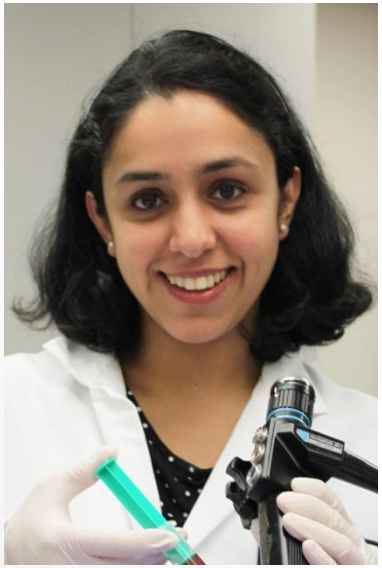
Endoscope Microbial Surveillance Testing Made Easy

Alpa Patel, B.S.RM (NRCM)
Senior Scientist
Nelson Laboratories



Kaumudi Kulkarni, M.S.
Manager of Research and Development
Healthmark Industries

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.**

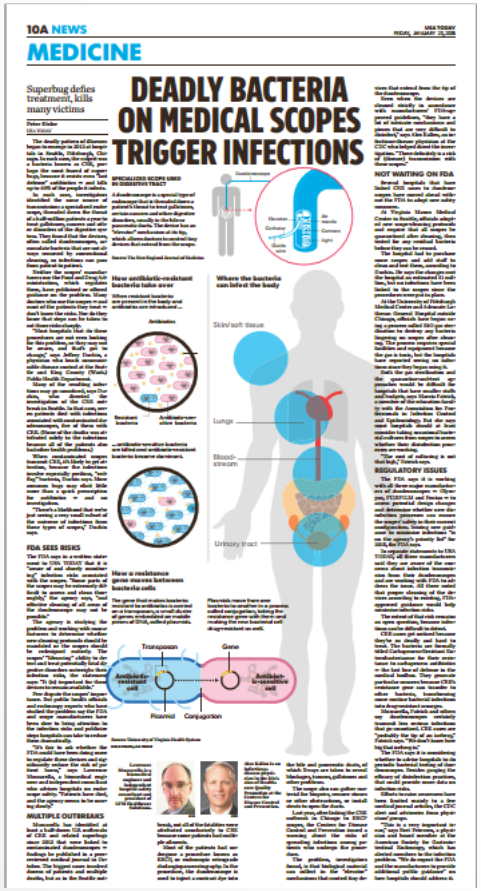
First Poll question

- Who is attending today?
  - Infection Prevention Professional
  - Operating Room Professional
  - Sterile Processing Professional
  - GI Nurse
  - GI Technician
  - Nurse Manager
  - Administration
  - Laboratory professional
  - 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

USA Today Front Page January 21st, 2015



10A NEWS

MEDICINE

Superbug defies treatment, kills many victims

DEADLY BACTERIA ON MEDICAL SCOPES TRIGGER INFECTIONS

SPECIALIZED SCOPE USED IN DIGESTIVE TRACT

NOT WAITING ON FDA

How antibiotic-resistant bacteria take over

Where the bacteria can infect the body

Skin/soft tissue

Lungs

Blood-stream

Urinary tract

How a resistance gene moves between bacteria cells

Transposon

Gene

Antibiotic-resistant cell

Antibiotic-sensitive cell

Plasmid

Conjugation

FDA SEES RISKS

REGULATORY ISSUES

MULTIPLE OUTBREAKS

$2.00

THE NATION'S NEWS

JANUARY 23 - 25, 2015

USA TODAY WEEKEND

A GANNETT COMPANY

IN NEWS

REAL SNIPERS FACE REAL CHOICES

IT 'SHOWS THE GREATEST AMOUNT OF RESTRAINT'

AT FORT BENNING, GEORGIA. BY H. DARR BEISER, USA TODAY

NEWSLINE

IN NEWS

Saudi Arabia's King Abdullah dies at age 90

He was a U.S. ally in fight against al-Qaeda.

Deadly bacteria on medical scopes killing patients

Superbug resists antibiotics; doctors, patients unaware of risks.

'Shocked'

IN SPORTS

"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

TSA FINDS RECORD NUMBER OF GUNS

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

Erin Kelly
USA TODAY

WASHINGTON A record 2,212 firearms — most of them loaded — were discovered in travelers' carry-on bags at U.S. airports last year, according to 2014 statistics released today by the Department of Homeland Security.

Senate Report List

- 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.

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

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?

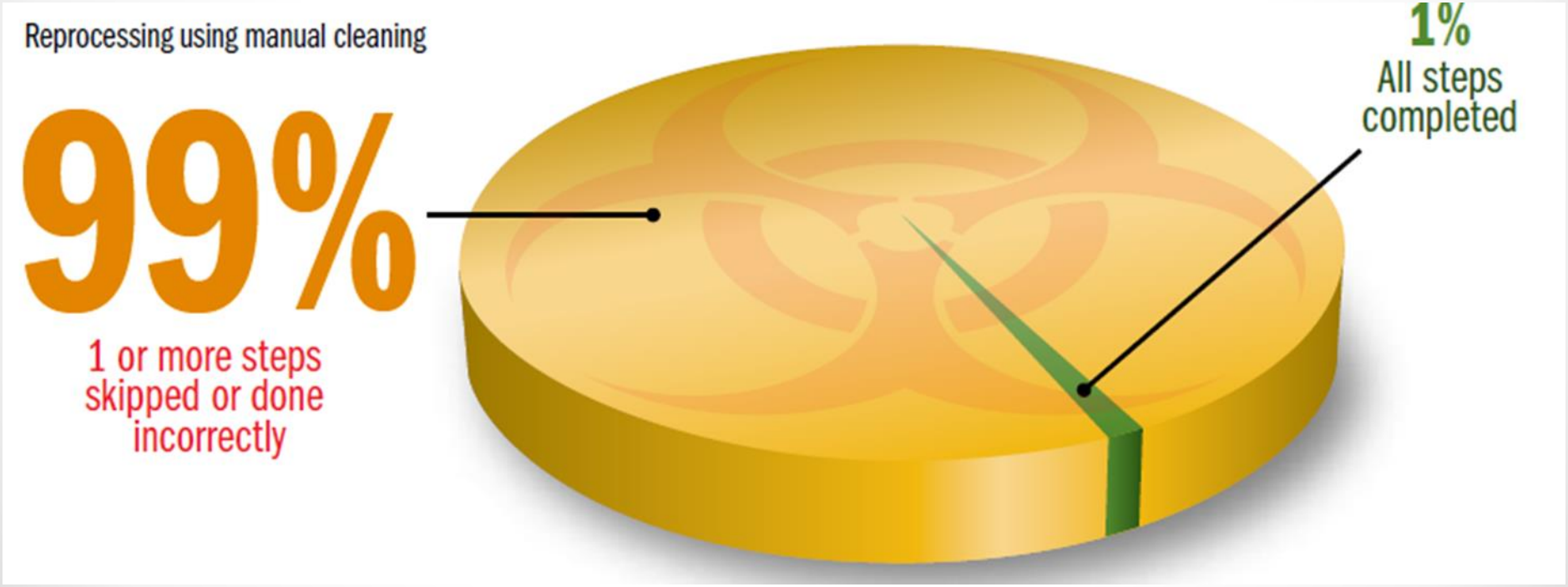
- Quality control
  - Assessment of reprocessing areas in HCF – as quality control marker of adequacy and completeness of reprocessing.
  - Assuring training competency through a monitoring program
  - Ensure the reprocessing steps that are outlined in the IFU are carefully carried out as specified
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

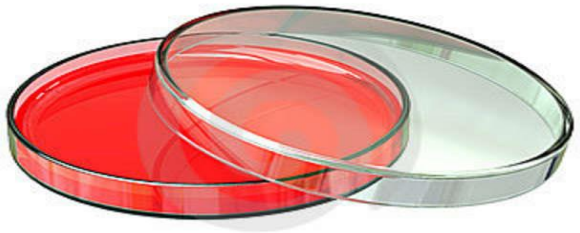


Manual cleaning n = 69; p = 0.001

Ofstead et al., *Gastroenterology Nursing*, 2010

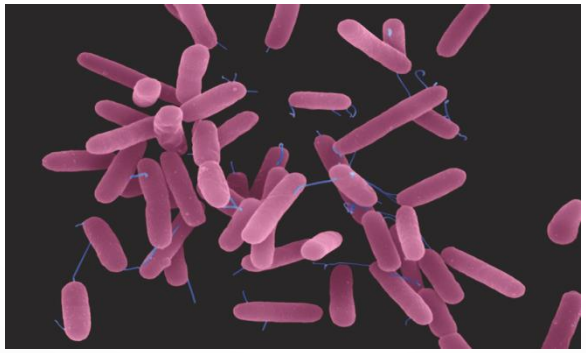
Organisms of Concern

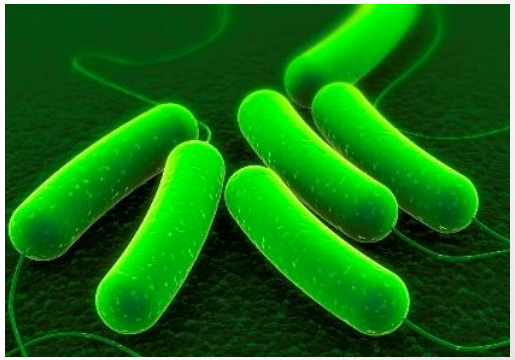
- Organisms of concern for microbiological surveillance should include:
  - Panel of organisms suggested by the CDC in their culturing protocol.
  - High concern organisms
    - Organisms that are more often associated with disease
    - Gram negative organisms



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

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

FDA U.S. FOOD & DRUG ADMINISTRATION

CDC Recommendations

- CDC has outlined Interim Guidance on culturing duodenoscopes updated 4/3/15
  - Targeted for HCF to utilize 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

Residual contamination found on endoscopes in an ambulatory surgery center

Cori L. Ofstead, MSPH[1], John E. Eiland, RN, MS[1], Miriam R. Amelang, BA[1], Otis L. Heymann, BA[1], Sarah B. Held, RN, MBA[2], Michael J. Shaw, MD[3]

[1]Ofstead & Associates, Inc., Saint Paul, MN, USA; [2]Fairview Maple Grove Medical Center, Maple Grove, MN, USA; [3]Division of Gastroenterology, Department of Medicine, University of Minnesota Medical School, Minneapolis, MN, USA

Introduction

- Contaminated endoscopes have caused outbreaks of multidrug-resistant organisms[1-5]
- During one outbreak investigation, investigators dismantled an endoscope and identified:[5]
  - Brown staining, scale, and a small crack in the distal tip
  - *Pseudomonas aeruginosa* identical to outbreak strain
- In another outbreak investigation:[2]
  - Infections were tied to contaminated endoscopes
  - The manufacturer found critical defects in every duodenoscope
- This study was designed to answer two questions:
  - How much do damage and debris accumulate in endoscopes over time?
  - Is it possible to get old endoscopes clean?

Methods

- Longitudinal study in an ambulatory surgery center
- Three assessments conducted over a 7-month period
- Baseline data collection in April 2015:
  - Auditing reprocessing practices
  - Compiling data on endoscope age, usage, and repair history
  - Evaluating 17 clinically-used endoscopes:
    - Rapid indicator tests for ATP and protein
    - Microbial cultures
    - Borescope examinations of interior components
- Implementation of more rigorous reprocessing methods (beginning in May 2015)*

*Results of routine monitoring and follow-up assessments pending

OFSTEAD & associates
supporting {excellance} in healthcare

Results

At the baseline assessment:

- All endoscopes were < 2.5 years old
- Endoscopes had been used 36-541 times
- Nine endoscopes had been repaired
- There was good adherence to reprocessing policies
- 16 of 17 endoscopes were still contaminated after manual cleaning
- Contamination levels were higher for gastroscopes than colonoscopes (Figures 1 and 2)

- Borescope examinations of patient-ready endoscope channels identified:
  - Residual fluid (Photos 1 and 2)
  - Irregular surfaces and brown staining (Photo 3)
  - Scratches, non-intact lining, and brown staining (Photo 4)
- Among endoscopes tested after high-level disinfection:
  - 71% failed to meet criteria for patient-ready endoscopes**
  - 29% harbored viable bacteria

**Criteria: No viable microbes and ATP and protein levels below "clean" benchmarks

Photo 1. Fluid inside the biopsy port of a gastroscope

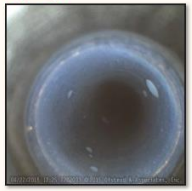


Photo 2. Fluid inside the suction/biopsy channel of a colonoscope

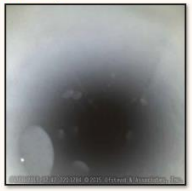


Photo 3. Irregular surfaces and brown staining inside the distal end of a colonoscope

Photo 4. Scratches, non-intact lining, and brown staining in the bending section of a colonoscope

Figure 1. ATP test results after manual cleaning

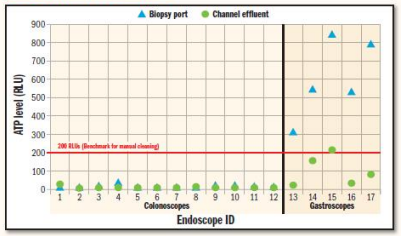
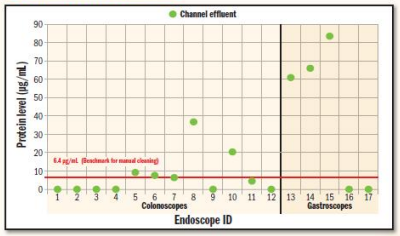


Figure 2. Protein test results after manual cleaning



Summary and next steps

Looking inside reprocessed endoscopes revealed damage and debris

- During the baseline assessment, researchers found:
  - Damage and debris inside channels
  - Contamination levels exceeding benchmarks
  - Residual fluid in channels and ports
- Findings indicated that current reprocessing methods were not sufficient
- Interventions included:
  - Sending endoscopes out for repair
  - Adopting more rigorous reprocessing practices
  - Implementing routine ATP monitoring of cleaning effectiveness
  - Increasing forced air drying times
- Results from the interim and final assessments are forthcoming
  - Observations from unannounced audits of reprocessing practices
  - Impact of interventions designed to improve reprocessing
  - Changes in contamination levels and visual appearance over a 7-month period

Disclosures and acknowledgements

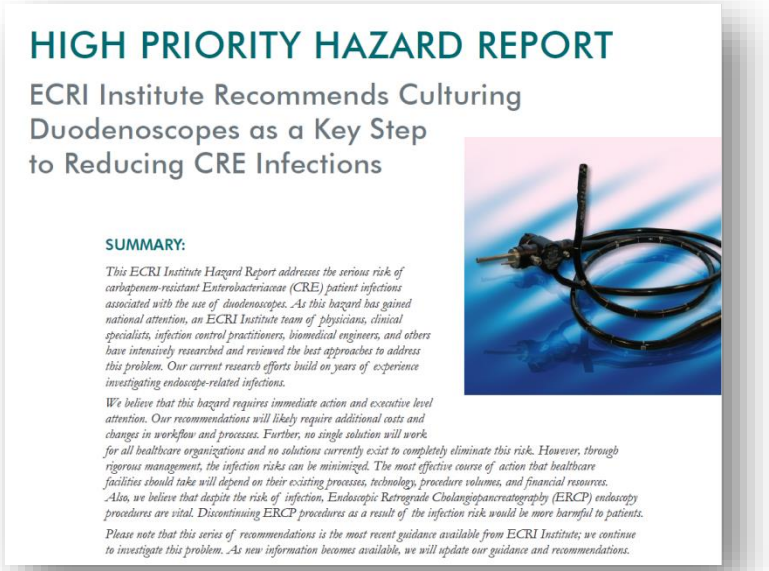
The study was conducted independently by researchers from Ofstead & Associates, Inc., the University of Minnesota, and Fairview Maple Grove Medical Center. The study was supported in part by research grants from 3M Company, Medivators, Inc., and HealthMark Industries. Study sponsors did not have access to the data nor participate in developing the content of this poster.

References

1. Epstein L, et al. *JAMA*. 2014;312(14):1447-1455.
2. Wendorf KA, et al. *ICHE*. 2015;36(6):634-642.
3. Marsh JW, et al. *PLoS One*. 2015;10(12):1-18.
4. Kovaleva J, et al. *Clin Microbiol Rev*. 2013;26(2):231-254.
5. Verfaillie CJ, et al. *Endoscopy*. 2015;47(6):493-502.

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

ECRI Recommendations



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.

- 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

Current Literature Showing Residual Contamination – Poster at SGNA 2016

Reprocessing effectiveness for gastroscopes and colonoscopes: Longitudinal comparison of two methods

Cori L. Ofstead, MSPH[1], Harry P. Wetzler, MD, MSPH[1], Miriam R. Amelang, BA[1], Otis L. Heymann, BA[1], John E. Eiland, RN, MS[1], Sarah B. Held, RN, MBA[2], Michael J. Shaw, MD[3]
[1]Ofstead & Associates, Inc., Saint Paul, MN, USA; [2]Fairview Maple Grove Medical Center, Maple Grove, MN, USA; [3]Division of Gastroenterology, Department of Medicine, University of Minnesota Medical School, Minneapolis, MN, USA

1. Introduction

- Outbreaks have been linked to contaminated gastroscopes and colonoscopes[1-3]
- Investigators have identified endoscope defects during outbreaks[4,5]
- Study conducted to determine:
  - How much damage and debris accumulate over time?
  - Is it possible to get old endoscopes clean?
  - 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) (Table 1)
- Baseline and interim data collection included:
  - Observation of reprocessing
  - ATP tests and cultures after cleaning and after HLD
  - Borescope examinations of channels

Table 1. Endoscope study groups

Reprocessing methods	Control	Intervention
Bedside pre-cleaning	✖	✖
Manual cleaning	✖	✖
Verification of cleaning effectiveness using ATP		✖
Repeat cleaning and HLD when ATP ≥200 RLU		✖
Automated cleaning in AER		✖
HLD with glutaraldehyde in AER	✖	
HLD with peracetic acid in AER		✖
Alcohol flush and forced air purge in AER	✖	✖
Vertical storage in ventilated cabinets	✖	✖

3. Results

- Baseline:
  - Manual cleaning and HLD commonly ineffective (Table 2)
  - Gastroscopes more contaminated than colonoscopes
  - Visible irregularities and residual fluid identified (Figures 1, 2)
- Interim:
  - Contamination and defects worsened over time
  - Discoloration reduced in intervention group (Figures 3, 4)
- Cleaning verification tests exceeded benchmarks:
  - 1% of colonoscope encounters (n=304)
  - 52% of gastroscope encounters (n=143) (Figure 5)

Table 2. Results for baseline and interim assessments

	Baseline (N=17)	Interim (N=19)	Interim results by group: Control (N=10)	Interim results by group: Intervention (N=9)
Post-cleaning ATP ≥200 RLU	29%	37%	30%	44%
Highest post-cleaning ATP (RLU)	841	2910	2910	1600
Positive cultures post-HLD	47%	58%	67%	50%
Number sent for repair*	2	4	2	2

*Due to study findings

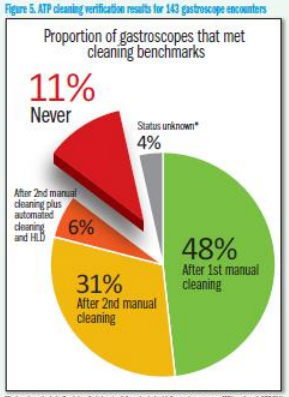
Figure 1. Discoloration and scratches in a channel

Figure 3. Control: Persistent discoloration and debris in a distal end

Figure 2. Residual fluid in a channel

Figure 4. Intervention: Reduction of discoloration in a distal end

Figure 5. ATP cleaning verification results for 143 gastroscope encounters



*Tests not conducted after 1st or 2nd cleaning failure due to tool failure or human error; ATP benchmark 200 RLU

4. Summary

Endoscope contamination accumulated over time

- Borescope examinations identified six endoscopes requiring repair
- Routine ATP tests detected endoscopes needing re-cleaning before HLD
- More rigorous reprocessing methods reduced discoloration

References

1. Bajolet O. J Hosp Infect. 2013;83(4):341-343.
2. FDA. MAUDE Report. MDR 926302 (2007), 1465336 (2009), 1579938 (2010).
3. England D. ICNE. 2016:1-2.
4. Wendorf KA. ICNE. 2015;36(6):634-642.
5. Vertellio CJ. Endoscopy. 2015;47(6):493-502.

Disclosures and acknowledgements

The study was conducted independently by researchers from Ofstead & Associates, Inc., the University of Minnesota, and Fairview Maple Grove Medical Center. The study was supported in part by research grants from 3M Company, Medivators, Inc., and HealthMark Industries. Study sponsors did not have access to the data or participate in developing the content of this poster.

OFSTEAD & associates
supporting excellence in healthcare

http://www.ofsteadinsights.com//wp-content/uploads/Ofstead_SGNA_Poster_Board_2016_SENT.pdf

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

Poll question #2

- Does your facility currently reprocess duodenoscopes used for ERCP procedures?
  - Yes
  - No

Poll question # 3

- Is your facility currently performing any type of culturing of your scopes?
  - Yes
  - No

Poll question # 4

- Of those performing culturing, is your facility performing the sampling and culturing in-house?
  - Yes
  - No

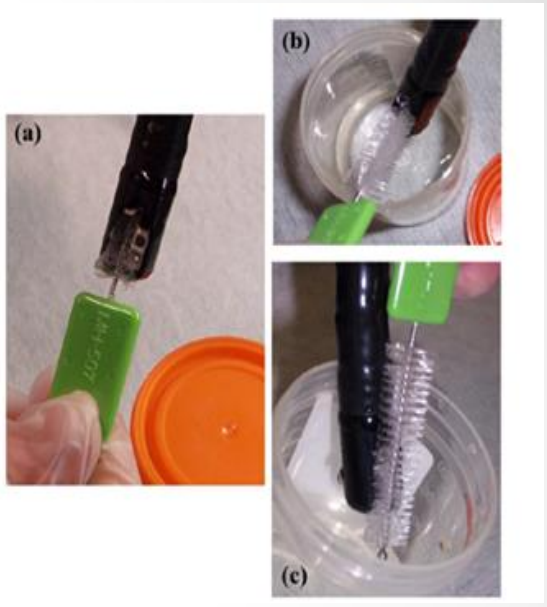
Surveillance Options for Reprocessed Endoscopes

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

http://www.cdc.gov/hai/organisms/cre/cre-duodenoscope-surveillance-protocol.html

CDC Culture

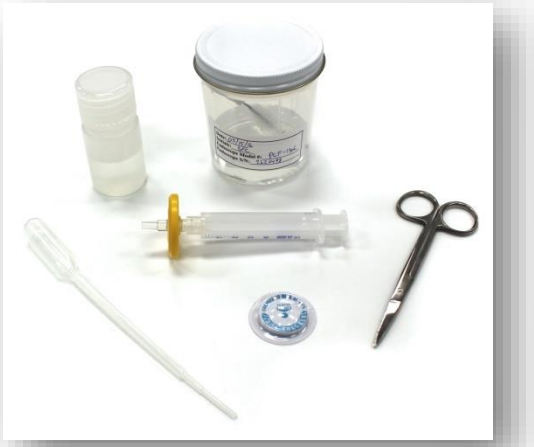
- Baseline levels of acceptable bacteria:
  - Fewer than 10 CFU of low concern microbes- does not require intervention
  - 1 CFU or greater of high concern (pathogenic) bacteria- warrants further remedial actions
- Other surveillance methods (e.g. non-culture methods such as enzyme based methods) can 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)



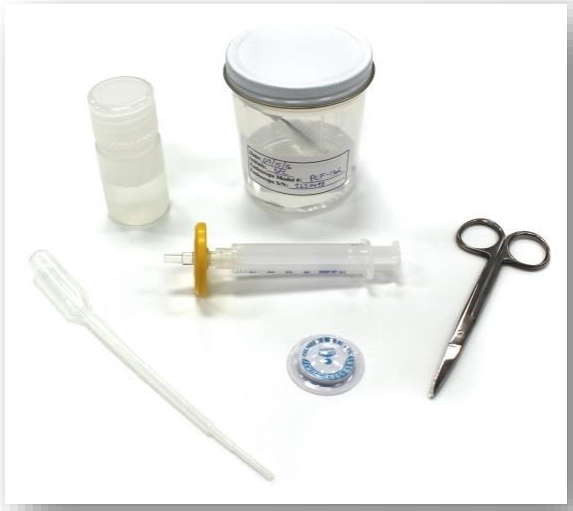
- Not ATP or cleaning verification tests

Mail Back 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.
  - 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: http://www.healthmarkgi.com/products.php?g=Surveillance%20Testing&p=Flexible%20Endoscope%20Sampling%20Kit



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?
- Contact Info:
  - Kaumudi Kulkarni, Healthmark, kkulkarni@hmark.com, www.healthmarkgi.com
  - Alpa Patel, Nelson Labs, alpa.patel@nelsonlabs.com, www.nelsonlabs.com

References

- CDC: http://www.cdc.gov/hai/organisms/cre/cre-duodenoscope-surveillance-protocol.html
- 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%20endoscopes_FINAL.pdf
- NOW! Test and endoscope surveillance kit: www.healthmarkgi.com
- Senate Report: http://www.help.senate.gov/imo/media/doc/Duodenoscope%20Investigation%20FINAL%20Report.pdf

CE Quiz Link

- To receive a CE credit for your participation in this webinar, please visit: www.hmark.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.