How do you define clean?
A tale of flexible endoscope reprocessing
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Learning Objectives
➢ Explain the differences between cleaning, high-level disinfection and sterilization.
➢ Understand how ATP, protein, hemoglobin and microbial counts are used to measure cleaning efficacy.
➢ Explain why monitoring manual cleaning efficacy should not be used to predict the risk of pathogen transmission.

Cleaning Verification
Microbial Surveillance
Rapid Cleanliness Monitors
ATP, Protein, Hemoglobin, Carbohydrate
CRE Outbreaks – A Wake Up Call

- Tampa
- Chicago
- Pittsburgh
- Seattle
- Wisconsin
- Los Angeles (1)
- Los Angeles (2)
- Los Angeles (3)

These events triggered a Senate Investigation into the issue

Preventable Tragedies:
Superbugs and How Ineffective Monitoring of Medical Device Safety Fails Patients, Jan.13, 2016
United States Senate Health, Education, Labor and Pensions Committee
Patty Murray, Ranking Member

- Between 2012 and spring 2015, closed-channel duodenoscopes were linked to at least 25 different incidents of antibiotic-resistant infections that sickened at least 250 patients worldwide.
- Hospitals, FDA and mfr’s all failed in their responsibility to report, notify and act on knowledge that outbreaks were occurring.

The Outbreaks: No consistent root cause

How did the duodenoscopes become contaminated?

- Occult defects in the flexible endoscope
- Inadequate cleaning
  - Elevator Guide wire 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
So what do we do now?

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

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.
Visual Inspection: Inspect for conditions that might affect HLD
High-Level Disinfection: Automated in AER or can be performed manually
Drying: Air and Alcohol flush, Wipe down external surfaces
Storage: Vertical Hang
Manual Cleaning only performed correctly 45% of the time....... 


How to improve cleaning?

VERIFICATION

We do not understand basic definitions

Cleaning
• Removal of organic soil
• Microbes and soil can still be present
• Device can still be infectious

High-Level Disinfection (HLD)
• Microbial kill under defined conditions
• Spores are not killed
• Effectiveness dependent on meticulous cleaning

Sterilization
• Kills all living organisms including spores
• Effectiveness dependent on meticulous cleaning
Organic soil.....just what are we cleaning?

- Tissue Cells
- Secretions
- Excretions
- Body Fluids

- Biofilm
- "SCUM"

So what is the big discussion again?

- Cleaning Verification
- Microbial Surveillance
- Rapid Cleanliness Monitors
- ATP

Most common question: Which is better?

- Microbial Surveillance
- ATP
- Bioluminescence
To decide which approach is better you must first understand the purpose of each approach.

Microbial Surveillance

Microbes transmitted by dirty scopes:
- Bacteria
- Viruses
- Fungi & Parasites
Microbes are “carried” to scopes in soil

- Cells/Tissues
- Secretions, Excretions & Body Fluids
- Biofilm
- Contaminated Water, Filters, Tubing

How are microbes detected?

Microbiological Counts
- Viable microbial numbers

Pathogen detection
- Culture (presence/absence)
- Molecular detection
- Methods are specific for each pathogen

CDC Interim Duodenoscope Protocol 3/12/15

- Look for pathogens and elevated levels of non-pathogens
- Test after HLD/Storage
- Pay Special attention to:
  - Inspection and Manual Cleaning
  - Drying

http://www.cdc.gov/hai/outbreaks/index.html
CDC Interim Duodenoscope Protocol 3/12/15

Interpretation of Results

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

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

The purpose of microbial surveillance (CDC surveillance protocol)

Answer two questions
How many bacteria are present?
Are they harmful?

ATP Bioluminescence
What is Adenosine Tri-Phosphate (ATP)?

- Universal energy management molecule
- ATP stores energy in the phosphate bonds.
- Carries energy to wherever it is needed inside cells

ATP Bioluminescence Technology

Converts ATP to a light signal

Fire-fly enzyme Luciferase uses ATP to produce Light

Simple Relationship

- Increase amount of light (RLU)
- Increase amount of ATP
- Increase organic contamination

Where do you find ATP?

- Animals: Tissues & Cells, Secretions, Excretions, Body Fluids
- Plants: Food-derived soil, Plant cells and tissues
- Microbes: Bacteria, Yeasts/Molds, Parasites, Biofilms, “Scum”
ATP as a rapid cleanliness monitor

Universal Cleanliness Marker
- Found in all organic soils

Used to verify cleaning efficacy for over 35 years
- Food Safety, Aerospace, Superconductor

The purpose of ATP Rapid Cleanliness Test

Provides the answer to the following question:
How much organic soil remains after cleaning?

Let's use this basic knowledge to clear up some misconceptions and address a few questions
Misception:

Microbial Surveillance is the gold standard for assessing efficacy of reprocessing endoscopes.

All other cleanliness measurement systems should mimic surveillance results.

When are these tests performed?

- ATP and other rapid cleanliness indicators

Microbial Surveillance

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, 2016

- 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.
Limitations of Bacterial Culture Methods (Aerobic Plate Count)

Sensitivity
- Not sensitive enough for low levels of bacteria
- Only grows 0.1-10% of bacteria present.

Biofilm
- Not appropriate to sample biofilm
- Majority of bacteria in endoscopes grow in biofilm

Specificity
- Does not detect all bacteria.
- Not testing for other microbes (anaerobic bacteria, viruses, parasites)

Currently, bacterial surveillance results (according to the American Society for Microbiology)

- Will not substantiate efficacy of cleanliness
- Will not tell you if the scope is adequately disinfected
- Will not indicate if a scope is sterile
- Does not detect all microbes

Misconception:
ATP is not a good cleaning verification method because it does not correlate with bacterial counts.
Should ATP measurements correlate with bacterial counts?

A common concern, a common misconception....

Correlation should not be expected as these two methods measure different things. A well documented fact.

- ATP is present in all organic soil.
- ATP comes from all living sources.
- ATP does not distinguish between living and dead ATP donors.
- Bacterial counts measure one thing – the presence of living bacteria.

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Simple Scenario: A scope is soiled with blood

Bacterial results are zero, ATP results are high

**CDC Surveillance Protocol**
- Only measures levels of live bacteria
- Bacterial counts are zero but the scope could still be contaminated with
  - Blood-borne viruses (HIV, Hep)
  - Anaerobic bacteria (C. diff)
  - Fungi, parasites

**ATP Bioluminescence**
- Measures removal of all organic soil including blood
- Remove the soil, remove the bugs....
  - Blood-borne viruses (HIV, Hep)
  - Anaerobic bacteria (C. diff)
  - Fungi, parasites

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Misconception

ATP “does not detect microbial contamination”
Yes, ATP does detect microbial contamination. So what is the issue?

• ATP tests do not ONLY measure bacteria?
• ATP tests do not distinguish between ATP donors?
• ATP tests do not distinguish between live and dead ATP donors?
• ATP tests do not correlate with bacterial counts?

None of these attributes are required to measure efficacy of cleaning.

Misconception

ATP monitoring is not valuable unless there is data demonstrating reduced infection risk.

RISK....

“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.”

When it comes to reprocessing endoscopes, infection risk is not determined by one test.

Misconception:
ATP assays should be validated as a risk-factor for patient-to-patient transmission.
The Pass/Fail cut off should assure safety.
The purpose of ATP Rapid Cleanliness Test

Provides the answer to the following question:

How much organic soil remains after cleaning?

ATP tests were NEVER designed to assess transmission risk

CDC Surveillance Protocol

- Not validated
- Sensitivity unknown
- Subject to well-documented limitations
- No recommended frequency of testing
- High-rate of false negative results

Culture results should be interpreted with extreme caution

Which is better? The question revisited.

Wrong question
Appropriate questions

- What is the test used for?
- Do I know the limitations so that I can interpret results correctly?
- Will the test give me the answer to the question I am asking?

Conclusions

1. The choice between implementing ATP monitoring or microbial surveillance is not an either/or decision.
2. ATP and other rapid cleanliness tests are not designed to assess if the scope is safe for patient use.
3. The current CDC surveillance protocol is still a work in progress; the utility of the data for assessing reprocessing effectiveness is unknown.
4. It is important to ensure that the test you are using actually answers the questions you are asking.

Thank you!
Questions?