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.
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• 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
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
  o 2017 is # 2
  o 2016 was # 1
  o 2015 was # 4
  o 2014 was # 6
  o 2013 was # 8
  o 2012 was # 4
  o 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:
  - Panel of organisms suggested by the CDC in their culturing protocol.
  - 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 ≥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.

AAMI on Culturing

• AAMI standards ST 91 –
• No recommendation is made in the current version because of the timing of release.
  • Studies have identified the nature of microbial contamination likely to be found in improperly reprocessed endoscopes and have demonstrated the value of surveillance testing
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:
  - 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
  - Targeted for HCF facilities and use
  - 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.
  - May provide insight regarding the quality of duodenoscope reprocessing.

www.cdc.gov
Current Literature Showing Residual Contamination

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.

Current Literature Showing Residual Contamination – Poster at SGNA 2016
Current Literature Supporting Culturing to Detect Residual Contamination

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 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

CDC Culture Method
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:
  - Traditional culturing in house or kits
  - Gram negative test kits (NOW! Test)

- Not ATP or cleaning verification tests

Mail Back Endoscopy 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 Endoscopy Surveillance Test Service

- Allows for independent testing of the sample for the presence of any microorganisms.
  - 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.
  - 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:
  - 200-300 = likely to be contaminated with gram negatives
  - >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: http://www.healthmarkgi.com/products.php?g=Surveillance%20Testing&p=NOW%20Test

Options for a scope that has tested positive for organisms

- High concern Organisms:
  - Potential limit: 1 CFU
  - Remove from USE!
  - Reprocessing practices should be reviewed to identify potential improvements in the process
  - Endoscope will be reprocessed again:
    - 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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References

- FDA: http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm454766.htm
- AAMI ST91: purchase at www.aami.org
- AORN: purchase at www.aorn.org
- SGNA: http://www.sgna.org/Portals/0/Standards%20for%20reprocessing%20of%20endoscopes/FINAL.pdf
- NOW! Test and endoscope surveillance kit: www.healthmarkgi.com

CE Quiz Link

- To receive a CE credit for your participation in this webinar, please visit: www.healthmark.com/becker_december2016.php
- There, you can review the PowerPoint and submit a short quiz. Your CE credit will then be sent to the email address you provide.
- All attendees will be sent a follow up email including this information.