Endoscope Microbial Surveillance Testing Made Easy
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Disclosure

• Kaumudi Kulkarni is an employee of Healthmark Industries Fraser, Michigan. I am involved with the manufacture and distribution of medical products to healthcare facilities and healthcare professionals.

• Alpa Patel is an employee of Nelson Laboratories, Salt Lake City, UT. I am involved in medical device laboratory services and testing.

• No compensation has been received for this presentation or for travel to and from the seminar.

• All opinions are those of the presenter.

• This presentation reflects the techniques, approaches and opinions of the individual presenter. This sponsored presentation is not intended to be used as a training guide or promotion. Before using any medical device, review all relevant package inserts with particular attention to the indications, contraindications, warnings and precautions, and steps for the use of the device(s).
Healthmark and Nelson Policy

Healthmark and Nelson Lab’s policy is to provide their customers and the healthcare community with the highest quality, state of the art medical products and support services in a timely and cost effective manner.

This goal is supported by a staff committed to individual accountability, professionalism, mutual respect, collaboration and service excellence. This presentation is part of that commitment, educating our customers.
First Poll question

• Who is attending today?
  o Infection Prevention Professional
  o Operating Room Professional
  o Sterile Processing Professional
  o GI Nurse
  o GI Technician
  o Nurse Manager
  o Administration
  o Laboratory professional
  o Other
Objectives:

1. Discuss outbreaks in the news and why facilities would want to perform surveillance of endoscopes
2. Outline what are considered organisms of concern in flexible endoscopes
3. Review what type of testing methods are currently available for surveillance of flexible endoscopes
4. Outline what are the options when a scope is positive for growth
DEADLY BACTERIA ON MEDICAL SCOPES TRIGGER INFECTIONS

DEadly bacteria on medical scopes killing patients

Saudi Arabia's King Abdullah dies at age 90

IN SPORTS

‘Shocked’

TSA FINDS RECORD NUMBER OF GUNS

USA TODAY WEEKEND

REAL SNIPERS FACE REAL CHOICES

IT SHOWS THE GREATEST AMOUNT OF RESTRAINT

IN NEWS

I didn’t alter the ball in any way. Everyone is trying to figure out what happened. I was as surprised as anybody when I heard Monday morning what was happening.”

Tom Brady

IN SPORTS

Over 80% loaded: also found — knife in an enchilada

IN NEWS

WASHINGTON: A record 3,262 firearms w/ no complaints loaded into conveyors at US airports but the TSA released today for the Department of Homeland Security...
Additionally, at least **25 separate incidences with over 250 patients infected.**

- Traced antibiotic-resistant infections directly to duodenoscopes
- Hospitals generally did not raise alarms about these infections with federal regulators.
  - Lack of reporting of the required adverse event form to the device manufacturers.

What is Microbial Surveillance?

• Surveillance culturing involves sampling endoscope channels and the distal end of the scope and culturing those samples to identify any bacterial contamination that may be present on the scope after reprocessing.

• Some facilities have successfully implemented routine or periodic surveillance culturing to assess the adequacy of duodenoscope reprocessing and to identify duodenoscopes with persistent contamination despite reprocessing.
Why Perform Microbial Surveillance?

• Quality control
  o Assessment of reprocessing areas in HCF – as quality control marker of adequacy and completeness of reprocessing.
  o Assuring training competency through a monitoring program
  o Ensure the reprocessing steps that are outlined in the IFU are carefully carried out as specified
    • Helps with internal investigation if patient infections are linked to reprocessing
• Monitoring program
  o Microbiological surveillance program
ECRI and Endoscope Warnings

- Over the last many years ECRI has warned us that scopes are an issue
  - 2017 is # 2
  - 2016 was # 1
  - 2015 was # 4
  - 2014 was # 6
  - 2013 was # 8
  - 2012 was # 4
  - 2011 was # 3

- Training and following the IFU is key to a clean, functional scope
CLEANR Study—Direct observation: Only half of the 183 scopes were reprocessed properly; manual cleaning was almost always inadequate.

Manual cleaning \( n = 69; p = 0.001 \)

Ofstead et al., *Gastroenterology Nursing*, 2010
Organisms of Concern

• Organisms of concern for microbiological surveillance should include:
  o Panel of organisms suggested by the CDC in their culturing protocol.
  o High concern organisms
    • Organisms that are more often associated with disease
    • Gram negative organisms
High Concern Organisms

- Gram negative organisms (e.g., *Escherichia coli*, *Klebsiella pneumoniae* or other *Enterobacteriaceae* and *Pseudomonas aeruginosa*), *Staphylococcus aureus*, Beta-hemolytic *Streptococcus*, *Enterococcus* species, and yeasts.
Low Concern Organisms

- Those organisms less often associated with disease.
- Small numbers of low-concern organisms might occasionally be detected for scope cultures.
- Example organisms: coagulase-negative staphylococci excluding *Staphylococcus lugdunensis*, *Bacillus* species, diphtheroids).
- Levels on a duodenoscope can vary depending on the reprocessing, handling, and culturing practices in a facility.
- Facilities can monitor the levels of these bacteria within the first month of surveillance testing to develop an expected baseline for those organisms.
- Fewer than 10 colony forming units (CFU) of low-concern microbes do not require intervention;
  - Results with $\geq 10$ CFU of low-concern microbes should be considered in the context of typical culture results at the facility.
Current Recommendations

• CDC recommends to perform a microbiological surveillance program where possible
• Several publications have acknowledged that countries in Europe have endorsed this program, and practice it routinely
SGNA on Culturing

- Routine culturing of endoscopes following reprocessing is not currently recommended in the United States but may be considered in the event of an identified outbreak.

- Surveillance cultures can be used as a method for assessing reprocessing quality and an aid in identifying particular endoscope defects that hamper effective reprocessing.

Society of Gastroenterology Nurses and Associates Inc.
AAMI on Culturing

• AAMI standards ST 91 –
• No recommendation is made in the current version because of the timing of release.
  o Studies have identified the nature of microbial contamination likely to be found in improperly reprocessed endoscopes and have demonstrated the value of surveillance testing

Association for the Advancement of Medical Instrumentation
AORN Recommendations

• Recommends that a multidisciplinary team that includes infection preventionists, endoscopists, endoscopy processing personnel, microbiologists, laboratory personnel, risk managers, and other involved personnel should evaluate the need to implement a program for regular microbiologic surveillance culturing of flexible endoscopes & specifically duodenoscopes.

• Team should also evaluate the following:
  o Method to use, frequency, benchmark levels for the facility, & what to do with the results

Association of periOperative Registered Nurses
FDA Recommendations

Supplemental Measures to Enhance Duodenoscope Reprocessing: FDA Safety Communication - August 4, 2015

• Provides a list of supplemental duodenoscope reprocessing measures that facilities can use in addition to current IFUs for additional risk mitigation.
  • Microbiological Culturing
  • Ethylene Oxide Sterilization
  • Use of a Liquid Chemical Sterilant Processing System
  • Repeat High-Level Disinfection

Food and Drug Administration
CDC Recommendations

• CDC has outlined Interim Guidance on culturing duodenoscopes updated 4/3/15
  o Targeted for HCF to utilize and use
  o Culturing methods are available but not distinguished in detail

• 30 days or 60 cycles

• Non-culture methods (such as enzymatic /verification methods) can be used to assess duodenoscope reprocessing by detecting residual organic material after cleaning. While individual facilities might choose to use such non-culture assays, more work is needed to interpret their results since non-culture methods lack consistent correlation to bacterial concentrations.
  o May provide insight regarding the quality of duodenoscope reprocessing.

www.cdc.gov
Residual contamination found on endoscopes in an ambulatory surgery center

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Introduction
- Contaminated endoscopes have caused outbreaks of multidrug-resistant organisms.1
- Among new outbreaks, investigation revealed an endoscope was contaminated:
  - Brown stain in the distal tip
  - Pseudomonas aeruginosa identical to an outbreak strain
- In another outbreak investigation:
  - Infections were linked to contaminated endoscopes.
  - Infections were linked to contaminated endoscopes:
  - The manufacturer’s critical defects in every endoscope.

This study was designed to answer two questions:
- How much damage and debris accumulate in endoscopes over time?
- Is it possible to get rid of endoscopes clean?

Methods
- Longitudinal study in an outpatient endoscopy center
- Three assessments conducted over a 1-month period
- Baseline data collection in April 2015:
  - Auditing reprocessing practices
  - Compliance data on endoscope age, usage, and repair history

- Evaluating 17 clinically-used endoscopes:
  - Rapid endoscope tests for ATP and protein
  - ATP tests for endoscope cleaning

- Endoscope reprocessing recommendations
- Implemented rigorous reprocessing methods (beginning in May 2015)

Results
- At the baseline assessment:
  - Endoscopes were in use for 2.5 years on average.

- Endoscopes had been used 30-54 times.
- New endoscopes had been repaired.
- There was good adherence to reprocessing policies.

- 16 of 17 endoscopes were still contaminated after manual cleaning.
- Contamination level was higher for gastroscope than colonoscope (Figure 1 and 2).

- Endoscope examinations of patient-ready endoscope channels identified:
  - Brown fluid (Photo 1 and 2)
  - Intraoral surfaces and brown staining (Photo 3)
  - Scars, rust, and brown staining (Photo 4)

- Among contaminated endoscopes:
  - 11% failed to meet criteria for patient-ready endoscopes.
  - 15% had visible debris on the endoscopes.

- ATP tests revealed endoscopes had levels of debris and protein (Figure 1 and 2).

Summary and next steps
Looking inside reprocessed endoscopes revealed damage and debris

- During the baseline assessment, endoscopes found:
  - Damage and debris inside channels
  - Contamination level exceeding benchmarks
  - Residual debris in channels and ports

- Findings indicated that current reprocessing methods were not sufficient.

- Interventions included:
  - Sealing endoscopes for repair
  - Revising reprocessing practices
  - Implementing routine ATP monitoring to improve effectiveness
  - Increasing training on reprocessing

- Results from the interim and final assessments are forthcoming:
  - Observations from reprocessed endoscopes reprocessing practices
  - Impact of interventions designed to improve reprocessing

Disclosures and acknowledgements

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References

http://www.ofsteadinsights.com/?p=2303
ECRI Recommendations

Consider instituting regular CRE surveillance through duodenoscope culturing.

Options:
- Do baseline cultures.
- Culture every duodenoscope after reprocessing is completed and waiting to release the cultured scopes until negative results are received.
- If not every scope, then weekly.

www.ecri.org/cre
Reprocessing effectiveness for gastroscopes and colonoscopes: Longitudinal comparison of two methods

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1. Introduction
- Outbreaks have been linked to contaminated gastroscopes and colonoscopes3
- Investigators have identified endoscope defects during outbreaks4
- Study conducted to determine:
  - How much damage and debris accumulate over time?
  - Is it possible to get rid of endoscope defects?
  - What is the effect of more rigorous reprocessing methods?

2. Methods
- Longitudinal study conducted over 7 months
- Standard reprocessing (control) compared with more rigorous methods (intervention) (rate 1)
- Baseline and interim data collected included:
  - Observation of reprocessing
  - ATP test cultures after cleaning and after HLD
  - Biopsies at different channels

3. Results
- Baseline:
  - Manual cleaning and HLD commonly ineffective (Table 1)
  - Gastroscopes more contaminated than colonoscopes
  - Visible impurities and residual fluid identified (Figures 1, 2)
- Interventions:
  - Contamination and defects measured over time
  - Discouragement induced in intervention group (Figures 3, 4)
  - Cleaning verification tests exceeded benchmarks:
    - 1% of colonoscope encounters (< 504)
    - 52% of gastroscopes encountered (< 45)

4. Summary

Endoscope contamination accumulated over time
- Biopsies at different channels
- ATP test cultures after cleaning and after HLD
- More rigorous reprocessing methods reduced discoloration

Table 1: Results for baseline and intervention groups

<table>
<thead>
<tr>
<th>Reprocessing methods</th>
<th>Control</th>
<th>Intervention</th>
</tr>
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<td>Biopsies pre-cleaning</td>
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<td>Manual cleaning</td>
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<td>Visible defects</td>
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<td>x</td>
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<td>ATP verification</td>
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<td>HLD with phenotyping</td>
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<tr>
<td>HLD with phenotyping</td>
<td>x</td>
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</tbody>
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References
1. Figure 1: Repro-Aqua, 2016. 2. Figure 2: Repro-Aqua, 2016. 3. Figure 3: Repro-Aqua, 2016. 4. Figure 4: Repro-Aqua, 2016. 5. Figure 5: Repro-Aqua, 2016.
Practical toolkit for monitoring endoscope reprocessing effectiveness: Identification of viable bacteria on gastrosopes, colonoscopes, and bronchoscopes

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Poll question #2

• Does your facility currently reprocess duodenoscopes used for ERCP procedures?
  o Yes
  o No
Poll question # 3

• Is your facility currently performing any type of culturing of your scopes?
  o Yes
  o No
Poll question # 4

• Of those performing culturing, is your facility performing the sampling and culturing in-house?
  ○ Yes
  ○ No
Surveillance Options for Reprocessed Endoscopes
CDC Culture Method

- CDC has published 3 Surveillance Protocols:
  1. Interim Duodenoscope Surveillance Protocol
     - Interim protocols for healthcare facilities regarding surveillance for bacterial contamination of duodenoscopes after reprocessing
  2. Interim Duodenoscope Sampling Protocol
     - Discusses areas/sites to be sampled and cultured
     - Methods of sampling
  3. Interim Duodenoscope Culture Method
     - Discusses options available for culturing
       - Centrifugation and filtration methods
       - Sampling media to be utilized for enumeration
Guidance on culturing

- CDC Interim Guidance on culturing duodenoscopes updated - 4/3/15
- Sites to be cultured:
  - Instrument channel (suction/biopsy channel)
  - Distal end (elevator mechanism, elevator recess)
  - Elevator channel (on older, unsealed)
- Frequency: Every 30 days or 60 cycles

CDC Culture

- Baseline levels of acceptable bacteria:
  - Fewer than 10 CFU of low concern microbes does not require intervention
  - 1 CFU or greater of high concern (pathogenic) bacteria warrants further remedial actions

- Other surveillance methods (e.g. non-culture methods such as enzyme based methods) can be used to assess duodenoscope reprocessing by detecting residual organic material after cleaning.
  - May provide insight regarding the quality of duodenoscope reprocessing.
CDC Culture

• Reprocess any contaminated duodenoscopes and re-culture.

• The scope should not be used again until it’s demonstrated to be free of high concern organisms or has an acceptable level of low concern organism.

• If a reprocessing breach is identified, appropriate personnel should be notified and corrective actions implemented immediately.

• If cultures are repeatedly positive (3 times or more), consider evaluating the cleaning/reprocessing technique and/or getting the scope evaluated by the manufacturer.
Options to perform Microbial Surveillance

• Options include:
  o Traditional culturing in house or kits
  o Gram negative test kits (NOW! Test)

• Not ATP or cleaning verification tests
Mail Back Endoscope Surveillance Test Service

- Not all hospital labs can do this type of testing
  - CLIA labs – do not test environmental samples
- Mail back service for endoscope samples are now available
- Healthmark and Nelson Labs together created a mail back surveillance culture service
- Meant for monitoring and reporting objective results from clinical scopes as a proficiency assessment for healthcare
- Up front purchase of kit, cost of shipping and performing cultures at the lab is included
- Facility takes sample, mails directly to Nelson Labs
Mail Back Endoscope Surveillance Test Service

• Allows for independent testing of the sample for the presence of any microorganisms.
  o If present, the organisms will be identified and quantified.

• Includes protocol based on CDC method, items needed to take the samples, refrigerated pre-labelled shipper with cold packs, etc.
  o Does not include PPE

• Timeline: 3 days if no growth; 7-10 days with growth

• Product info:
Monitoring for Gram-negative Organisms in Reprocessed Scopes – NOW! test

- Enzymes specific to Gram-negative bacteria hydrolyze the substrate in the reagent vial
  - This generates fluorescence, which is read by the fluorometer, which then gives a reading.

- ST91: Types of verification testing may include enzyme based tests
  - Such as the NOW! test kit for gram negative organisms
NOW! Test

• Simple, rapid test (~12 hours) for Gram negative bacteria.
• Monitoring for effective reprocessing, safe to use on the next patient.
• Detection limit of <10 CFU for Gram negative bacteria.
• Positive readings.
  o 200-300 = likely to be contaminated with gram negatives
  o >300 = highly likely to be contaminated with gram negatives
• Reprocess the endoscope following manufacturer guidelines prior to use. DRY!
• Repeated positives = investigate!
• IFU and validation studies available online:
Options for a scope that has tested positive for organisms

• High concern Organisms:
  o Potential limit: 1 CFU
  o Remove from USE!
  o Reprocessing practices should be reviewed to identify potential improvements in the process
  o Endoscope will be reprocessed again:
    o Cleaning and HLD
      • Perform screening again for organisms. If tested positive for high concern organism again perform reprocessing as needed.

• Quarantine scope until results are obtained before placing back to use

• INVESTIGATE!
Options for a scope that has tested positive for organisms

- Low/moderate concern organisms potential limits
  - ≤10 CFU no action
  - 11 to 100 CFU – Alert action
    - Reprocessing should be reviewed to ensure adequacy
    - Sampling method should be reviewed to minimize contamination.
  - >100 CFU – Action
    - High levels of low-concern organisms may be indicative of inadequate reprocessing and/or damage to the endoscope.
    - Reviewing endoscope reprocessing and sampling/culturing protocols and methods
    - Remove from reprocessing or use
Implementation strategies

• Any duodenoscope found to be contaminated should not be returned to use until the contamination has been eliminated from the device.
• Culturing is resource-intensive & includes added costs of microbiological testing and staff time needed to collect and process samples.
• Culturing services can be “outsourced” to environmental or contract laboratories due to lack of on-site experience with culturing, uncertainty in interpretation of results and workflow considerations.
• Surveillance culture results take time to produce.
• Assess your supply and clinical demand for duodenoscopes when considering microbiological culturing implementation.
• Rapid test for gram negatives are available.
Thank you!

• Questions?
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- NOW! Test and endoscope surveillance kit: www.healthmarkgi.com
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