csgna 2018
Entre fleuve et montagnes venez nous découvrir!
Between the river & mountains discover us!
SEPTEMBER 20–22 SEPTEMBRE Québec City

Implementing an Endoscope Surveillance Program

Mary Ann Drosnock, MS, CIC, CFER, RM (N
Senior Manager of Clinical Education
Healthmark Industries and
Co-chair AAMI WG84 for Endoscope Reprocessing - ST91

Disclosure

- Mary Ann Drosnock is an employee of Healthmark Industries Fraser, Michigan, which manufactures and distributes medical products to healthcare facilities and healthcare professionals
- 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).

Objectives:

- Define what the current Canadian and world standards and guidelines state regarding culturing of flexible endoscopes.
- List what type of testing methods are currently available for surveillance of flexible endoscopes.
- Discuss what literature and facilities describe for the results of their surveillance programs.

WHY ARE WE HERE?

Recent Headlines – STILL!

Clinical Leadership & Infection Control

500+ patients potentially infected by dirty endoscopes

Health & Science

Study: Nearly Three-Quarters Of Commonly Used Medical Scopes Tainted By Bacteria

AAMI News February 2018

Standards Spotlight: Endoscope Reprocessing Working Group Strives toward Stronger Guidelines

Endoscope care comes into focus at 2018 IAHCSMM Annual Conference

By Julie E. Williamson - January 22, 2018 601 0

Senate Report 2016

- Between 2012 and Spring of 2015 duodenoscopes were linked at least **25 separate incidences with over 250 patients infected.**
- Though at least 16 U.S. hospitals traced infections directly to duodenoscopes, they did not raise alarms about these infections with federal regulators.
- Failure of the FDA to rapidly identify duodenoscope related, antibiotic-resistant infections should serve as a appeal for post-market surveillance systems.
- 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

http://www.help.senate.gov/imo/media/doc/Duodenoscope%20Investigation%20FINAL%20Report.pdf

ECRI and Endoscope Warnings

- Over the last many years ECRI has warned us that scopes are an issue
  - 2018 it is # 2
  - 2017 was # 2
  - 2016 was # 1
  - 2015 was # 4
  - 2014 was # 6
  - 2013 was # 8
  - 2012 was # 4
  - 2011 was # 3

2. Endoscope Reprocessing Failures Continue to Expose Patients to Infection Risk

ECRI Endoscope Recommendations

- To achieve more reliable and effective endoscope reprocessing, ECRI Institute recommends that healthcare facilities:
  1. Establish processes for assessing the quality of the cleaning step
     a. through magnification-aided visual inspections and the use of biochemical testing
  2. Implement measures to dry endoscope channels after reprocessing

Reference ECRI 2018: https://www.ecri.org/Resources/Whitepapers_and_reports/Haz_18.pdf

WHAT ARE WE TALKING ABOUT?

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 WOULD A FACILITY PERFORM MICROBIAL SURVEILLANCE?

Why Perform Microbial Surveillance?

- Quality control
  - ✓Determine adequacy and completeness of reprocessing
  - ✓Assuring training competency through monitoring program
  - ✓Ensure IFU reprocessing steps are carefully followed
  - ✓Helps with internal investigation if patient infections are linked to reprocessing
  - ✓Verifying change in processes

RECENT RESEARCH ON CULTURING

Recent Research 2018

Endoscopy

OPEN ACCESS

ORIGINAL ARTICLE

High prevalence rate of digestive tract bacteria in duodenoscopes: a nationwide study

Arjan W Rauwers,[1] Anne F Voor in 't holt,[2] Jolanda G Buijs,[3] Woutrinus de Groot,[2] Bettina E Hansen,[1] Marco J Bruno,[1] Margreet C Vos[2]

► Study showed high prevalence rates of duodenoscope contamination in Endoscopic Retrograde Cholangiopancreatography (ERCP) centers in the Netherlands.

► In a substantial proportion of the cultured duodenoscopes, organic material of previous patients was still present, as they were contaminated with microorganisms of gastrointestinal or oral origin. These results suggest that the current combination of reprocessing and process control does not suffice.

► In this study, contamination occurred with all types of duodenoscopes, independent of type specific design.

Conclusions:

► Patients undergoing ERCP procedures remain to be at risk of being treated with contaminated equipment.

► Efficient surveillance strategies and reprocessing control measures are required to reduce the number of contaminated duodenoscopes, minimizing the chance of interpatient transmission of microorganisms.

http://gut.bmj.com/content/early/2018/04/19/gutjnl-2017-315082.1

What do we know about HLD failures?

Findings from Ofstead studies

Endoscope types	% with bacteria
Bronchoscopes, EBUS	**58%**
Bronchoscopes, colonoscopes, EGD	**60%**
Colonoscope/EGD	**64%**
GI, pulmonary, urologic	**71%**

Sources: Ofstead “Persistent contamination” AJIC 2015; Ofstead “Residual moisture” AJIC 2018; Ofstead bronchoscope study, 2018 in press

Clinical relevance:

Study	Situation	Findings
2016 Ofstead	“Practical Toolkit” study	Germs on 60% of EGDs, colons, bronchs; Pathogens on all types
2016 England	“Documented Transmission” superbug investigation	Superbug persisted on EGD after 9 clinical uses; 12 HLD cycles
2017 Loor	“ERCP and cholecystectomy” study	Cholecystectomy only 1.8% SSI (0.2% resistant pathogens) Cholecystectomy + ERCP 4.1% SSI (1.1% resistant pathogens)

Double HLD failures reported 2017

Study	Location	% with bacteria
Rex	Indiana U	5%
Brandabur	Providence/Swedish	7-8%
Snyder	Beth Israel/Harvard	16%
Visrodia	Mayo Clinic	40%

CURRENT GUIDELINES AND RECOMMENDATIONS

PHAC Guidelines on Surveillance

- There are two potential problems that may arise during the reprocessing of flexible endoscopes:

  i) persistence of organic material if cleaning is inadequate and

  ii) presence of residual microorganisms if high-level disinfection /sterilization are suboptimal or if endoscopes are not dried before storage. The role of ongoing environmental endoscopic surveillance cultures to monitor the effectiveness of routine cleaning and disinfection techniques remains controversial

- Australian, French, and the European Society of Gastrointestinal Endoscopy (ESGE) and the European Society of Gastroenterology and Endoscopy Nurses and Associates (ESGENA) guidelines advocate routine culturing of flexible endoscopes and AER for specific pathogens.

INFECTION PREVENTION AND CONTROL GUIDELINE for Flexible Gastrointestinal Endoscopy and Flexible Bronchoscopy – Public Health Agency of Canada - 2011

Canadian PHAC Guidelines

- North American guidelines, for the most part, do not recommend routine monitoring of endoscope channels unless infection transmission, an outbreak, or a reprocessing error has been identified. NOT TRUE Anymore
- Routine bioburden monitoring of flexible endoscope channels may be useful as a "process monitor" by providing a valuable quality assurance tool to help identify previously unknown problems with the reprocessing process.
- The results of this monitoring could be used to reinforce staff compliance with proper reprocessing techniques or identify a need to revise reprocessing policies and procedures.

INFECTION PREVENTION AND CONTROL GUIDELINE for Flexible Gastrointestinal Endoscopy and Flexible Bronchoscopy – Public Health Agency of Canada - 2011

Canadian PHAC Guidelines

- Bioburden monitoring should not be used to identify a specific endoscope in need of better reprocessing before use.
- Whether patient disclosure is required post-endoscopy if deficiencies in reprocessing are identified through the process monitor is controversial.
- **Appendix D** provides an outline of how bioburden testing could be performed as part of an outbreak investigation.

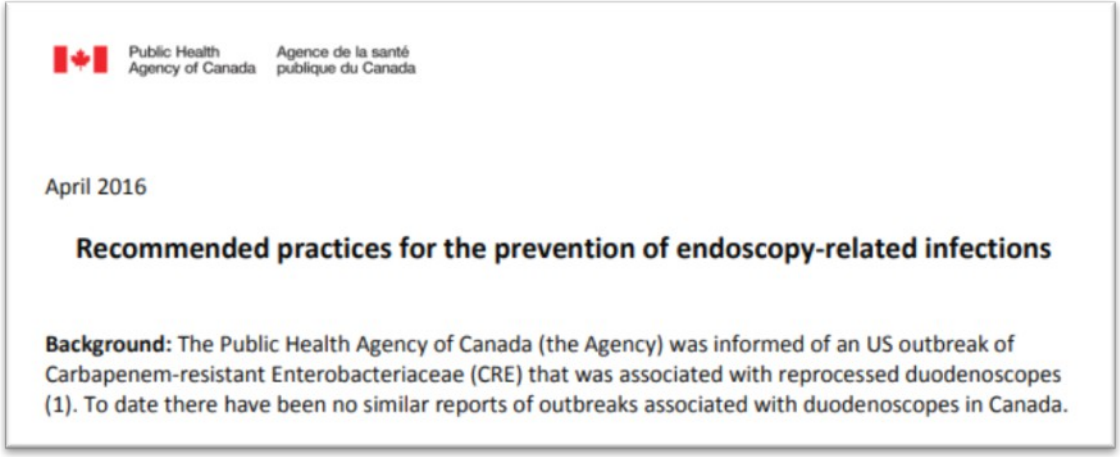
INFECTION PREVENTION AND CONTROL GUIDELINE for Flexible Gastrointestinal Endoscopy and Flexible Bronchoscopy – Public Health Agency of Canada - 2011

Appendix D: Bioburden test method

- Sample collection requires two people.
- Use Aseptic Technique and wear appropriate PPE
- Gives a basic method and how to interpret results
- Interpretation: Was there residual moisture in the channels during storage (review the procedure for alcohol rinsing and forced air drying prior to storage)? ***This is the most common reason for sporadic unacceptable bioburden levels***.

CSA Recommendations

- At this time, the Agency is not recommending enhanced reprocessing procedures for duodenoscopes nor periodic microbiologic surveillance cultures of endoscopes.



Public Health Agency of Canada | Agence de la santé publique du Canada

April 2016

Recommended practices for the prevention of endoscopy-related infections

Background: The Public Health Agency of Canada (the Agency) was informed of an US outbreak of Carbapenem-resistant Enterobacteriaceae (CRE) that was associated with reprocessed duodenoscopes (1). To date there have been no similar reports of outbreaks associated with duodenoscopes in Canada.

https://www.canada.ca/en/public-health/services/infectious-diseases/nosocomial-occupational-infections/recommended-practices-prevention-endoscopy-related-infections.html

Current US 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 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
- Currently being updated

AORN Recommendations

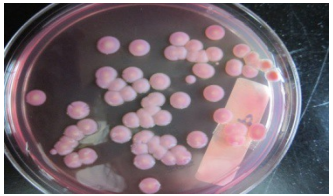
- Recommends that a multidisciplinary team that includes infection preventionists, endoscopists, endoscopy processing personnel, microbiologists, laboratory personnel, risk managers, and other involved personnel should evaluate the need to implement a program for regular microbiologic surveillance culturing 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,

CDC Recommendations

- CDC has outlined Interim Guidance on culturing duodenoscopes updated 4/3/15
  - Targeted for HCF to utilize and use
  - Culturing method[illegible]re available b[illegible]ot distinguished in detail

- 30 days or 60 cycles

- Non-culture methods (such a[illegible]ethods) can be used to assess duodenoscope reprocessi[illegible]material after cleaning. While individual facilities might c[illegible]se such n[illegible]assays, more work is needed to interpret their results since [illegible]ulture methods la[illegible]sistent correlation to bacterial concentrations.
  - May provide insight regarding the quality of duodenoscope reprocessing.



www.cdc.gov

CDC Culture Information

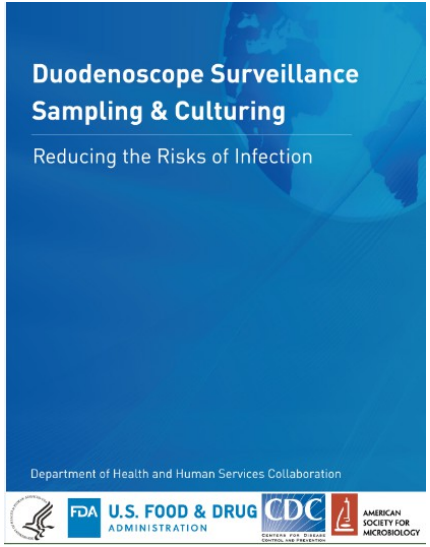
- Superseded by new FDA/CDC/ASM method
- Baseline levels of acceptable bacteria:
  - Fewer than 10 CFU of low concern microbes- does not require intervention
  - 1 CFU or greater of high concern (pathogenic) bacteria- warrants further remedial actions

- Other surveillance methods (ex. 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

FDA/CDC/ASM Recommendations

Duodenoscope Surveillance Sampling & Culturing

Reducing the Risks of Infection - February 2018



- Intended to minimize the workload for healthcare facilities that implement duodenoscope surveillance sampling and culturing while maximizing the potential for detecting viable microbes
- Culturing information may be collected to monitor the facility-specific procedures for reprocessing duodenoscopes, and could be used to identify systematic errors in reprocessing or damaged endoscopes and equipment
- The protocol is designed to identify most organisms of concern that could be present on a duodenoscope

https://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/ReprocessingofReusableMedicalDevices/UCM5979

FDA Culture method info

- No time frames for performing culturing
- Sample channel, around forceps elevator with flushing
- Swab around distal tip
- Samples are combined
- Use of a neutralizer broth added to collected sample
- Sample with sterile water
- Longer incubation time for plates

FDA Recommendations

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

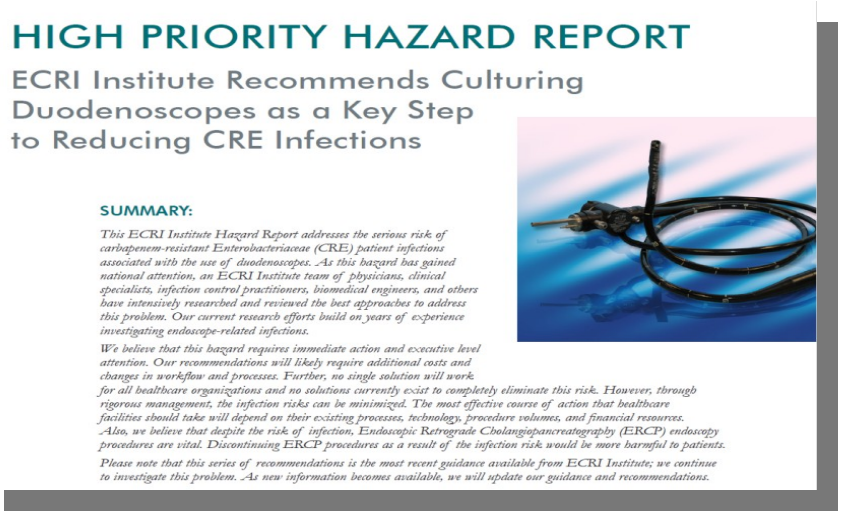
- Provides a list of supplemental duodenoscope reprocessing measures that facilities can use in addition to current IFUs for additional risk mitigation.
  - Microbiological Culturing
  - Ethylene Oxide Sterilization
  - Use of a Liquid Chemical Sterilant Processing System
  - Repeat High-Level Disinfection

FDA U.S. FOOD & DRUG ADMINISTRATION

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

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.**



HIGH PRIORITY HAZARD REPORT

ECRI Institute Recommends Culturing Duodenoscopes as a Key Step to Reducing CRE Infections

SUMMARY:

This ECRI Institute Hazard Report addresses the serious risk of carbapenem-resistant Enterobacteriaceae (CRE) patient infections associated with the use of duodenoscopes. As this hazard has gained national attention, an ECRI Institute team of physicians, clinical specialists, infection control practitioners, biomedical engineers, and others have intensively researched and reviewed the best approaches to address this problem. Our current research efforts build on years of experience investigating endoscope-related infections.

We believe that this hazard requires immediate action and executive level attention. Our recommendations will likely require additional costs and changes in workflow and processes. Further, no single solution will work for all healthcare organizations and no solutions currently exist to completely eliminate this risk. However, through rigorous management, the infection risks can be minimized. The most effective course of action that healthcare facilities should take will depend on their existing processes, technology, procedure volumes, and financial resources. Also, we believe that despite the risk of infection, Endoscopic Retrograde Cholangiopancreatography (ERCP) endoscopy procedures are vital. Discontinuing ERCP procedures as a result of the infection risk would be more harmful to patients.

Please note that this series of recommendations is the most recent guidance available from ECRI Institute; we continue to investigate this problem. As new information becomes available, we will update our guidance and recommendations.

https://www.ecri.org/Resources/Superbug/Culturing_Duodenoscopes_Key_Step_to_Reducing_CRE_Infections.pdf

www.ecri.org/cre

Current Literature Supporting Culturing to Detect Residual Contamination

ARTICLE IN PRESS

American Journal of Infection Control ■■ (2016) ■■-■■

Contents lists available at ScienceDirect

American Journal of Infection Control

journal homepage: www.ajicjournal.org

Original Research Article

Practical toolkit for monitoring endoscope reprocessing effectiveness: Identification of viable bacteria on gastroscopes, colonoscopes, and bronchoscopes

Cori L. Ofstead MSPH [a,*], Evan M. Doyle BS [a], John E. Eiland MS, RN [a], Miriam R. Amelang BA [a], Harry P. Wetzler MD, MSPH [a], Dawn M. England MPH, CPHQ [b], Kristin M. Mascotti MD, CPE [c], Michael J. Shaw MD [d]

[a] Ofstead & Associates, Inc, St Paul, MN

American Gastroenterological Association

Feb. 27, 2018

AGA Supports New Government Scope Safety Protocols

While voluntary, AGA encourages GIs to review and consider adopting sampling and culturing of reprocessed duodenoscopes.

AGA encourages hospitals and health care facilities that utilize duodenoscopes to:

1. Continue to meticulously follow manufacturer reprocessing instructions.
2. Take the additional steps, including those outlined in these protocols, to further reduce the risk of infection and increase the safety of these medical devices.

https://www.gastro.org/news/fda-cdc-release-new-protocols-to-ensure-safety-of-repr

Review of Current Recommendations

- **Canada PHAC** not recommended unless part of an outbreak investigation
- **CDC** recommends performing a microbiological surveillance program where possible
- **FDA** lists several supplemental duodenoscope reprocessing measures including microbial culturing
- **ERCI** suggests instituting regular surveillance through duodenoscope culturing
- **AORN** recommends implementing a program for regular microbiologic surveillance and culturing of scopes—specifically duodenoscopes.
- Several countries in **Europe, Australia** have endorsed, and practice, microbial surveillance routinely
- AGA supports performing culturing
- New FDA/CDC/ASM method available
- AAMI and SGNA support its use as a quality assurance mechanism

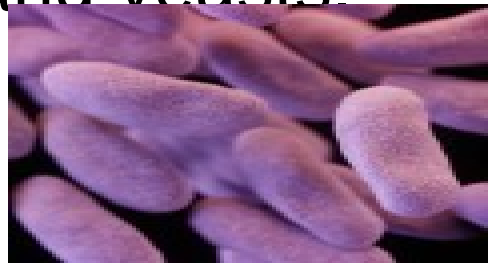
INTERPRETATION OF RESULTS

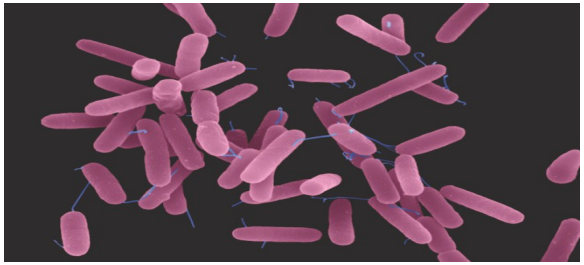
Organisms of Concern

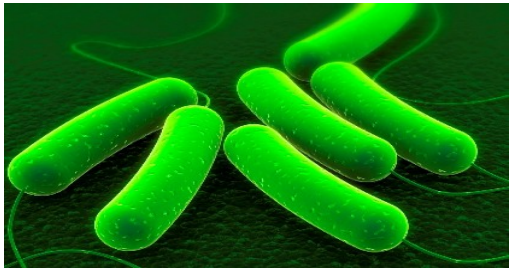
- Organisms of concern for microbiological surveillance should include:
  - Panel of organisms suggested by the CDC in their culturing protocol.
  - High concern organisms
    - Organisms that are more often associ
    - Gram negative organisms

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 does not require intervention;
  - Results with ≥ 10 CFU of low-concern microbes should be considered in the context of typical culture results at the facility.

Options for a scope that has tested positive

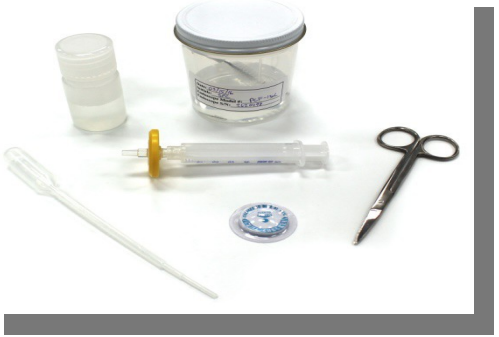
- High concern Organisms:
  - Potential limit: 1 CFU
  - Remove from USE!
  - Reprocessing practices should be reviewed to identify potential improvements in the process
  - Endoscope will be reprocessed again:
    - Cleaning and HLD
      - » Perform screening again for organisms.
      - » If tested 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

- 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

Options to perform Microbial Surveillance

- Options include:
  - Traditional culturing in house or kits
  - Gram negative test kits



- Not cleaning verification tests
  - NOT ATP, protein tests, combination tests
- Cleaning verification = after manual cleaning process
- Surveillance = after AER / in storage, not after manual cleaning

Gram Negative Test Kits

- 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!

Monitoring for Gram-negative Organisms in Reprocessed Scopes

- 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.

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

Recent peer-reviewed study on Gram Negative Tests

- Washburn and Pietsch, “Assessment of test methods for evaluating effectiveness of cleaning flexible endoscopes”
  - Am J Infect Control. 2018 Jan 9. pii: S0196-6553(17)31259-2. doi: 10.1016/j.ajic.2017.11.014.
  - Positive traditional cultures = positive gram negative test

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. ~ 7 days

Implementation strategies

- Assess your supply and clinical demand for duodenoscopes and other scopes when considering microbiological culturing implementation.
- Assess what are your high risk scopes
  - Duodenoscopes, Bronchoscopes, EUS, Ureteroscopes
- Rapid test for gram negatives are available.
  - Tool for more rapid surveillance on a more frequent

Thank you !

- Questions?
- Contact Info:

Mary Ann Drosnock

Healthmark Industries

mdrosnock@hmark.com

www.healthmarkgi.com