Flexible Endoscopes: Cleaning up the Assumptions on Safety

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Learning Objectives

- Summarize the current evidence related to the risk of transmission of endoscopy-associated infections (EAIs).
- Discuss how implementation of a Quality Improvement program can help address the risk of EAIs.
- Review current recommendations from AAMI, FDA and CDC.
The Outbreaks: In the news but not new.....
There is a well documented history of outbreaks
CRE Outbreaks – A Wake Up Call

- Tampa
- Chicago
- Pittsburgh
- Seattle
- Wisconsin
- Los Angeles (1)
- Los Angeles (2)
- Los Angeles (3)
- Unreported – CDC has info on at least 5 others (ID week, 2014)
- CDC and FDA believe this list to be the “tip of the iceberg”
What is the issue?

In the past year there has been a significant increase in reports of outbreaks related to the use of Duodenoscopes for ERCP.
What is ERCP?

- Endoscopic retrograde cholangiopancreatography (ERCP) is a procedure that combines the use of endoscopy and fluoroscopy to diagnose and treat certain problems of the biliary or pancreatic ductal systems.

- You will often see the term “ERCP scope” used. ERCP is a procedure that uses a side-view duodenoscope (an upper GI flexible endoscope).
The Outbreaks: The Microbes are changing the game

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

www.cdc.gov/drugresistance/threat-report-2013/
More than 20 million GI endoscopic procedures are performed every year in the USA.

GI endoscopy is considered a very safe procedure. What is the incidence of pathogen transmission? Experts assume it is a rare event.... Are the assumptions valid?
Assumptions Drive Behavior

- Assumptions
- Investigation of Lapses
- Training Programs
- Design of Quality Programs
- Patient Notification
What are the current assumptions?

- Current quality programs are fine!
- Reprocessing lapses are rare
- EAIs are rare & inconsequential

Following the guidelines results in scopes that are clean and safe
Assumption 1: Reprocessing guidelines are being followed and lapses are rare.
“Flexible endoscope reprocessing has been shown to have a narrow margin of safety. Any slight deviation from the recommended reprocessing protocol can lead to the survival of microorganisms and an increased risk of infection.”


- Looked for reprocessing lapses in peer-reviewed literature, gov’t reports, state health depts, CDC, FDA, Dept of Veteran affairs and media reports
- The study was limited to Jan. 2005 – June 2012.
- They found that improper endoscope reprocessing is an ongoing and pervasive problem.
- Over 30,500 people exposed and this is just the “tip of the iceberg”.
- > 99% of these cases were not found in peer-reviewed medical journals

Reprocessing lapses are rarely reported in medical journals leading to the false conclusion that reprocessing lapses are rare.
<table>
<thead>
<tr>
<th>Observed Activity</th>
<th>Steps Completed (%)</th>
<th>(n = 69)</th>
</tr>
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<tbody>
<tr>
<td>Leak test performed in clear water</td>
<td>77</td>
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<tr>
<td>Disassemble endoscope completely</td>
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<td><strong>Brush all endoscope channels and components</strong></td>
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<tr>
<td><strong>Use forced air to dry endoscope</strong></td>
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<td>Wipe down external surfaces before hanging to dry</td>
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Multiple steps skipped 45% of the time.

Manual cleaning and automated high-level disinfection done correctly only 1.4% of the time.

ECR (automated cleaning and disinfection) performed correctly 75.4% of the time.

Ofstead, Cori L., Wetzler, Harry, P., Alycea Snyder, Rebecca A. Horton
Assumption 2: When guidelines are followed the result is an endoscope that is clean and safe.
EVEN AFTER PROPER REPROCESSING YOUR SCOPES COULD STILL BE DIRTY
Flexible Endoscope Reprocessing
What are we doing wrong?
We do not understand basic definitions

<table>
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<th>Cleaning</th>
<th>High-Level Disinfection (HLD)</th>
<th>Sterilization</th>
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<tr>
<td>• Removal of organic soil</td>
<td>• Microbial kill under defined conditions</td>
<td>• Kills all living organisms including spores</td>
</tr>
<tr>
<td>• Microbes and soil can still be present</td>
<td>• Spores are not killed</td>
<td>• Effectiveness dependent on meticulous cleaning</td>
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Overview of Flexible Endoscope Reprocessing

Pre-Cleaning: Occurs in procedure room. Wipe down and flush scope. Prepare for transport to reprocessing.

Leak testing: Followed by complete disassembly of scope

Manual Cleaning: Flushing, brushing all parts and channels of the scope, purge with air

High-Level Disinfection: Automated in AER or can be performed manually

Drying: Air and Alcohol flush, Wipe down external surfaces

Storage: Vertical Hang
Why are flexible endoscopes difficult to reprocess?

- Complex design
- Multiple, long, narrow, channels that are difficult to clean
- Lack of consistent effective training
- Lack of time and resources for adequate reprocessing
- Visual inspection not adequate to monitor efficacy of reprocessing.
- > 120 step involved in reprocessing!!
The Outbreaks: No consistent root cause

How did the duodenoscopes become contaminated?

- Occult defects in the flexible endoscope
- Inadequate cleaning
  - Elevator Guidewire Channel, Elevator Mechanism, Suction/Biopsy Channel
- Complex design of duodenoscope
- Current Reprocessing Guidelines are not adequate
  - Residual contamination found after scopes have been reprocessed, overhauled by mfr, subjected to enhanced cleaning.
- Staff training inadequate, questions on competency
Duodenoscopes have added complexity.

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

All duodenoscopes (plus some therapeutic gastrosopes) have an elevator-wire channel inlet above the suction valve.
How can microbes survive High Level Disinfection (HLD)?

If you expose CRE bacteria to chemicals used for HLD – they die.

Somehow these bugs are surviving reprocessing.
How can microbes survive reprocessing?

- **Inadequate cleaning**
  - In order for HLD to work, the scope must be meticulously cleaned.
  - Use the correct brush
  - Take the correct amount of time
  - Monitor the effectiveness of cleaning
    - ATP bioluminescence, Protein, Hemoglobin, Carbohydrate tests available
How can microbes survive reprocessing?

- Inadequate manual cleaning and drying support the formation of biofilm
  - Biofilm is
    - Notoriously resistant to the action of disinfectants
    - Almost impossible to remove once established
    - Requires brushing, flushing to physically remove biofilm
    - Drying is critical – biofilm unlikely to form on a dry surface.
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How can microbes survive reprocessing?

- **Lack of proper contact time with detergents and disinfectants**
  - Microbial kill requires sufficient contact time with surface. Mfr recommendations should be strictly followed. Anything less leaves living microbes behind….
  - Make sure disinfectant is properly made and is not expired

- **The Joint Commission Survey found:**
  - Recommended soaking cycle – 20 minutes
  - Cycle reprogrammed to 5 minutes
  - Patients exposed? Transplant, HIV, Oncology, Cystic Fibrosis
Manual Clean a Side-view Duodenoscope
How long does it take to clean?

Follow Manufacturer Instruction for Use – 25 min
Clinical Observation – 6.5 min

ALFA ET AL. 2006 AMERICAN JOURNAL OF INFECTION CONTROL 34, 561-570
What are we doing wrong?

- Non-compliance with guidelines
- Failure to pre-clean
- Inadequate contact time with HLD
- Using expired disinfectants
- Dirty scopes allowed to dry
- Inadequate brushing of channels during manual cleaning, missing EGW channel
- Improper storage
- Incorrect programming of AER
- Insufficient training and competency program
- Unaware or failure to report staff/equipment failures


What is the response?

FDA
CDC
Manufacturers Associations
FDA Safety Communication  Feb. 19, 2015

- The complex design of duodenoscopes may impede proper reprocessing
- Meticulous manual cleaning should reduce risk of transmission of infection
- Implement a comprehensive Quality Control program
- Quarantine scopes suspected of association with patient infection until shown to be free of pathogens

http://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm434871.htm
“Duodenoscopes and AERs do not provide a reasonable assurance safety and effectiveness”

“Manual Cleaning is a critical component.”

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

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

http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/Gastroenterology-UrologyDevicesPanel/ucm445590.htm

- After consideration of the various opinions published by the FDA Advisory Panel on Gastroenterology and Urology Devices in May, 2015, the FDA has issued recommendations for additional supplemental measures for healthcare facilities to consider for reprocessing duodenoscopes in order to reduce the risk of transmission of infection.

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

- It was recognized that implementation of these additional measures may not be feasible for many institutions and that the limitations of each of these measures must be taken into consideration.

- These measures are to be considered in addition to following manufacturer’s instructions for reprocessing, meticulous manual cleaning and the implementation of a comprehensive quality control program.

URL: [HTTP://WWW.FDA.GOV/MEDICALDEVICES/SAFETY/ALERTSANDNOTICES/UCM454766.HTM](HTTP://WWW.FDA.GOV/MEDICALDEVICES/SAFETY/ALERTSANDNOTICES/UCM454766.HTM)

• WHY?
  – “Subset of devices that pose a greater likelihood of microbial transmission and represent a high risk of infection if they are not adequately reprocessed”
  – “FDA is proactively investigating these devices to determine if additional steps should be taken.”

• FDA analysis to date has identified two recurrent themes:
  – Failure to meticulously follow manufacturer instructions for reprocessing
  – Continued use of devices despite integrity, maintenance and mechanical issues.

• FDA Recommendation: comprehensive reprocessing quality control program.
  – Should include written procedures for monitoring, training and adherence to the program
  – Documentation of equipment tests, processes, and quality monitors used during the reprocessing procedure.

• http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm462979.htm
Are there any new recommendations?

Multiple statements

- Follow manufacturer’s instructions for reprocessing
  - Olympus published new IFU
- Pay special attention to manual cleaning
  - Meticulous cleaning required
  - Elevator mechanism needs special attention
- Implement Comprehensive Training
- Verify Competency
- Periodic review of policies and procedures
ANSI/AAMI ST91:2015  Flexible and semi-rigid endoscope reprocessing in health care facilities

- Design of the endoscope processing area, including work flow considerations
- Personnel issues such as training, hygiene, clothing, policies, and immunizations
- Processing steps: pre-cleaning, leak-testing, manual cleaning, high-level disinfection, sterilization, storage
- Various topics including automated endoscope reprocessors (AER), sterile endoscope sheaths, and processing accessories
- Storage and transport
- Quality control
- Bibliography
Common responses to the current outbreak information

- Wait for new guidelines, new scope designs, definitive research
- Don’t do anything because you believe you don’t have transmission issues.
- Don’t worry because you don’t use duodenoscopes.
- We’ve never had a problem so there is nothing to fix.

Doing nothing is no longer an option
Implementation of a Quality Control (QC) Program

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

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

http://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm434871.htm
What can you do now? What does everyone agree on?

Focus on Manual Cleaning

- It is a problem
- It is critical to success of HLD and Sterilization
- Lack of proper manual cleaning contributed to outbreaks
- It can be improved
- Use validated, real-time indicators of cleaning efficacy
  - Commercially available kits that test for ATP, protein, hemoglobin, carbohydrate
ANSI/AAMI:ST91 Verification of Cleaning Process

• Visual inspection may not be sufficient, consider a method that measures organic residues: ATP, Protein, Bioburden, Carbohydrate
  ○ Pass/Fail thresholds are defined in the standard

• A defined, documented process for verifying the efficacy of manual cleaning step should be implemented.

• Frequency – weekly, preferably daily

• At a minimum, suction biopsy channel should be monitored

• Have a process in place to deal with cleaning/processing failures

• Education/Training/Competency program in place to address cleaning
ANSI/AAMI ST91  Section 12: Quality Control

- QC is critical to successful reprocessing
- All facilities should have a comprehensive QC program
  - Product identification and traceability
  - Documentation and record-keeping
  - **Verification and monitoring of the cleaning process**
  - Monitoring of high-level disinfection and sterilization processes
  - Product recalls
  - Quality process improvement
ST91 – Cleaning Verification

What do the Pass/Fail benchmarks mean?

- This is an issue that needs to be clearly understood.
- The Pass/Fail benchmarks were developed to assess if a scope was cleaned according to manufacturer’s instructions.
- Pass/Fail benchmarks for CLEANING VERIFICATION are not a measure of the risk of pathogen transmission
  - Patient Safety claims are based on the successful performance of the entire reprocessing procedure
  - Only the disinfection or sterilization step has any claim on microbial kill
Assumption 3: 
Endoscopy-associated infections (EAI) are rare and often inconsequential
The current risk estimates are unknown


• Where did the risk estimate of 1:1.8million come from and was it correct?

• Findings
  • Math was wrong: Long division error, counting errors led to wrong numerator
  • Flawed methods
    – Population size unsubstantiated (unsupported denominator)
    – Incidence of infection not assessed among at risk population
    – Counted only cases of infection that were reviewed in a single 1993 article

CONCLUSION – NO CREDIBLE ESTIMATE OF INFECTION RISK
Looking in all the wrong places……

- Currently test for HIV, Hepatitis B & C

- What would we find if we started looking for microbes that were present on scopes?
  - *C. difficile*
  - NDM- *E. coli* (CRE), *Klebsiella* (CRE)
  - *Salmonella, Shigella, MRSA, Pseudomonas*

- There are gaps we need to fill…..
  - Treat with antibiotics, no investigation
  - CRE is being tracked only in certain areas
  - Not connecting the dots
  - Look at all scopes, not just duodenoscopes

- Still working on protocol so is subject to change
- Look for pathogens and elevated levels of non-pathogens
- Frequency of testing not defined
  - Weekly, monthly, every time, every 60 procedures
- Pay Special attention to
  - Inspection and Manual Cleaning
  - Drying

http://www.cdc.gov/hai/outbreaks/index.html

Safety Alerts:

ERCP Duodenoscopes

- Interim DuodenoScope Surveillance Protocol
- Interim DuodenoScope Sampling Method
- Interim DuodenoScope Culture Method
- CDC Statement: Los Angeles County/UCLA investigation of CRE transmission and duodenoscopes
- NDM-Producing CRE Associated with ERCP
- NDM-Producing CRE Associated With DuodenoScope Exposure
- See CRE homepage

U.S. Food and Drug Administration (FDA) resources:

- Design of Endoscopic Retrograde Cholangiopancreatography (ERCP) Duodenoscopes May Impede Effective Cleaning
- FDA Guidance: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling
- Notice of Meeting: Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee
Highlights of the CDC Interim Guidance

- When should cultures be taken?
  - After reprocessing (after drying step)

- How often should duodenoscopes be cultured?
  - Periodically, but has not been established.
    - Monthly
    - After every 60 procedures (for each scope)
    - Weekly
    - Every time
Highlights of the CDC Interim Guidance

- **What sites on the duodenoscope should be cultured?**
  - Instrument Channel (Suction/Biopsy Channel)
  - Distal end (elevator mechanism, elevator recess)
  - Elevator channel (on older, unsealed duodenoscopes)

- **What is the recommended protocol for sampling?**
  - A detailed protocol is outlined on CDC website.
    - Interim Duodenoscope Sampling Method
    - Interim Duodenoscope Culture Method
Highlights of the CDC Interim Guidance

- How should results be interpreted?
  - Two types of results are assessed

1. **High concern organisms** (more often associated with disease)
   - Gram negatives – *E. coli*, *Klebsiella*, *Pseudomonas*, etc
   - Gram positives – *S. aureus*, *Enterococcus*
   - ≤ 1 CFU of high-concern organisms warrants remedial action

2. **Low concern organisms** (less often associated with disease, result of sample contam.)
   - Coagulase-negative staphylococcus (excluding *S. lugdunensis*)
   - *Bacillus* sp
   - Dipheroids (e.g. *Corynebacterium*, *Propionibacterium*)
   - < 10 CFU: No intervention
   - > 10 CFU – compare to baseline history, repeated high levels warrants remedial action
Highlights of the CDC Interim Guidance

Non-culture methods – ATP Bioluminescence

- Can be used to “provide insight regarding the quality of endoscope reprocessing if systematically validated”

- Concerns that ATP and CFU (microbial numbers) do not “correlate”
  - ATP measures organic contamination from all living sources
    - Microorganisms, Human cells, secretions, excretions, body fluids
  - ATP levels measure overall cleaning efficacy
  - CFU measures only bacteria
  - Correlation should not be expected as these two methods measure two different things (well documented fact)

A common worry, but often misunderstood

[Chemical structure of ATP]

adenosine triphosphate (ATP)
CDC Interim Protocol: The Jury is Still OUT……

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

“Sensitivity unknown”  
*CDC Interim Protocol for Duodenoscope Surveillance*

“…clinical microbiology labs should not perform routine cultures of reprocessed duodenoscopes due to lack of data on utility of such culturing”

*American Society for Microbiology statement on CDC Interim Protocol.*
What is the problem with culturing scopes?

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

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

- Current methods not appropriate for sampling duodenoscopes
  - Biofilm bacteria must be cultured differently
  - Bacteria exposed to disinfectants need special culture conditions
Multiple Species of CRE
*Klebsiella* (KPC), NDM-*E.coli*
Multiple strains found in same endoscope
Detection of all antibiotic resistance genes is complex

Emerging drug resistant strains
AMP-C *E.coli*, CR-*E.coli*
*Shigella* now on CDC radar
*Pseudomonas* acquiring superbug status

Outbreak Microbiology is Complex

CRE reporting
Not required in all states
WI did not report outbreak
Recent outbreaks detected only when specific surveillance protocols were active
The issue is global!

CRE not the only problem
*Acinetobacter*
*Pseudomonas*
MSSA and MRSA (*S. aureus*)
Fungi, Viruses

The issue is global!
What do we do now?

We can no longer assume that GI endoscopy is a low risk procedure.

IMPLEMENT QA PROGRAMS
- Written policies
- Training/Competencies
- Regular Audits and continued oversight
- Make sure IFUs are up to date, they are changing!
- Informed consent for patients

IMPLEMENT A MONITORING PROGRAM
- Multiple sampling sites
- Multiple methods
- Every scope, Every time

EO STERILIZATION
The future of Endoscopy procedures?
A safer, non-invasive approach.....