EXCELLENTIA ADVISORY GROUP

INFECTION PREVENTION STRATEGIES FOR AMBULATORY SURGERY CENTERS

What's Required for Handling Endoscopes Properly in Storage and Transport

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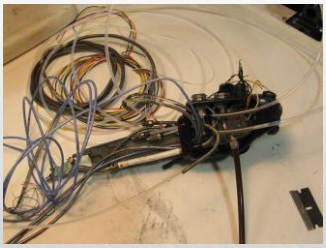
Objectives

- Concerns about Bacterial Growth inside Endoscopes
- Implications of Gram Negative and Multidrug Resistant Bacteria
- Need for Surveillance Testing for Microorganisms
- Microbial Culturing of Endoscope Lumen
- Endoscope Storage National Guidelines
- Risk Assessment of Endoscopes in Storage
- Transport of Flexible Scopes

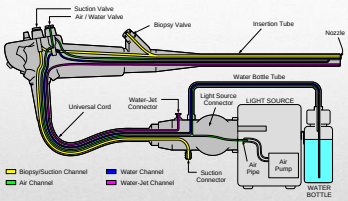
Scope Processing is a Multistep Process

- Pre-cleaning
  - **Transport from Patient to Reprocessing Area (Contaminated Transport)**
- Leak Testing
- Cleaning with approved detergent solution
- Rinsing
- Monitoring the cleaning process
- Disinfectant/Sterilant process
- Rinsing
- Drying & Alcohol Flush
  - **Transport from AER/Manual HLD to Storage**
- **Storage**
  - **Transport from Storage to Procedure room**

Guts of a Flexible Endoscope

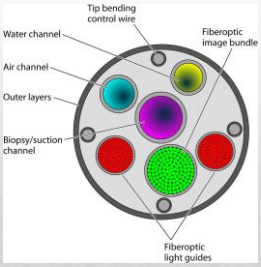


Flexible Endoscopes Anatomy



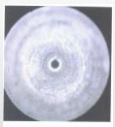
- Endoscopes are complex medical instruments having long and narrow working channels that are subjected to torque and angulation forces
- Endoscopes have state of the art electronics, including fiber optics and imaging technology

Cross Section of a Flexible Endoscope

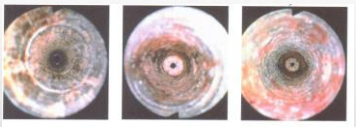


Kovaleva J et al. Clin. Microbiol. Rev. 2013;26:231-254

Organic Contaminants in Lumen



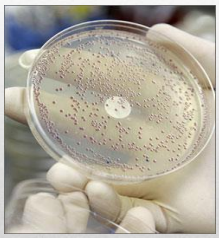
A New Device. Inspected right out of the package. No Red/dark discoloration seen.



Contaminated Lumen

E. coli

On a Petri plate



Under a Microscope

Image Courtesy of the Helmholtz Center for Research on Infectious Diseases.

How Fast Can Bacteria Multiply? Time is our Enemy!

Time from First Survivor	Number of Bacteria
One Survivor	1
20 minutes	2
40 minutes	4
1 hour	8
2 hours	64
3 hours	512
4 hours	4,096
5 hours	32,768
6 hours	262,144
7 hours	2,097,152

Depends on many parameters, but this is an example.

Gram Positive and Gram Negative Bacteria

2 Classes of Bacteria based on differences in the Cell Structure

Gram Positive Bacteria:

Skin flora
Non pathogenic

- *S. epidermidis*
- *S. salivarius*

Gram Negative Bacteria:

Implicated in hospital acquired infections

- *E. coli*
- *Legionella*
- *Pseudomonas*
- *Salmonella*

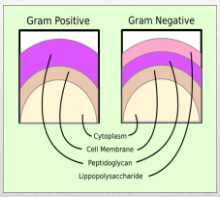
Image courtesy: piperreport.com

Impact of Gram Negative Bacteria

- Frequently reported in endoscope acquired infections
- Replicate easily in moisture
- **Indicators for bacterial contamination** in endoscopes
- Reduce the risk of false positives associated with the gram positive bacteria- normally occurring as skin flora.

The Problem with Gram Negative Bacteria

- Presence of double membrane surrounding bacterial cell.
- The outer membrane excludes certain drugs from penetrating the cell.
- Confers more Antibiotic-resistance than Gram positive bacteria.



CRE

- Family of Gram negative bacteria
- Multidrug resistant
- Nearly immune to the 'Carbapenem' class of antibiotics- considered the last line of defense against Gram-negative infections
- Recent outbreaks of the deadly CRE bacteria linked to Duodenoscopes/ ERCP endoscopes

Image courtesy: www.dailymail.co.uk/news/article-2285729/Rare-antibiotic-resistant-superbug-outbreak-U-S-health-officials-high-alert.html

Duodenoscopes and CRE

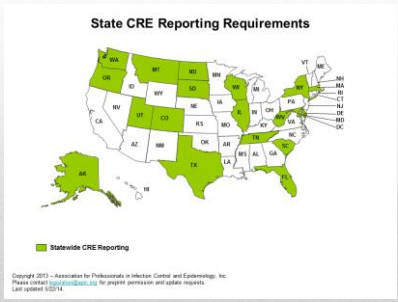
The design of the ERCP endoscopes poses a particular challenge for cleaning and HLD

- ERCP is an effective technique for diagnosing and treating problems in the liver, gallbladder, and pancreas.
- To prevent risk of disease transmission during ERCP, the duodenoscope's complex internal surfaces (including its long and narrow elevator-wire channel)— require special attention and thorough reprocessing.
- Many alerts in the last couple years on the ERCP

Image Courtesy: www.gastrohep.com/ebooks/thumbnails.asp?book=1405120762&id=4

Recent Gram Negative Bacteria Outbreaks

- University of Cincinnati Health, June 2016
- Lehigh Valley hospitals, PA April 2016
- University of Colorado Hospital, Jan. 2016
- Huntington Hospital in Pasadena, Aug. 2015
- Hartford Hospital, March, 2015
- Cedars-Sinai, March, 2015
- North Carolina, February, 2015
- UCLA, January 2015
- Seattle Hospital, 2012-2014
- Lutheran General Hospital in Park Ridge IL, December 2013
- UPMC , November 2012



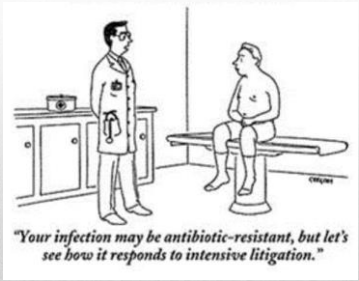


Image courtesy: Cartoonbank.com

What's Hiding Inside the Endoscope Lumen?

- Is there any **residual bioburden** in the lumen that we cannot visualize?
- Do we need **periodic surveillance** to monitor this?
- Are endoscopes **in storage** safe?

A Survey of Stored Flexible Endoscopes

A team of researchers examined 71 reprocessed endoscopes in 22 hospitals and 4 ambulatory care centers:

Found ~24% of samples taken from devices' channels had over 100,000 CFU/channel!

Periodic surveillance – significant role

Australian Biofilms study

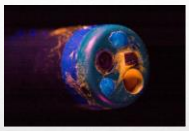
- Channels of **13** endoscopes were examined.
- **Biofilm** was present on the suction/biopsy channels of **5** scopes.
- **Biofilm** was also present on the air/water channels of **12** scopes, with the level of contamination determined to be EXTENSIVE on **9** of those.

What are Biofilms?

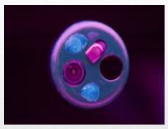
- 'Microbial cities'
- A complex mixture of diverse neighborhoods, transportation and communication networks
- Protect the inhabitants from harm and a constant urban renewal program
- Removal of some neighborhoods is balanced by the growth of new ones.

Image courtesy: http://karenquinto.com/science-rendezvous-ryerson-university/

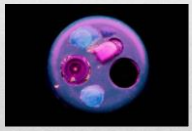
Biofilm on a Colonoscope Tip



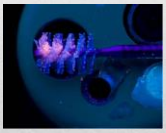
Biofilm on the tip of scope



After high level disinfection



After manual cleaning



Biofilm debris on brush

http://www.educationaldimensions.com

Biofilms Life Cycle

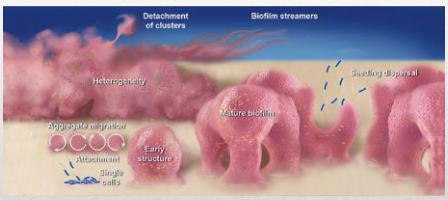
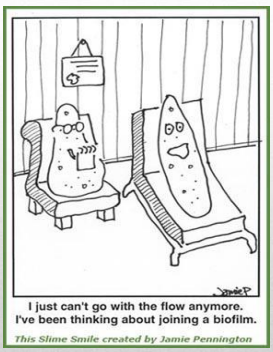


Image courtesy: Costerton B. Proc Natl Acad Sci U S A. 2004



Microbial Surveillance

- Options include:
  - Traditional culturing
  - Gram negative test kits (new technology)
- AAMI - No recommendation is made in the current version

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: Base decision on a risk assessment

CDC – Interim Guidance on Sampling Duodenoscopes

Sites to be Sampled

- Instrument channel (suction/biopsy channel) -Flushing
- Elevator channel (on older, unsealed)- Flushing
- Distal end (elevator mechanism, elevator recess)- Using sterile distal tip brush

Sampling the elevator mechanism

Figure 3. Sampling the elevator mechanism in the (a) 'lowered/ closed' position, (b) 'raised/ opened' position, and (c) sampling the elevator mechanism and lens face (photos taken by CDC DHQP). Note: the brush pictured below is no longer available and is used for demonstration purposes only.

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

CDC Guidance on Culturing Duodenoscopes

Baseline levels of 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

Frequency: Every 30 days or 60 cycles

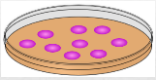
Not all labs in healthcare facilities can do this type of testing

Mail back service for endoscope samples is now available

CDC Interim Surveillance Protocol

Remedial Actions

- 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



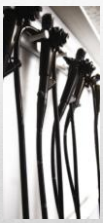
- If a reprocessing breach is identified, appropriate personnel should be notified and corrective actions implemented immediately.
- If cultures are repeatedly positive (3 times or more), consider evaluating the culturing technique and/or getting the scope evaluated by the manufacturer.

New Technology - 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.

- DOES NOT REPLACE CULTURING METHOD
- ST91: Types of verification testing may include enzyme based tests
  - Such as the gram negative test kit
- Commercial products are now available

Storage of Flexible Endoscopes and Hang Time Issues



Current Recommendations for Length of Storage

AAMI ST91: Does not recommend a specific storage time. Recommends to perform a risk assessment to establish maximum length of storage.

AORN: Supports performing a risk assessment with a multi-disciplinary team to establish a policy, to determine the maximum length of storage.

SGNA: Supports 7 days storage interval- based on a systematic review if scopes are effectively reprocessed and stored in a way that keeps them completely dry and free from environmental and human contamination.

AAMI ST91: 2015 Recommendations on Endoscope Storage

- Stored endoscopes should be hung vertically, with the distal tip hanging freely in a well ventilated, clean area.
- Angulation locks should be in the open position.
- There should be sufficient space between endoscopes.
- All removable parts (valves and caps) should be detached, but kept together with the scope.
- Have policies and procedures in place regarding storage.

CDC Recommendations on Endoscope Storage

- Develop protocol to identify if an endoscope has been cleaned and high-level disinfected or sterilized.
  Attach a Tag/ Label on a scope stating that.

- Flush ALL channels with alcohol to facilitate drying.
- Purge ALL channels with filtered medical grade air at the correct psi. (per manufacturer's IFU).
- Do not use the carrying case designed to transport clean and processed endoscopes to store an endoscope.

AORN (2015) Recommendations on Flexible Endoscope Storage

- Storage cabinets should have doors and be located at least 3 feet from any sink
- Scopes should be stored in a drying cabinet that circulates filtered air and also forces the filtered air through the endoscope channels
- If a drying cabinet is not available, scopes should be stored in a closed cabinet with HEPA filtered air that provides positive pressure and allows air circulation around the scopes.

- Storage cabinets should be cleaned and disinfected on a regular (e.g. daily, weekly) basis or when visible soiled.

AORN (2015) Recommendations on Flexible Endoscope Storage- contd.

- Visually inspect endoscopes for cleanliness before placing into or removing from storage.
- Wear clean gloves when handling processed scopes and when transporting them to and from the storage cabinet.
- Store scopes with all valves open and removable parts detached (but stored with the endoscope).
- Clearly identify scopes with a distinct visual cue as processed and ready for use.
- Scopes should NOT be stored in the original shipment cases.

What's Wrong in this Picture?

Improper Storage

- Looped endoscopes (can allow microbial growth if not completely dry)
- Touching each other (may cause cross contamination)
- Touching the base of the cabinet (distal tip might get damaged)
- Not all endoscopes are tagged (Difficult for the techs to know the reprocessing details of a particular scope).

Poorly Hung Endoscope

Protecting the Distal Tip of Flexible Endoscopes

Protecting the distal tip in storage - from touching another scope, or cabinet wall

Identification of Patient Ready Scope

ST 91 - Endoscope Storage Risk Assessment Checklist

Storage of high-level disinfected endoscopes	Yes	No	Action
Endoscopes are stored so that residual fluid does not remain in the channels			
Endoscopes are stored, with their detachable parts dismantled, in a manner that keeps them secure and together with the endoscope as a unique set			
Endoscopes are stored in a vertical non-coil position			
Tracking is available for each endoscope, including last episode of HLD			
If a storage cabinet is used, all manufacturer's written IFU should be followed and documented			
Storage of sterilized endoscopes	**Yes**	**No**	**Action**
Endoscopes are rotated according to policy			
Storage conditions are monitored according to ANSI/AAMI ST79			
Endoscopes are identified and labeled			

Transport of Endoscopes

Transport of Endoscopes

- From Patient to Reprocessing Area (Contaminated Transport)
- From AER/Manual HLD to Storage
- From Storage to Patient

Contaminated Transport

From Patient to Reprocessing area:

- Use transport system that is closed, puncture resistant and leak proof
- Place a single endoscope in a container by naturally coiling it in large loops.
- Separate endoscopy accessories from the endoscope to prevent puncture and damage.

Contaminated Transport

Not leak proof or puncture resistant

Not labelled

Example of Poor Practice
Returned Patient-used Scope in an Unmarked Bag

- The system should be marked with a biohazard label, must meet **OSHA** (29 CFR 1910.1030) requirements for transporting hazardous items.

- The system should be large enough to accommodate a single endoscope without the need to over-coil the insertion or light guide tubes.

Container Labelling during Transport

- Must be clearly marked
- OSHA
- AAMI ST 79
- AAMI ST 91

Manually Cleaned Endoscope going from Decontam to the Clean side through a Pass-Through window

Transport of Scopes from Processing to Storage- ST91

- **Use fresh/clean gloves**
- **Remove the scope in a clean environment** (whether gloves and gowns worn by personnel placing the endoscope in the AER, were changed before removal of scope from the AER

Transport of High-level Disinfected Endoscopes from Storage– ST 91

- The endoscope should be protected from recontamination.
- Before removing the endoscope from the storage cabinet, don new exam gloves.
- Then transport the endoscope using an impervious barrier method that will prevent re-contamination.
  - Examples: a clean plastic bag, endoscope transfer system (scope in a tote bin with a cover), or similar method.
- The endoscope should be loosely coiled to prevent damage.
- The transport system should not be reused for clean transport.

Summary

- With heightened public concern and documented cases of improper reprocessing of endoscopes, it is imperative that we reduce the risk of exposure to improperly reprocessed medical devices.
- Look to the following for guidance of getting to and maintaining Best Practices in Endoscopy:
  - AAMI ST 91
  - AORN
  - SGNA
  - APIC
  - FDA
  - CDC
- Always follow the original Manufactures Instruction s for Use

Remember it Takes a Lot of Time to Properly Process Any Scope

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