevator Guide wire channel: Sealed or Open?
- Elevator housing and mechanism on distal tip.

All duodenoscopes (plus some therapeutic gastroscopes) have an elevator-wire channel inlet above the suction valve.
Cleaning = Effective Removal of Clinical Soil

What is in Clinical Soil?
- Microorganisms: bacteria, fungi, viruses
- Microbes found in all soil components
- Tissue
- Blood and other body fluids
- Secretions/Excretions (vomit, diarrhea, mucous, phlegm, etc)

Can presence of soil be measured?
- Yes, but it is not easy
Components Found in Clinical Soil

To measure effectiveness of cleaning - a component is selected to measure.
Common Universal Cleanliness Markers
Present in all types of soils, used for general monitoring

Protein

Adenosine Triphosphate (ATP)

adenosine triphosphate (ATP)
<table>
<thead>
<tr>
<th>Characteristics of Cleaning Markers</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ATP</strong></td>
</tr>
<tr>
<td>Universal Marker</td>
</tr>
<tr>
<td>Mature technology</td>
</tr>
<tr>
<td>Commercially available</td>
</tr>
<tr>
<td>Rapid tests are objective, numeric</td>
</tr>
<tr>
<td>ATP is stable under reprocessing conditions</td>
</tr>
<tr>
<td>Will detect microbial ATP</td>
</tr>
<tr>
<td>Cannot be used when prions are an issue</td>
</tr>
<tr>
<td>Different manufacturer’s use different measurement scales so cannot compare different systems.</td>
</tr>
</tbody>
</table>
Rapid Cleaning Verification Tests: Rapid Protein Detection

- Qualitative Test
- Colorimetric (color change)
- Subjective interpretation
- Gives presence/absence results
- Analysis of data is limited
- Validation data unavailable for most tests
- Data needed to verify sensitivity claims
  - Sensitivity dependent on sample prep?
- Mature technology, well known
Rapid Cleaning Verification Tests: Multi-test Strip

- Three pads with protein, carbohydrate and hemoglobin tests
- Qualitative, subjective interpretation
- Presence/absence test
- Analysis of data is limited
- Validation data shows little utility for protein and carbohydrate pads, hemoglobin test drives detection of dirty scopes
  - Because Hg test is specific, the number of dirty scopes detected is lower than expected, when compared to current literature.
Rapid Cleaning Verification Tests: ATP Bioluminescence

- Quantitative numerical results
- Results are given in Relative Light Units (RLU)
- Different mfr’s use different measurement scales
- Numerical results can be analyzed – statistics!
- Validation data available (must be carefully interpreted)
- Technology has been used to assess cleaning efficacy for over 35 years. (Food Safety, Aerospace, Clean-Room manufacturing)
ATP Bioluminescence Technology

Converts ATP to a light signal

Fire-fly enzyme Luciferase uses ATP to produce Light

\[
\text{ATP} + \text{O}_2 \rightarrow \text{A} + \text{PP} + \text{Luciferin} + \text{CO}_2 + \text{Light}
\]

Simple Relationship

- Increase amount of light (RLU)
- Increase amount of ATP
- Increase organic contamination
Benchmark for Clean

- The Pass/Fail benchmarks were developed to assess if a scope has been cleaned (soil removal) to an acceptable level.
  - Acceptable levels for ATP, protein, hemoglobin, carbohydrate, bioburden, endotoxin and sodium ion are defined in AAMI ST91

- Pass/Fail benchmarks for any cleaning verification test are not a measure of the risk of pathogen transmission, nor does a “pass” guarantee that the scope is safe to use on a patient.

- Ensure Pass/Fail thresholds have been validated for the technology used.
Quantitative or Qualitative Cleaning Verification Test

Things to consider

• Is there a validation study available?
• Are there studies that show the product can detect dirty scopes in a clinical setting?
• Do the claims make sense given the technology used?
• Ease of interpretation
• What are you getting for your time and money?
Standards and Guidelines Positions on Cleaning Verification

Discussion – Quality Control

1. Are current quality control practices acceptable for flexible endoscopes?
2. What are the factors that prevent better quality control?
3. Cleaning verification – how often should it be performed?
4. Use of lubrication aids – how does this impact cleaning effectiveness? How can policy be established to reduce/eliminate use?
5. What is needed for better training and competency assessment?
Microbial Surveillance of Endoscopes

Guideline recommendations

- ESGE/ESGENA: Minimum every three months
- ASGE/Multisociety: Consider monthly for duodenoscopes
- GoSA: Varies based on scope type; monthly for high risk. Included monthly testing of AER and Water
- APSIC: Periodic surveillance

Periodic surveillance of duodenoscopes recommended by US CDC 2015, 2017

- Controversial
  - Lack of validated method and requires environmental culture
  - Questions on appropriate frequency
  - Questions on validity as method does not detect all pathogens
  - CDC Recommendation is 1x/mo or after 60 procedure

**AORN 2016 and SGNA 2017**

- Recommend to conduct a risk assessment and may be considered in event of an outbreak
- Can be used as a method for assessing quality of reprocessing or defects in endoscopes

**AAMI 2015**: No guidance; 2018 - TBD

Source: Guidelines cited
Specific Tests: Used for Investigations or Answering Very Specific Questions.

Microbiological Counts
- Viable microbial numbers
- Pathogen detection
- Effectiveness of entire process

Hemoglobin
- Blood
Culturing of Endoscopes: Limitations

Current methods are not sensitive enough to detect low-levels of bacteria, limitations of these methods not being discussed

Current methods:
- Do not detect all bacteria
- Do not detect viruses or parasites
- Do not substantiate cleanliness
- Do not substantiate any level of sterilization or disinfection

Current methods not sufficient for sampling duodenoscopes
- Biofilm bacteria must be cultured differently
- Bacteria exposed to disinfectants need special culture conditions
Should ATP measurements correlate with bacterial counts?

_A common concern, a common misconception..._

Non-culture methods: ATP Bioluminescence

- ATP: measures cleaning effectiveness of reduction in soil to ‘threshold’ validated value
  - ATP measures organic contamination from _all_ living sources
    - Microorganisms, Human cells, secretions, excretions, body fluids, food residue

Microbial culture:

- Does not ‘correlate’ to ATP
- Measures bacteria only
- Indication of effectiveness of entire disinfection or sterilization process

_Correlation of ATP and Microbial Counts is not possible as they measure two different things and provide different pieces of Quality Control information._
Sequence of QC testing

1. Pre-cleaning
2. Leakage Testing
3. Manual Cleaning
4. Rinsing
5. High Level Disinfection (HLD)
6. Drying & Storage

- ATP or other rapid cleanliness indicators
- Microbial Surveillance
Recommendations

No longer consider Endoscopy as a low risk procedure

Implement QA programs
- Written policies
- Training/Competencies
- Regular Audits and continued oversight
- Make sure IFUs are up to date
- Informed consent for patients

Implement a monitoring program for manual cleaning
- Multiple sampling sites
- Multiple methods
- Every scope, every time

Implement periodic microbial surveillance for HLD procedures as an audit tool
Summary Points

- Patient-ready endoscopes are contaminated
- Viable microbes commonly survive and patient infection transmission occurs
- Patient outcomes have been catastrophic and public health is at risk due to superbugs
- Guidelines and instructions for use are too complex
- Employees rarely do or are able to follow the steps in guidelines and IFU
- Quality improvement is urgently needed
Thank you for your time and attention!
References - web


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• AAMI ST91  Flexible and semi-rigid endoscope reprocessing in health care facilities  

References (2)


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References (3)