Outbreaks, Investigations and Evidence for Flexible Endoscope Reprocessing – Overcoming the Challenges

HONG KONG HOSPITAL AUTHORITY - ADVANCED COURSE FOR INFECTION CONTROL – NOVEMBER 2017

Learning Objectives

- Present overview of recent endoscope related outbreaks
- Discuss factors that have contributed to the use of contaminated flexible endoscopes
- Understand key recommendations in new endoscope reprocessing guidelines and standards
- Review quality control requirements
- Discuss practical aspects and rationale for using various methods to detect damaged or dirty endoscopes, including enhanced visual inspections, biochemical indicators, and microbial cultures

Janet Prust - Disclosure

Employee of 3M Health Care

Infection Prevention Division

Association for Advancement of Medical Instrumentation (AAMI)
Positions held:

AAMI Board of Directors – Director representing industry since 2015

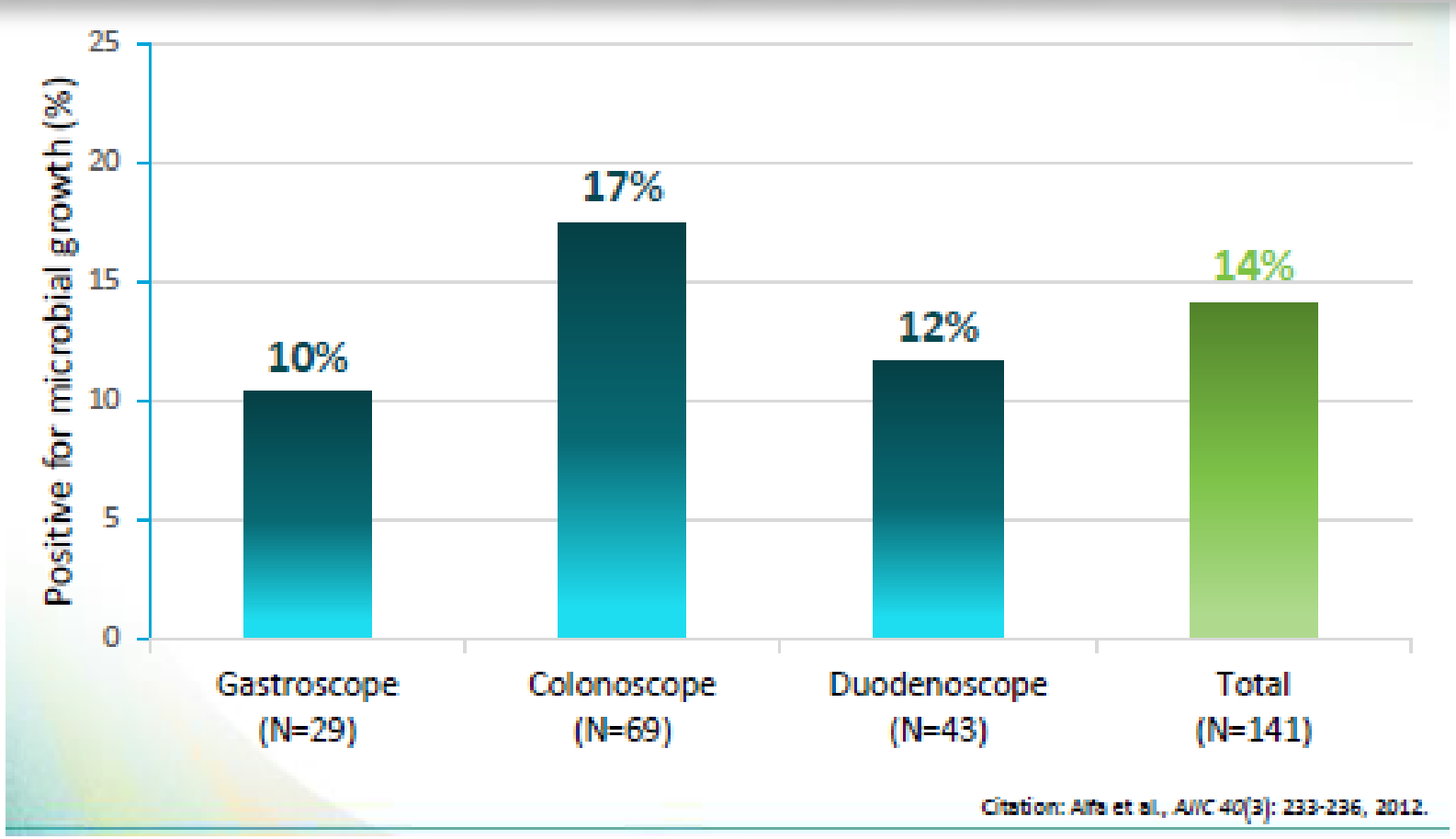
Member:

AAMI Finance committee
Sterilization Standards Committee
WG 61: Chemical sterilants hospital practices – co-chair
WG 84: Endoscope reprocessing
WG 40: Steam sterilization hospital practices
WG 13: Washer disinfectors; TAG to ISO TC 198 WG 13
WG 93: Cleaning of reusable devices
Sterilization of endoscopes stakeholders group
Task group – HVAC conditions in OR

The Outbreaks

Flexible Endoscope Remain Contaminated After Reprocessing – Alfa 2012

Report of contaminated endoscopes well before publicized outbreaks



Contamination and Outbreaks Occurring – Kovaleva ***2013***

Report of outbreaks occurring in published literature before media reporting

Endoscope	Outbreaks	Primary organism	Patient contaminated	Patients infected	Root cause
Upper GI	19	*P. aeruginosa, H. pylori, Salmonella*	169	56	Cleaning or disinfection gaps
Sigmoidoscopy/ colonoscopy	5	*Salmonella,* HCV	14	6	Cleaning or disinfection gaps
ERCP	23	*P. aeruginosa*	152	89	C/D, water bottle, contaminated AER
Bronchoscopy	51	*P. aeruginosa*, Mtg, Mycobacteria	778	98	C/D, AER, Water
Totals	**98**		**1,113**	**249**	

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

Reported gastrointestinal endoscope reprocessing lapses: The tip of the iceberg. Alexandra M. Dirlam-Langlay, Cori L. Ofstead, Natalie J. Mueller, Pritish K. Tosh, Todd H. Baron, Harry P. Wetzler. American Journal of Infection Control 2013 Dec;41(12):1188-94.

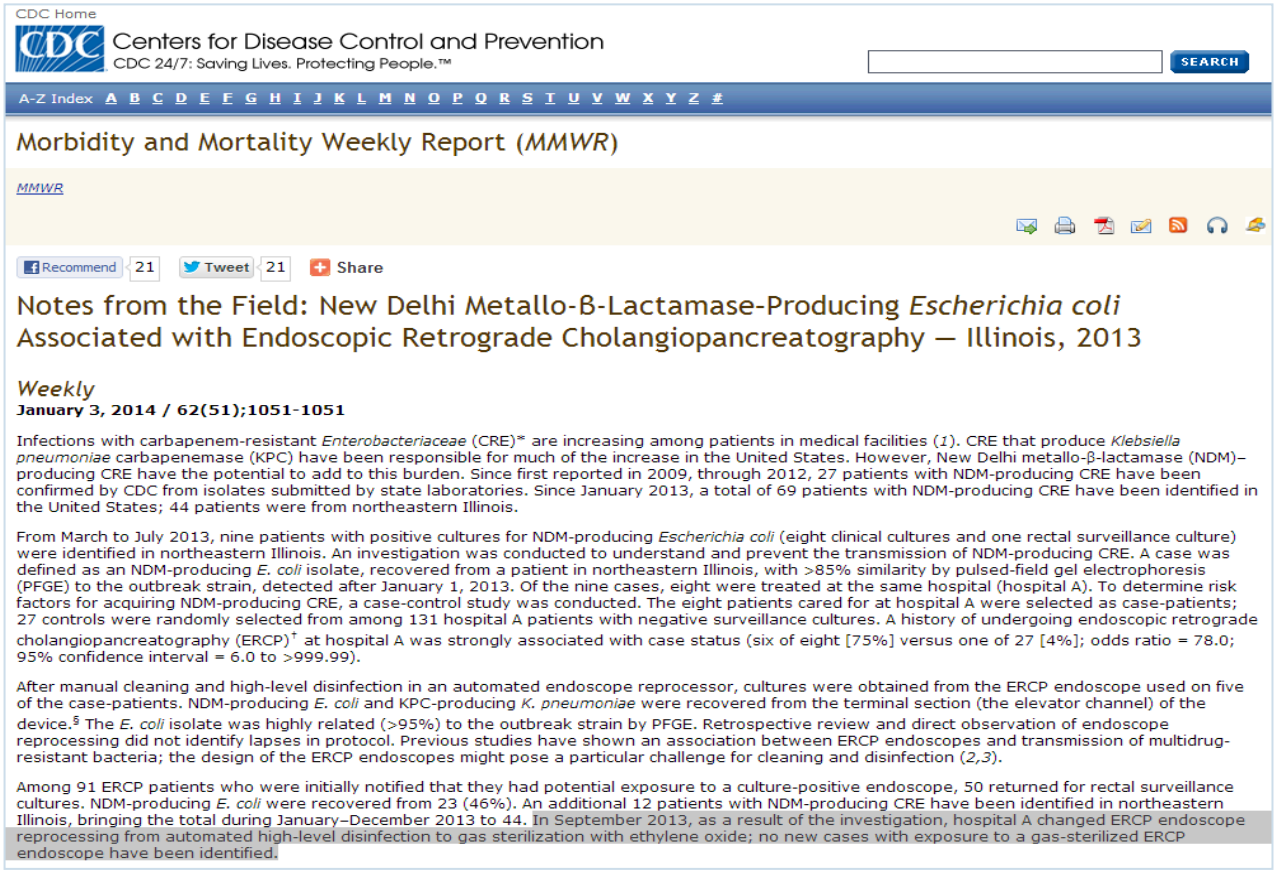
- Looked for reprocessing lapses in peer-reviewed literature, gov't reports, state health depts, CDC, FDA, Dept. of Veteran affairs and media reports
- The study was limited to Jan. 2005 – June 2012.
- ***They found that improper endoscope reprocessing is an ongoing and pervasive problem.***
- Over 30,500 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.

First reports of duodenoscope CRE related outbreaks

US government action related to outbreaks occurring in published literature before media reporting

- 2012 outbreaks with multi-drug resistant organisms seen
- US CDC published alert January 2014



CDC Home

Centers for Disease Control and Prevention
CDC 24/7: Saving Lives. Protecting People.™

SEARCH

A-Z Index A B C D E F G H I J K L M N O P Q R S T U V W X Y Z #

Morbidity and Mortality Weekly Report (*MMWR*)

MMWR

Recommend 21 Tweet 21 Share

Notes from the Field: New Delhi Metallo-ß-Lactamase-Producing *Escherichia coli* Associated with Endoscopic Retrograde Cholangiopancreatography — Illinois, 2013

Weekly
January 3, 2014 / 62(51);1051-1051

Infections with carbapenem-resistant *Enterobacteriaceae* (CRE)* are increasing among patients in medical facilities (*1*). CRE that produce *Klebsiella pneumoniae* carbapenemase (KPC) have been responsible for much of the increase in the United States. However, New Delhi metallo-β-lactamase (NDM)–producing CRE have the potential to add to this burden. Since first reported in 2009, through 2012, 27 patients with NDM-producing CRE have been confirmed by CDC from isolates submitted by state laboratories. Since January 2013, a total of 69 patients with NDM-producing CRE have been identified in the United States; 44 patients were from northeastern Illinois.

From March to July 2013, nine patients with positive cultures for NDM-producing *Escherichia coli* (eight clinical cultures and one rectal surveillance culture) were identified in northeastern Illinois. An investigation was conducted to understand and prevent the transmission of NDM-producing CRE. A case was defined as an NDM-producing *E. coli* isolate, recovered from a patient in northeastern Illinois, with >85% similarity by pulsed-field gel electrophoresis (PFGE) to the outbreak strain, detected after January 1, 2013. Of the nine cases, eight were treated at the same hospital (hospital A). To determine risk factors for acquiring NDM-producing CRE, a case-control study was conducted. The eight patients cared for at hospital A were selected as case-patients; 27 controls were randomly selected from among 131 hospital A patients with negative surveillance cultures. A history of undergoing endoscopic retrograde cholangiopancreatography (ERCP)† at hospital A was strongly associated with case status (six of eight [75%] versus one of 27 [4%]; odds ratio = 78.0; 95% confidence interval = 6.0 to >999.99).

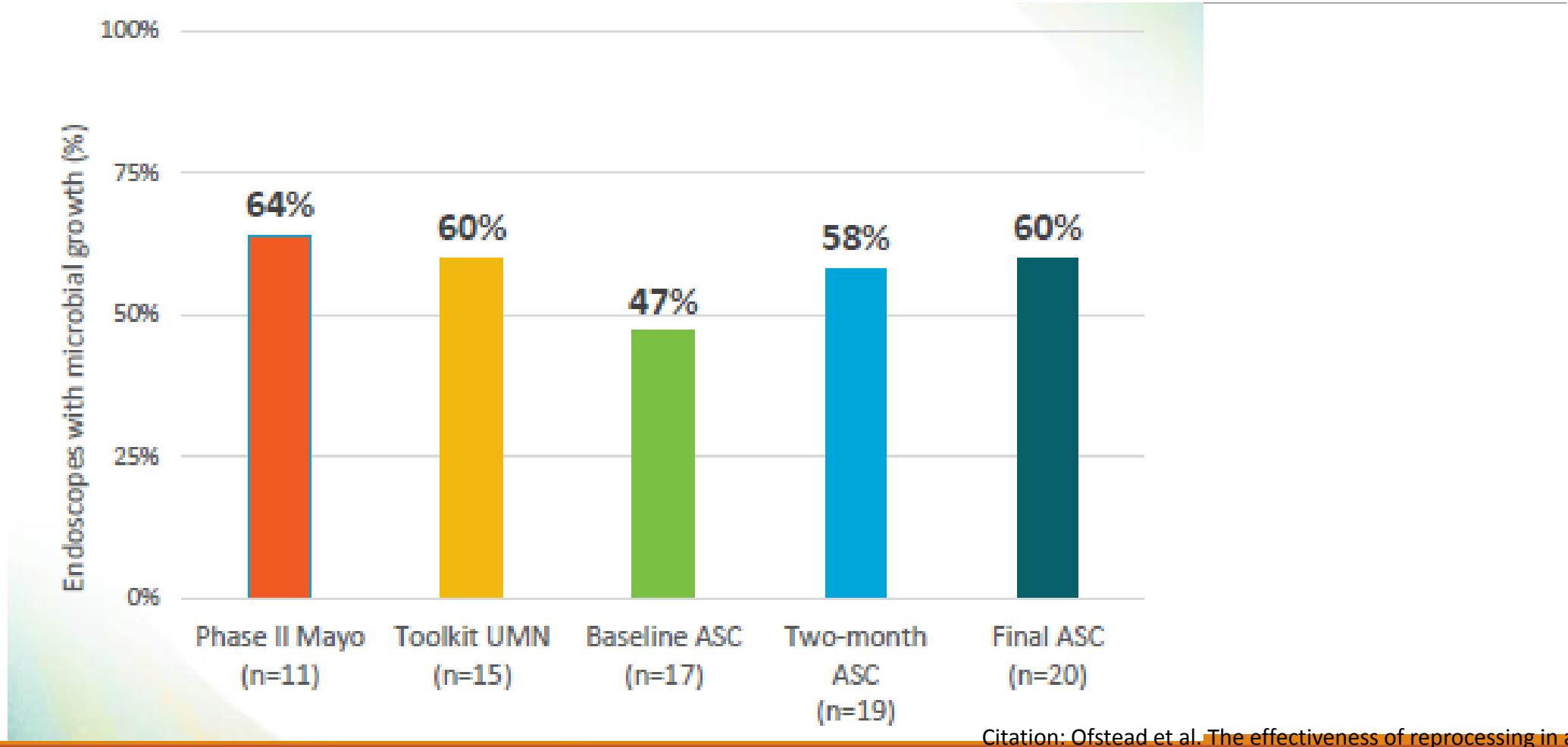
After manual cleaning and high-level disinfection in an automated endoscope reprocessor, cultures were obtained from the ERCP endoscope used on five of the case-patients. NDM-producing *E. coli* and KPC-producing *K. pneumoniae* were recovered from the terminal section (the elevator channel) of the device.§ The *E. coli* isolate was highly related (>95%) to the outbreak strain by PFGE. Retrospective review and direct observation of endoscope reprocessing did not identify lapses in protocol. Previous studies have shown an association between ERCP endoscopes and transmission of multidrug-resistant bacteria; the design of the ERCP endoscopes might pose a particular challenge for cleaning and disinfection (*2*,*3*).

Among 91 ERCP patients who were initially notified that they had potential exposure to a culture-positive endoscope, 50 returned for rectal surveillance cultures. NDM-producing *E. coli* were recovered from 23 (46%). An additional 12 patients with NDM-producing CRE have been identified in northeastern Illinois, bringing the total during January–December 2013 to 44. In September 2013, as a result of the investigation, hospital A changed ERCP endoscope reprocessing from automated high-level disinfection to gas sterilization with ethylene oxide; no new cases with exposure to a gas-sterilized ERCP endoscope have been identified.

The Outbreaks: 2015 - In the news but not new…..

After a well documented history of outbreaks

High levels of Persistent Contamination on Patient Ready Endoscopes – Ofstead 2013, 2014, 2016



Citation: Ofstead et al. The effectiveness of reprocessing in accordance with current guidelines. SGNA Conference Poster. 2015.

Published CRE Outbreaks – A Wake Up Call

Primary Author	Multi-drug resistant organism	Number of patients impacted	Yr. of publication
Carbonne	*K. Pneumoniae*	13	2010
Smith	*E. Coli*	3	2015
Marsh	*K. Pneumoniae*	34	2015
Kim	*K. Pneumoniae*	15	2016
Epstein	*E. Coli*	39	2015
Kola	*K. Pneumoniae*	12	2015
Wendorf	*E. Coli*	35	2015
Vertaillie	*P. Aeruginosa*	22	2015
Total		173	

Additional Cited Outbreaks:

1. Bajolet O, Ciocan D, et.al. **Gastroscopy-associated transmission of extended-spectrum beta-lactamase-producing *Pseudomonas aeruginosa*.** J Hosp. Infect 2013 (83)

2. Epstein L, Hunter J, et. Al. **New Delhi Metallo β-Lactamase-producing carbapenem-resistant *Escherichia coli* associated with exposure to duodenoscopes**. JAMA 2014. (312:1447-55

3. Kovaleva J, Degener J., et.al. **Methylobacterium and its role in health care associated infection. J Clin Microbiol.** 2014 (52). 1317-21

4. Wendelboe A, BaumbachJ., et.al. **Outbreak of cystoscopy related infections with *Pseudomonas aeruginosa*: New Mexico. 2007**. J Urol 2008. (N180). 588-92.

5. Wendorf K, Kay M., et.al. **Endoscope retrograde cholangiopancreatography-associated Amp C *Escherichia coli* outbreak.** Infect Control Hosp Epidemiol 2015. (#^). 634-42.

6. Guy M, Vanhems P. , et.al. **Outbreak of pulmonary Pseudomonas aeruginosa and *Stenotrophomonas matlophilia* infections related to contaminated bronchoscope suction valve**s, Lyon, France. Euro Surveil. 2014. 2016:21.

Additional Evidence Detail

- Saliou, et al. 2016. **Persistent Contamination on Endoscopes – Micro surveillance post processing with 8 day incubation**
  - 34% exceeded target of <25 CFU of indicator organism

- England, et al. 2016. Transmission of MDRO from **gastroscope** – 5 patients with CRE (9 more exposed)
  - Superbug persisted through 12 reprocessing cycles

- **Duodenoscope** ERCP / CRE Outbreaks
  - Illinois 2013 – 156 patients exposed to CRE/ 39% transmission rate
  - Washington 2014 - 39 cases/ 18 deaths.
  - Wisconsin 2014 – 3 deaths
  - California – 2014 - 2 deaths

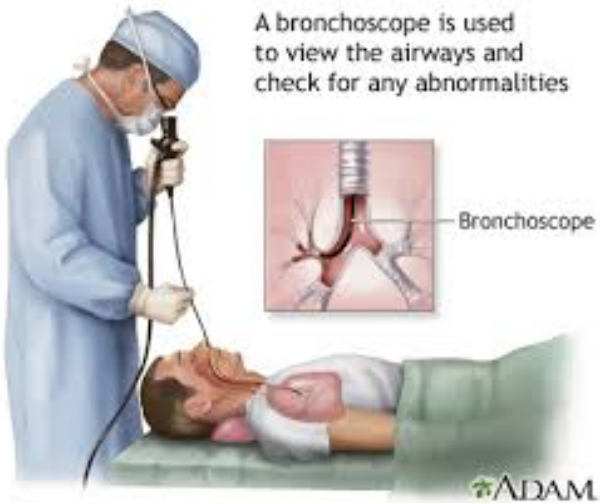
- DiasGranadose, et al. 2009. **Bronchoscope** related outbreak.
  - 19 patient exposed, 12 infected, 2 deaths

- FDA MDRO Reports:
  - 2015. Contaminated **cystoscopes**. 4 patients infections
  - 2015. Contaminated **ureteroscopes**. 7 infections. Damaged endoscopes.

Outbreaks occurring with all types of flexible endoscopes and a variety of organisms

Flexible GI Endoscope are not the only risk….

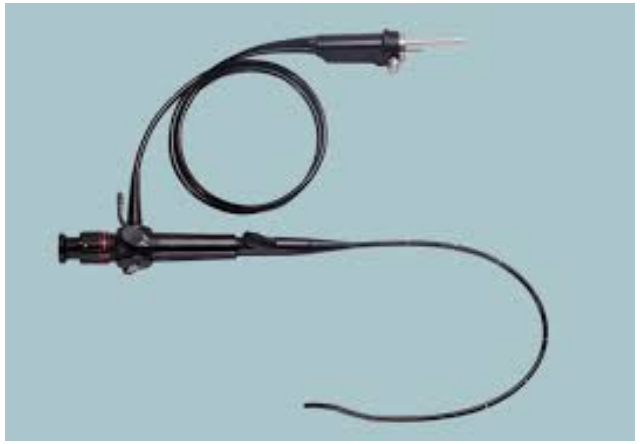
Reprocessed Flexible Bronchoscopes: FDA Safety Communication - Risk of Infection Sept. 7, 2015



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: “Implement a comprehensive reprocessing quality control program. 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.”



Other reprocessing lapses and patient exposure to contaminated endoscopes

US Location	Facility types	Errors in reprocessing	Patients impacted
Colorado	Medical center	Improper cleaning	71
Minnesota 1	ASC; Outpatient clinic; 5 hospitals	7 incidents reported: improper cleaning/HLD; reprocessing single use device; inadequate training	6 – 2000 per incident
North Carolina	Hospital	No cleaning/sterilization of one channel	10
New Jersey	ASCs	Improper reprocessing; unchanged water/cleaning solution	Not reported
Ontario, Canada	Clinic	Multiple cleaning/HLD breaches	6800
Louisiana	Medical center	Wrong HLD temperature	360
British Columbia, Canada	Hospital	Bioburden allowed to dry before cleaning	536
California	Hospital; surgery center	Improper HLD; expired disinfectant	3400
Minnesota 2	Medical center	No HLD of one channel	2600
Florida	Hospital; cancer treatment center	Improper cleaning of elevator channel	191
Georgia	Surgery center	Wrong HLD time	1300

Non-endoscopic Related Outbreaks

Poor Infection Control Practices:

- New York – improper handling of intravenous sedation tubing, multi-dose vials and reuse of needles.
- Las Vegas – Outbreak of Hepatitis C due to cross-contamination from syringes - ~40,000 patient exposed. No follow-up information.

Source: ASGE 2017

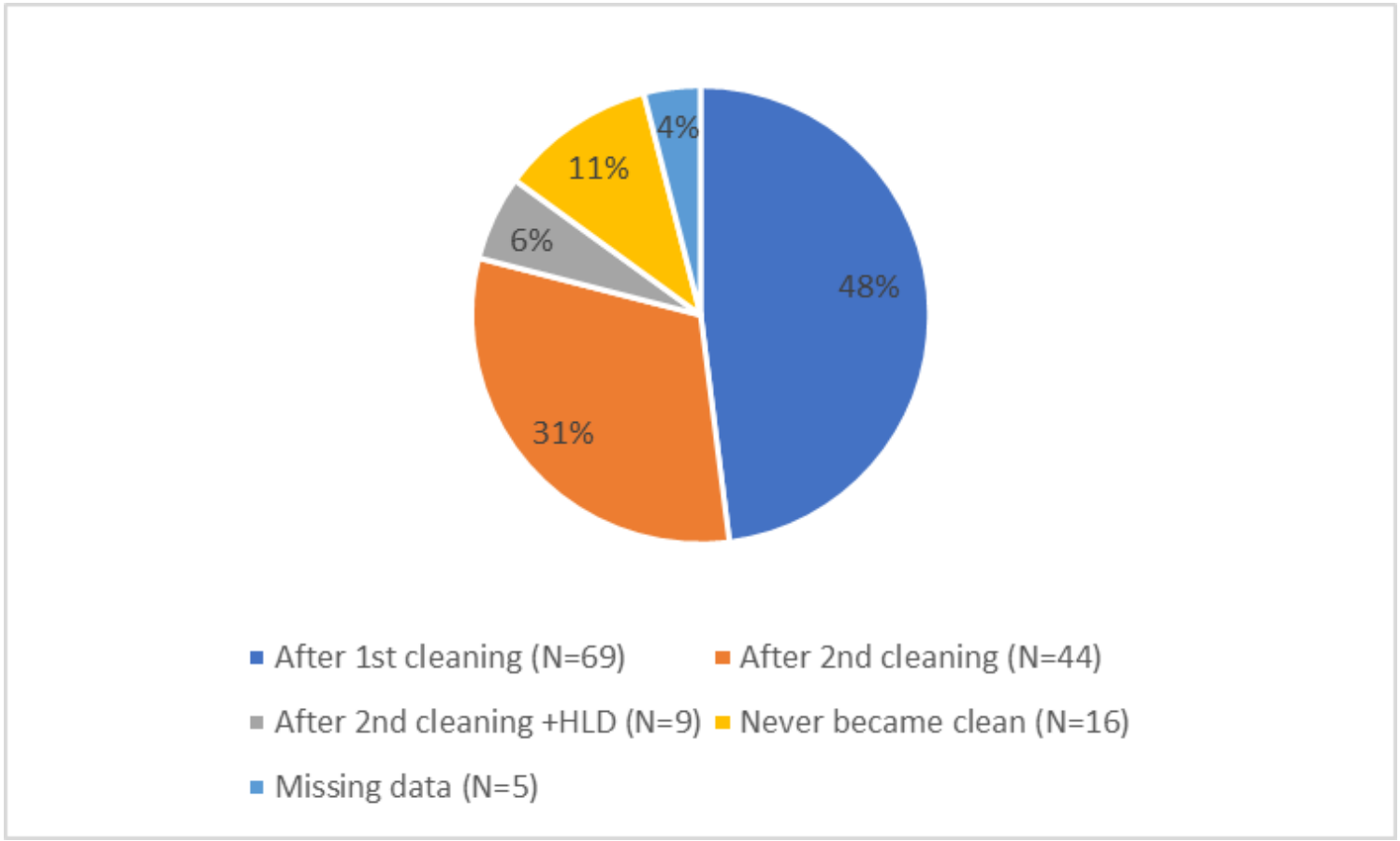
Outbreaks Related to Tubing, Water Bottles and other sources

- Hep C outbreak related to malfunctioning one-way valves contaminated water bottles (water and bottles not changed between patients)
- Biofilm formation on tubing
- Contamination of endoscope from hands of HC workers
- Failure to sterilize biopsy forceps

Source: ASGE 2017

Ofstead et al., Assessing residual contamination, *AJIC*, 2016; Ofstead et al., Longitudinal assessment, *AJIC*, 2017.

143 gastroscope testing encounters (June-October)



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/

Guidelines

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

Gastroenterology and Urology Devices Panel Meeting May 14-15, 2015

FDA seeking expert scientific and clinical opinion. 19 member advisory panel.

"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."

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

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

---

Enhanced measures include:

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

This recommendation currently questioned regarding lack of evidence for liquid disinfection recommendations.

- Implementation of these additional measures **may not be feasible**
- 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.**

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

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.

New Guidelines Issued

SGNA (4): Society for Gastroenterology Nurses and Associates

AAMI: Association for Advancement of Medical Instrumentation

AORN: Association of periOperative Registered Nurses

APSIC: Asia Pacific Society of Infection Control

ASGE: American Society for Gastrointestinal Endoscopy/ Multisociety update

CDC/HICPAC: Healthcare Infection Control Practices Control Advisory Committee

To varying level of detail, guidelines agree on:

- Implement quality control program
- Follow manufacturer's instructions for reprocessing
  - New, revalidated IFUs
- Pay special attention to manual cleaning
  - Meticulous cleaning required
  - Elevator mechanism needs special attention
- Implement comprehensive training with competency assessment by qualified personnel
- Periodic review of policies and procedures
- AORN, AAMI, APSIC and SGNA recommend use or assessment of cleaning verification
- ASGE, CDC recommends microbial surveillance

SGNA Guidelines

- Standards of Infection Prevention in Reprocessing Flexible Gastrointestinal Endoscopes 2015
- Standards in Infection Prevention in Gastroenterology Settings 2015
- Standards of Infection Prevention in Reprocessing Flexible Gastrointestinal Endoscopes 2016
- Guideline for Use of High-Level Disinfectants & Sterilants in the Gastroenterology Setting 2017

http://www.sgna.org/Portals/0/Standards

ANSI/AAMI ST91:2015 Flexible and semi-rigid endoscope reprocessing in health care facilities – currently under revision

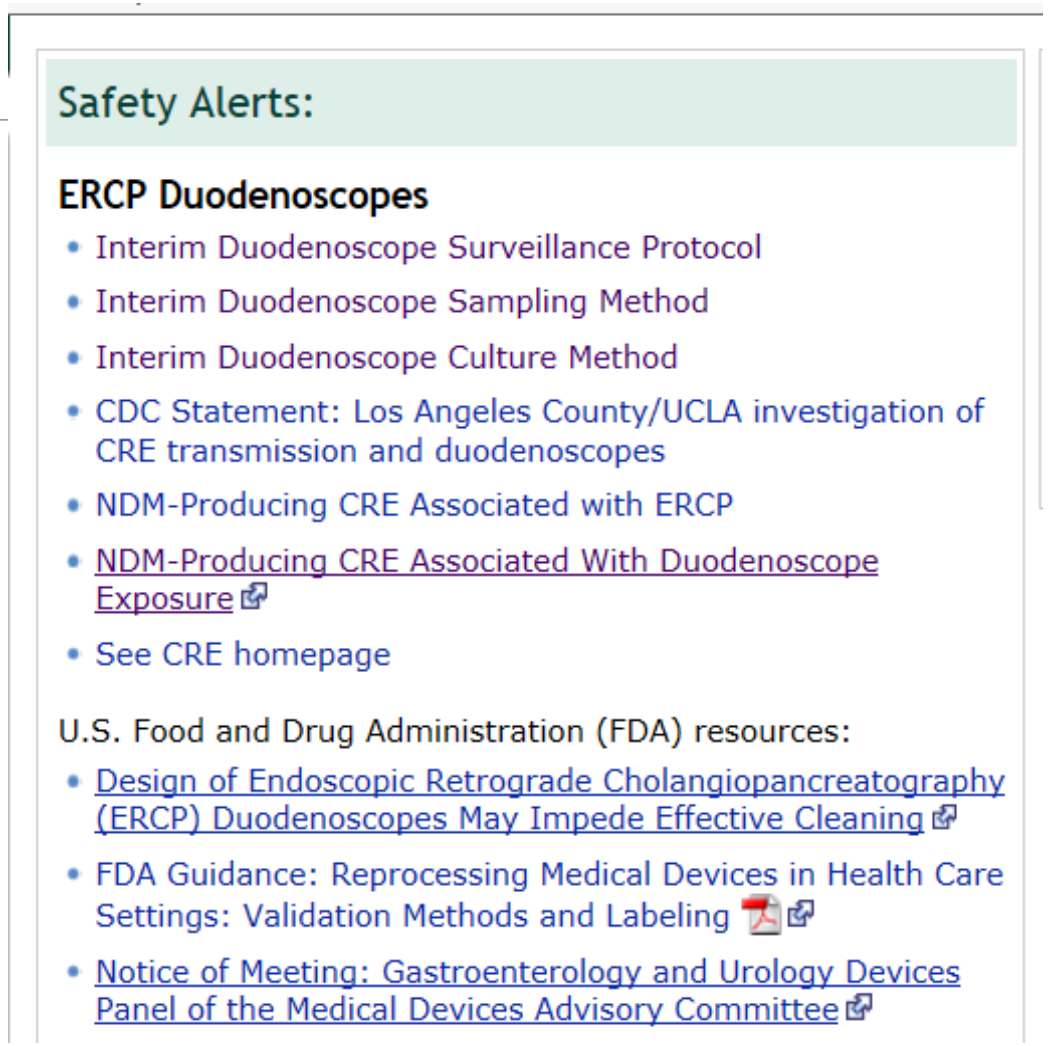
- Design of the endoscope processing area, including work flow considerations
- Personnel issues such as training, hygiene, clothing, policies, and immunizations
- Processing steps and recommendations including sterilization
- Addresses other related topics including automated endoscope reprocessors (AER), sterile endoscope sheaths, and processing accessories
- Storage and transport
- Quality control
- Bibliography

http://my.aami.org/store/SearchResults.aspx?searchterm=st91&searchoption=ALL

CDC Interim Microbial Surveillance Protocol - March 2015

- Protocol suggested but not yet validated
- Sensitivity of this method is unknown
- 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

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.*

Discussion - Outbreaks

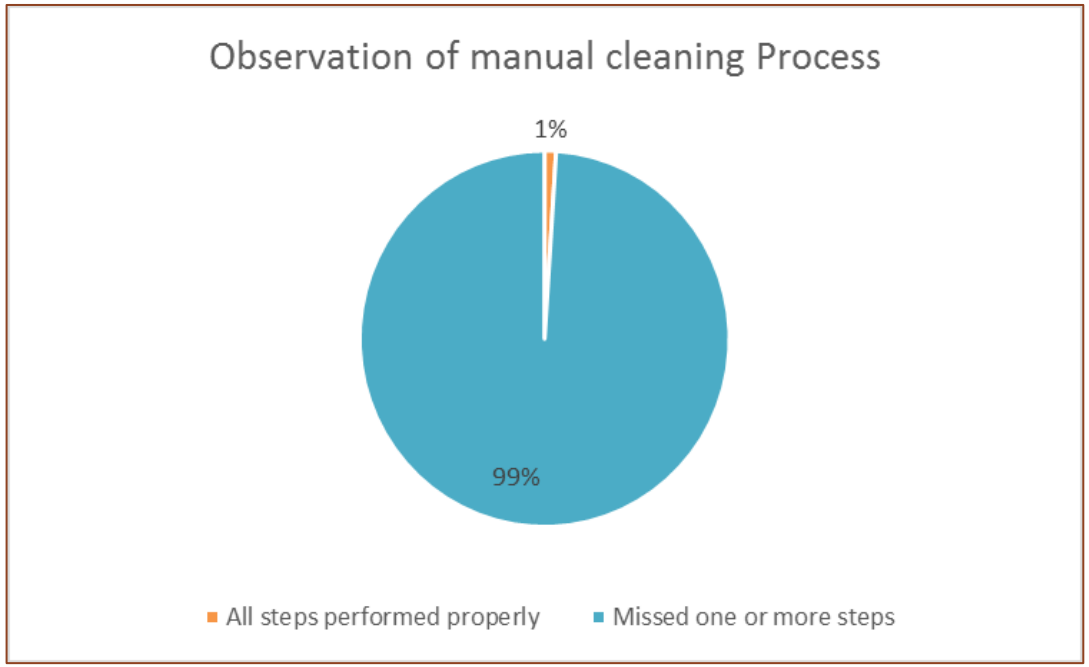
1. Why are we seeing the increase level of outbreaks?
2. What has changed?
3. How can these be detected?
4. Any experiences in your facilities to share?
5. What is the level of awareness and concern by administration/management? Auditors?

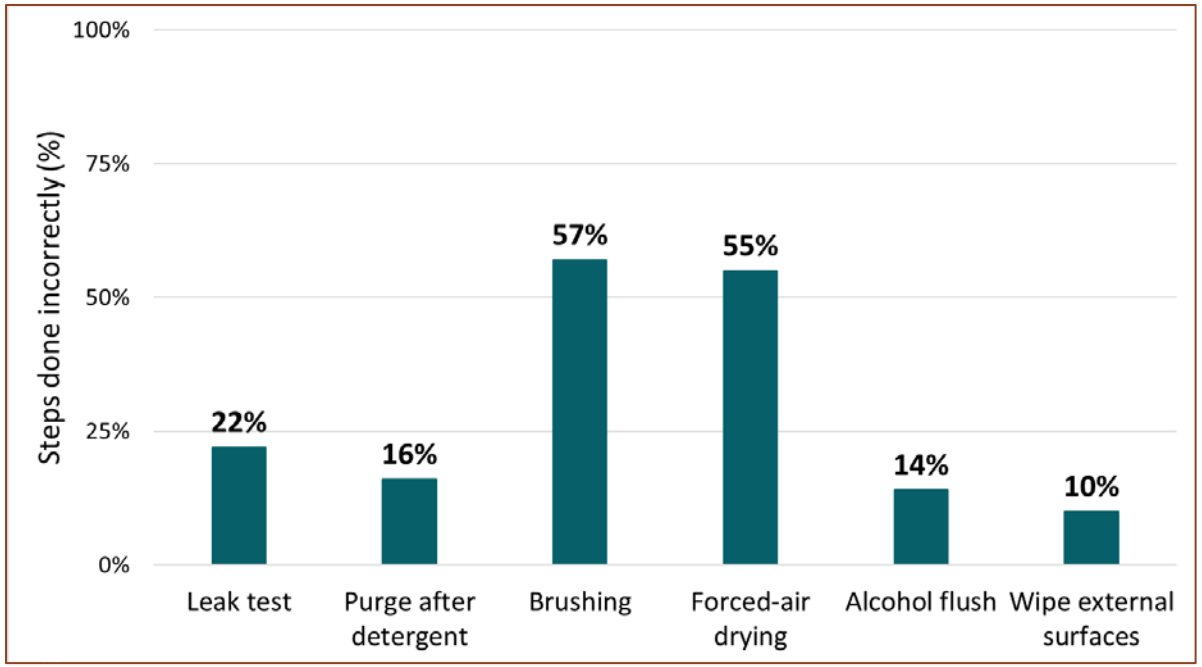
Human Factors

Ofstead C, Wetzler H, Snyder A**. Endoscope Reprocessing Methods: A prospective study on the impact of human factors and automation.** Gastroenterology Nursing, **2010**. Vol 33 (54): 3-10.

(N = 69 GI endoscopes)

2 or more steps performed improperly nearly half of the time ***while being observed***





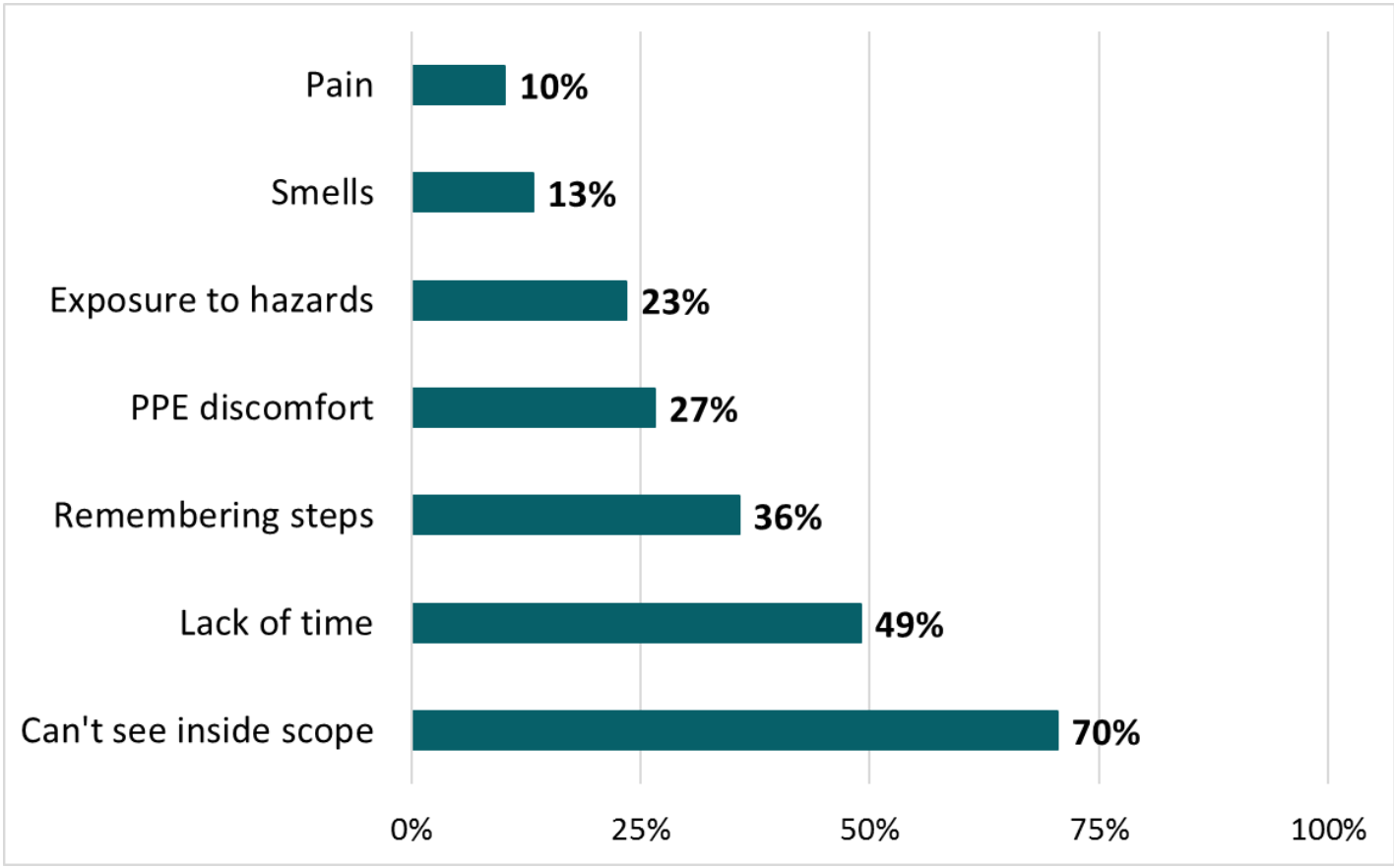
Citation: Ofstead et al., *Gastroenterology Nursing,* 2010

Reprocessing staff comments

- 50% didn’t like performing manual cleaning
- 53% reported discomfort due to working with scopes
- 13% problems with lungs, sinuses, or breathing
- 27% bothered by odors or fumes
- 50% physical discomfort or bothersome symptoms
- 75% felt pressure to work quickly while reprocessing
- 37% observed procedural delays due to reprocessing

Citation: Ofstead et al., *Gastroenterology Nursing,* 2010

IAHCSMM Survey: 2017
Staff report of issues encountered during reprocessing.
N = 67



Source: IAHCSMM Communique. Jan/Feb. 2017. A glimpse at the true cost of reprocessing an endoscope: results of pilot project. Ofstead, Wetzler, et.al.

Factors that contribute to patient risk related to flexible endoscopy procedures:

- Complicated reprocessing guidelines
- Lack of training by qualified instructors
- Non-adherence to guidelines
- Repeated exposure of endoscopes to organic debris and pathogens
- Inability to see pathogens and internal endoscope damage with the naked eye
- Resistance to testing for contamination
- Increasing pressure to do more, faster, with less resources
- Longstanding belief that there's no risk – 1 in 1.8 million often cited by GI community

Flexible Endoscope Reprocessing – Basic Steps*:

- Bedside pre-cleaning and transport
- ☐Leak testing
- ☐Thorough manual cleaning
- ☐Visual inspection and verification
- ☐Rinsing
- ☐High-level disinfection
- ☐Rinsing
- ☐Drying
- ☐Storage

* This is an oversimplification. It is a very complex process with over 200 steps.

Complicated Guidelines

Guideline or Standard	Pages	# reference to IFU
AORN Guideline for processing flexible endoscopes (2016)	84	73
SGNA Standards of Infection Prevention in Reprocessing Flexible GI Endoscopes (2015)	31	66
SGNA Standards of Infection Prevention in the Gastroenterology Setting (2015)	22	13
SGNA Guideline for Use of High-Level Disinfectants & Sterilants in Gastroenterology Setting. (2017)	5	13
AAMI ST 91: Flexible and semi-rigid endoscope processing (2015)	70	149
CDC (US Centers for Disease Control and Prevention). Essential Elements of a Reprocessing Program for Flexible Endoscopes – Recommendation of the Healthcare Infection Control Practices Advisory Committee (2017)	12	4
APSIC	9	12

Clinical Use of products Containing Simethicone

Active ingredient: silicone …

- In bowel prep formulations
- Lubricants/de-foaming agents sued in procedures, e.g. simethicone
  - Silicone is NOT WATER SOLUALBE
- Add substance to water bottle or injected into endoscopes using a syringe to reduce foam, bubbles, gas
- Sprayed on surfaces to facilitate procedure

- Other ingredients in products include thickeners, sweeteners, preservatives, and water

Citation: Ofstead et al., Simethicone residue, *AJIC*, 2016

Discussion – Human Factors

1. Describe your experience regarding staff or human factors issues?
2. What works well? What doesn't.
3. What are the key factors that prevent effective reprocessing from a staff or management factors?
4. What Guidelines are available and followed?
5. How are staff trained and assessed?

Process Effectiveness and Quality Control

How Fast do Microbes Multiply?

Time	# organisms
After HLD reprocessing	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	2,097,153

Prompt initiation of cleaning is critical to an effective cleaning process.

Current guidelines recommend documentation of time pre-clean was completed to determine if delayed reprocessing procedures are needed.

Source: Wava Truscott, PhD. Truscott MedSci Associates, LLC. 2017

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

What to consider? Quality Control through the implementation of rapid cleanliness indicators, ethylene oxide sterilization to replace HLD and appropriate use of microbial monitoring audits.

Endoscope Reprocessing Quality System Requirements

- Training and routine competency assessments
  - Certification
- **Visual inspection**
- **Cleaning Verification**
- Disinfectant concentration testing
- Physical/mechanical monitoring
- **Water quality testing to ensure no contamination**
- Ensure AER / Washer Disinfection functioning and **not contaminated**
- **Effective drying**
- **Storage and handling to prevent contamination**
- **Validation of equipment and processes***

* Required in some regions

Training and Competency

- **Complete and thorough training programs**
  - Standards
  - Manufacturer's instructions for use
  - Certification through formal program recommended

- **Competency assessment**
  - Direct observation of competency
  - Routine assessment (e.g. quarterly)
  - Assessment performed by knowledgeable, experienced individual in endoscope reprocessing

Visual Inspection for gross soil and damage

SGNA

- "Due to recent issues with reprocessing, **visual inspection warrants its own step. It** may be considered a "time out" or safety stop to verify that the endoscope is at least visually clean before proceeding to HLD."
- "Look for conditions that could impact HLD (corrosion, discoloration, cracks, and retained debris)
  -

Brand new

Damaged

AORN

- "**Lighted magnification should be used** to inspect endoscopes and accessories for cleanliness and damage."
- "An endoscope that appears clean may harbor debris that cannot be seen without magnification. Lighted magnification may increase the ability to identify residual soil or damage."
- "Internal channels of flexible endoscopes may be inspected using an endoscopic camera or borescope."
- "**Defective endoscopes, accessories, and equipment should be removed from service and repaired or replaced**

Images: Ofstead AJIC poster 15, 16

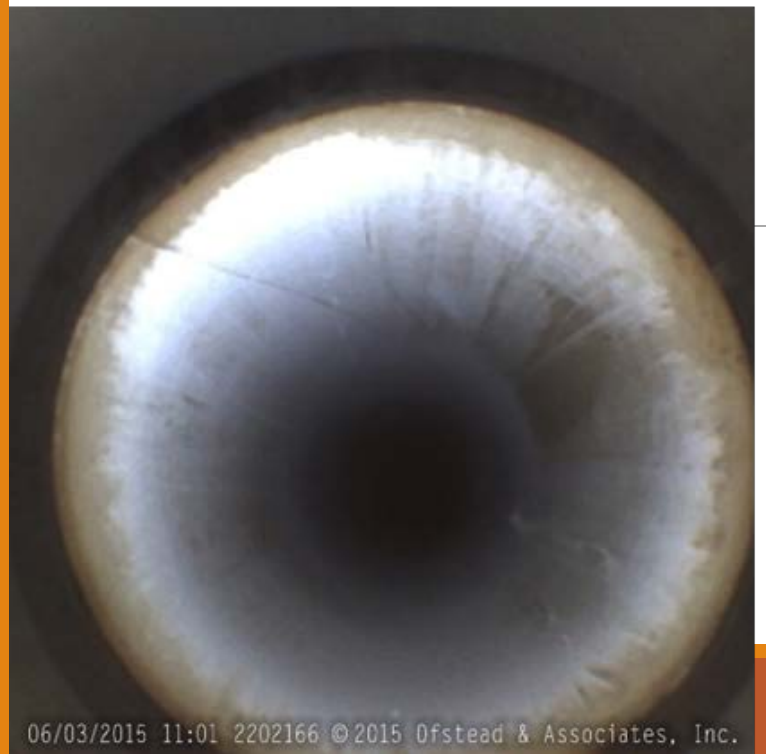
Borescopes – a new approach to inspection

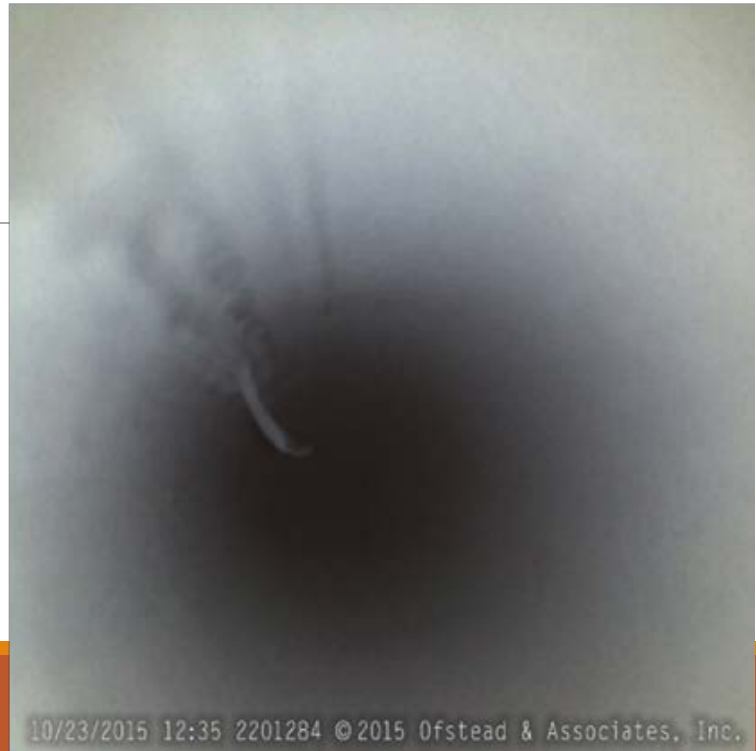
- Small fiberoptic camera to view inside channels
- Greatly magnified image
- Available for S/B channel size
- Can capture images
- Valuable for inspection of damage and gross debris
- Challenges:
  - No benchmark as acceptable wear and tear
  - Disinfection between uses
  - Sizes not available for all channels

- Guidelines referencing for inspection

Image: Courtesy of SP Concepts

Borescope images





Images: Ofstead 2016

What does everyone agree on?

Focus on Manual Cleaning

- It is a problem
- It is critical to success of HLD or 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 ST91:2015 Section 12: Quality Control

QC is critical to successful reprocessing

- All facilities should have a comprehensive QC program
  1. Product identification and traceability
  2. Documentation and record-keeping
  3. **Verification and monitoring of the cleaning process**
     - **Technologies: ATP, protein, hemoglobin, carbohydrate, bioburden**
     - **Provides Pass/Fail threshold measuring effective soil removal**
  4. Monitoring of high-level disinfection and sterilization processes
  5. Product recalls procedure
  6. Quality process improvement program

Cleaning Verification Recommendations

AORN:

"Manual cleaning of flexible endoscopes **should be verified using cleaning verification tests** when new endoscopes are purchased and **at established intervals (eg, after each use, daily**)."

AAMI:

"The frequency of **testing the efficacy of the manual cleaning step should occur on a regular basis, weekly or preferably daily**…"

SGNA:

If the test results for organic soil are positive, the endoscope should be **re-cleaned** before HLD

APSIC:

Cleaning verification should be performed at least daily and prefer every time the endoscope is manual cleaned.

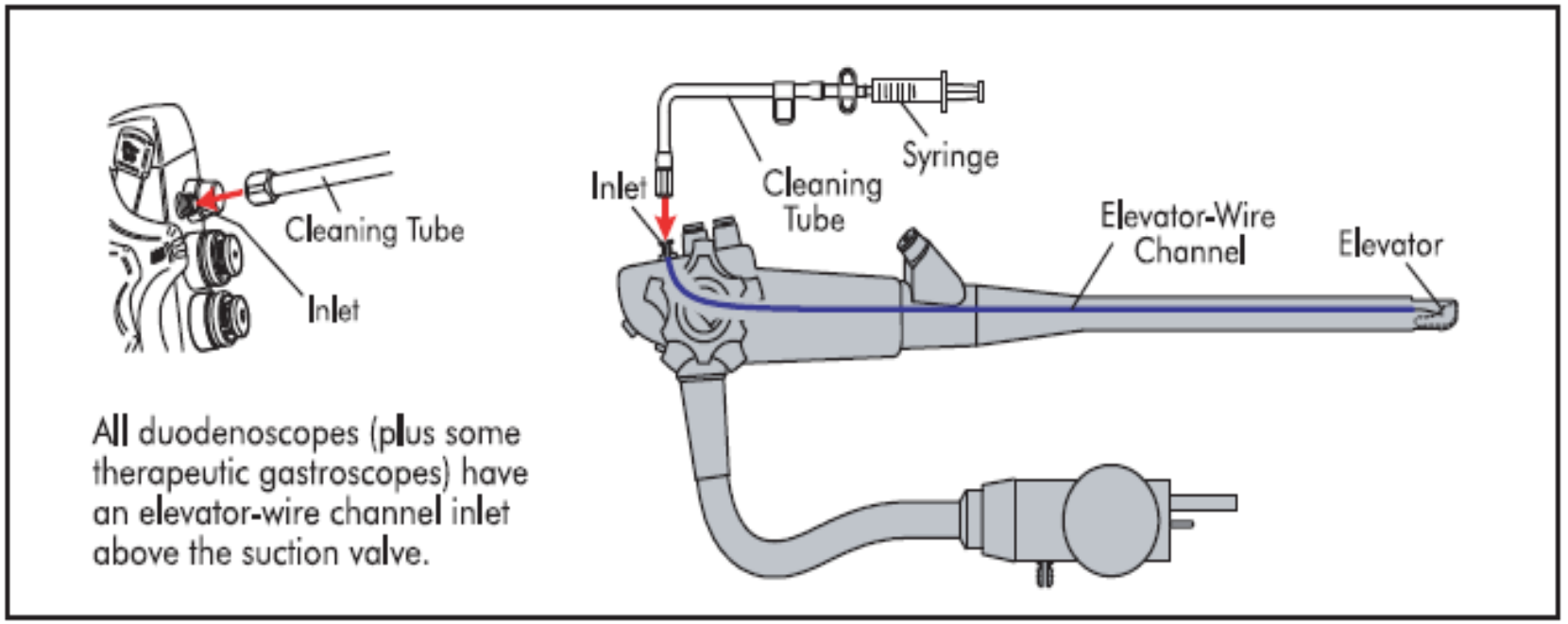
Cleaning Verification Practices

Samples endoscope surfaces and channels after manual cleaning:

- Swab the insertion tube, distal end, and ports
- Flush sterile water through channels and collect effluent
- Run rapid biochemical cleaning verification tests for residual contamination
  - ATP
  - Protein (less sensitive)
  - Hemoglobin (only detects presence of blood)
- Re-clean whenever results exceed benchmarks for “clean”
- Re-test after re-cleaning
- Repeat until test passes or a decision is made to send it for repair

Duodenoscopes Have Added Complexity

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



OLYMPUS

Cleaning = Effective Removal of Clinical Soil

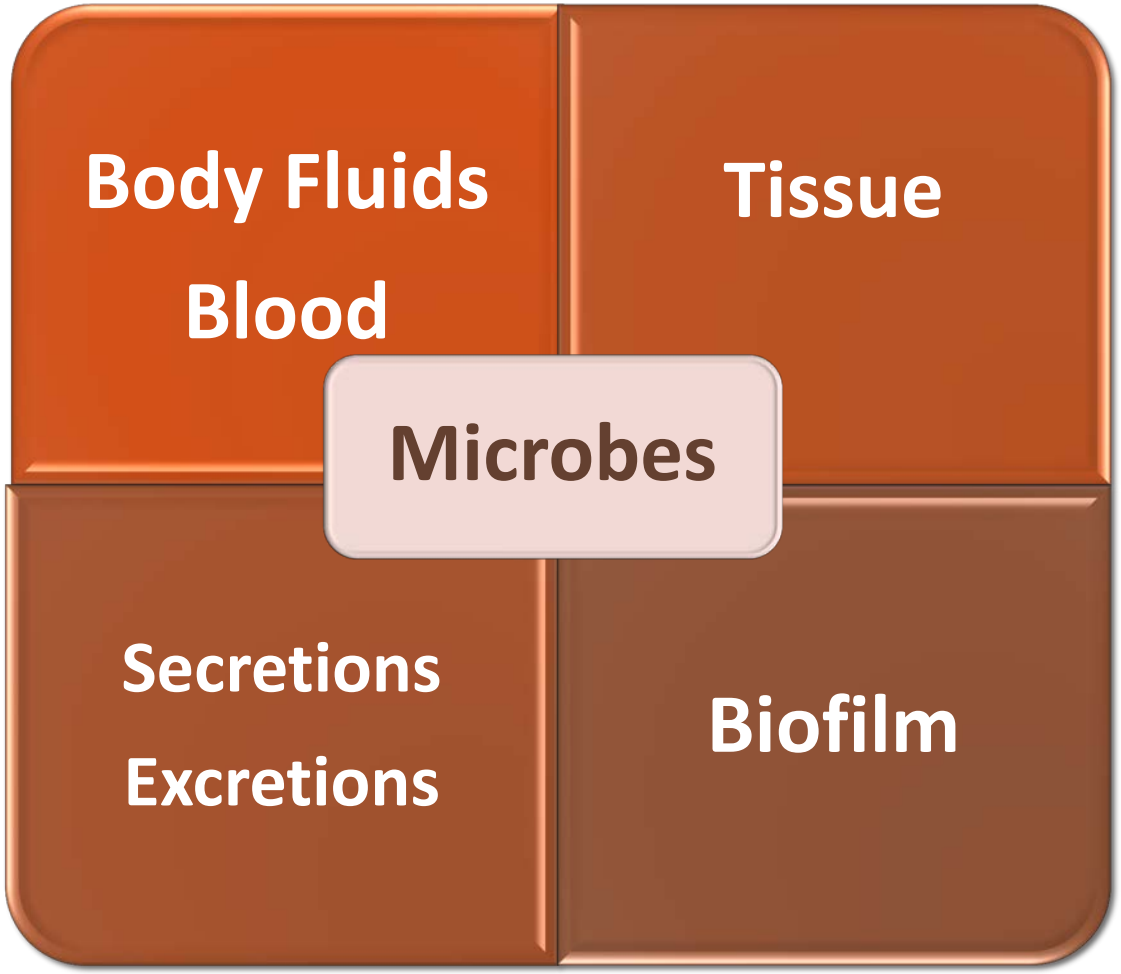
What is in Clinical Soil?

- Microorganisms: bacteria, fungi, viruses
  - Microbes found in all soil components
- Tissue
- Blood and other body fluids
- Secretions/Excretions

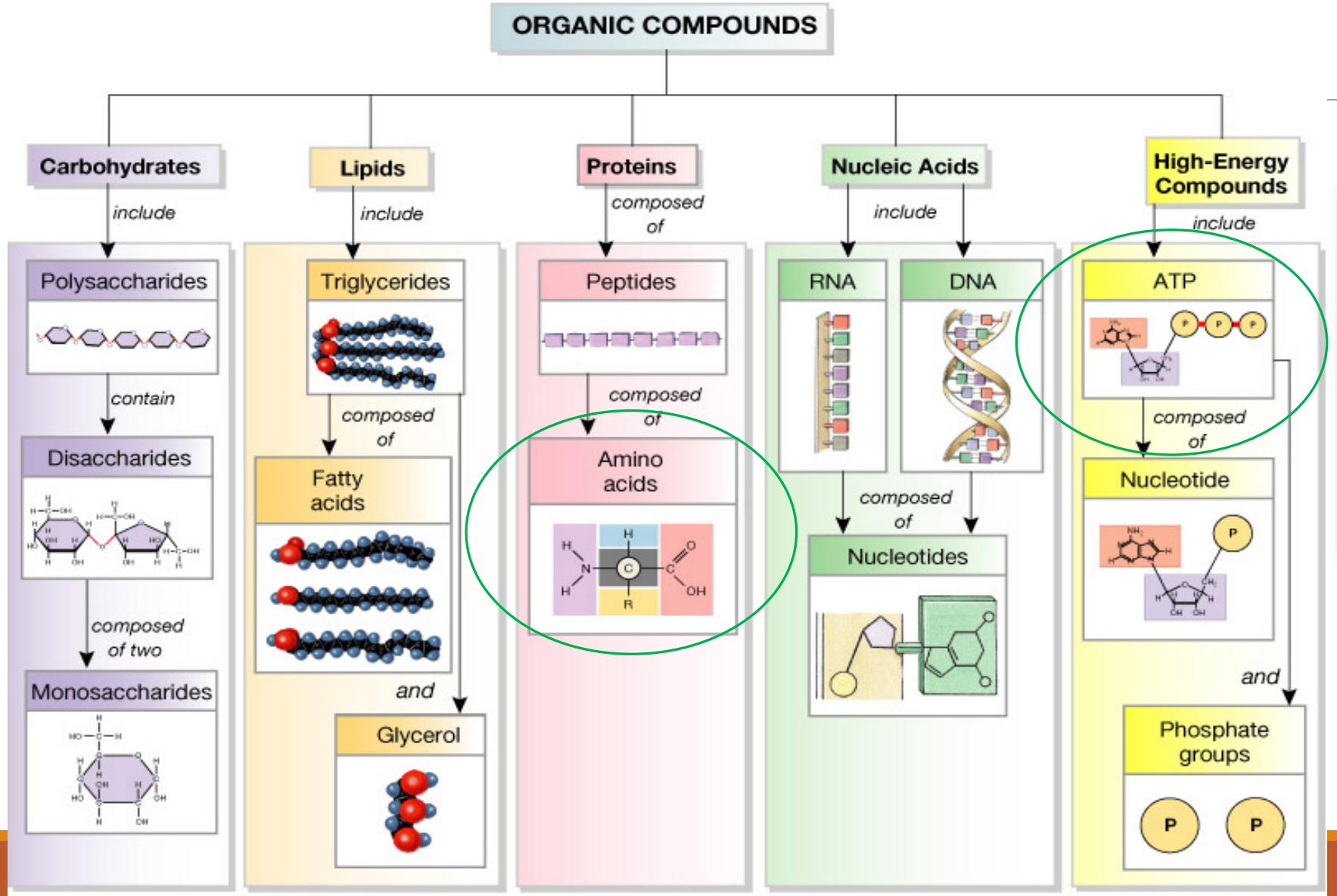
(vomit, diarrhea, mucous, phlegm, etc)

Can presence of soil be measured?

- Yes, but it is not easy



Components Found in Clinical Soil

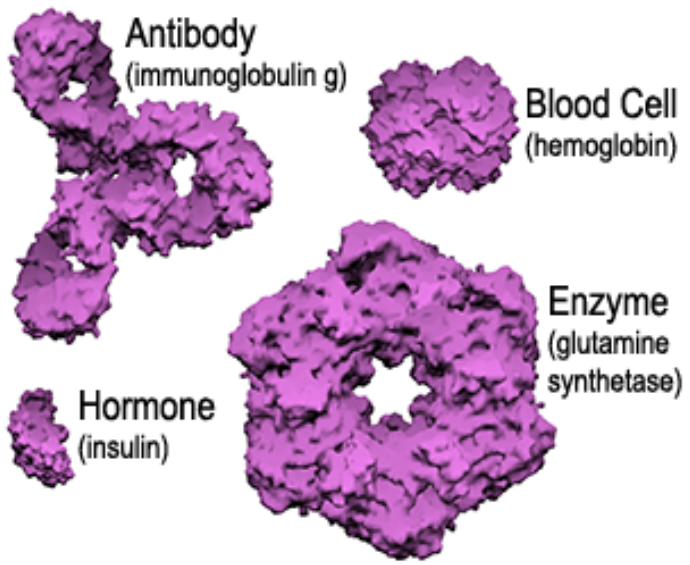


To measure effectiveness of cleaning - a component is selected to measure.

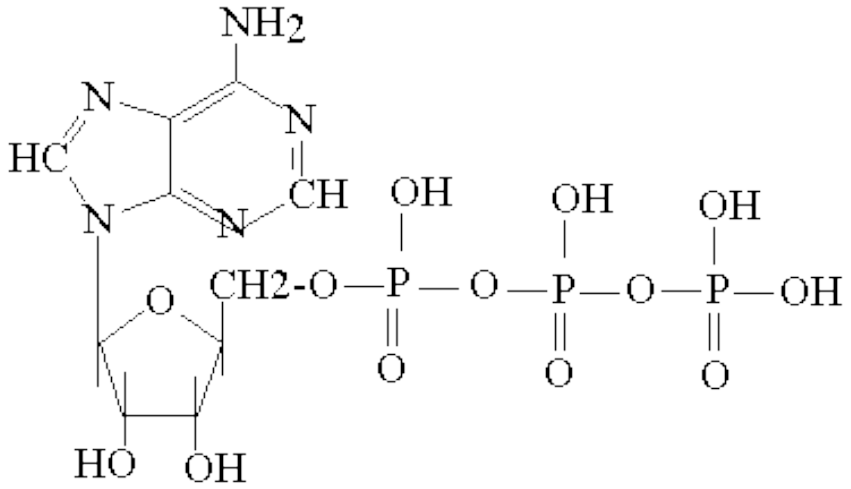
Common Universal Cleanliness Markers

Present in all types of soils, used for general monitoring

Protein



Adenosine Triphosphate (ATP)



adenosine triphosphate (ATP)

Characteristics of Cleaning Markers

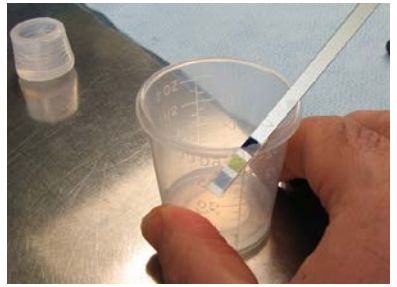
ATP	Protein
Universal Marker	Universal Marker
Mature technology	Mature technology
Commercially available	Commercially available
Rapid tests are objective, numeric	Rapid tests are subjective, colorimetric
ATP is stable under reprocessing conditions	Rapid tests cannot measure proteins that are denatured under reprocessing conditions.
Will detect microbial ATP	Does not detect microbial proteins: requires additional sample prep for detection
Cannot be used when prions are an issue	Used when prions are an issue
Different manufacturer's use different measurement scales so cannot compare different systems.	Measurement scale is in standardized µg

Rapid Cleaning Verification Tests: Rapid Protein Detection

- Qualitative Test
- Colorimetric (color change)
- Subjective interpretation
- Gives presence/absence results
- Analysis of data is limited
- Validation data unavailable for most tests
- Data needed to verify sensitivity claims
  - Sensitivity dependent on sample prep?
- Mature technology, well known

Rapid Cleaning Verification Tests: Multi-test Strip

- Three pads with protein, carbohydrate and hemoglobin tests
- Qualitative, subjective interpretation
- Presence/absence test
- Analysis of data is limited



- Validation data shows little utility for protein and carbohydrate pads, hemoglobin test drives detection of dirty scopes
  - Because Hg test is specific, the number of dirty scopes detected is lower than expected, when compared to current literature.

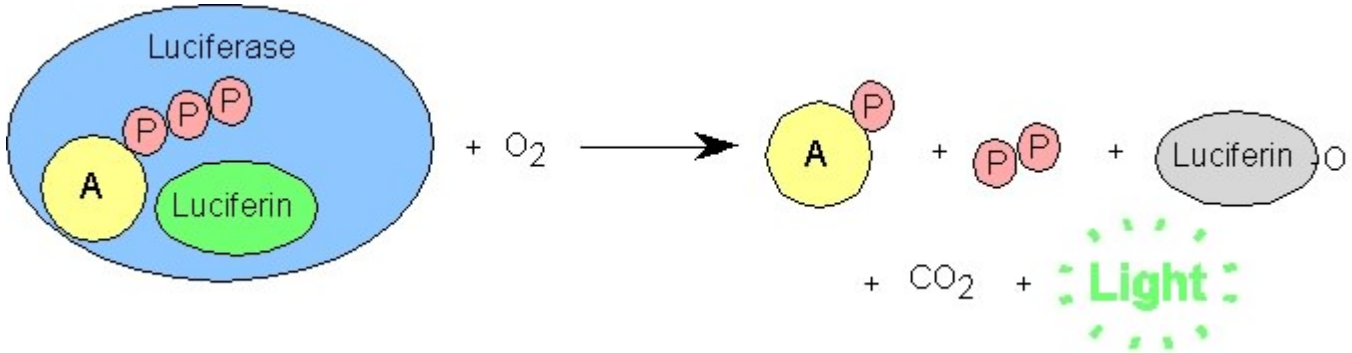
Rapid Cleaning Verification Tests: ATP Bioluminescence

- Quantitative numerical results
- Results are given in Relative Light Units (RLU)
- Different mfr's use different measurement scales
- Numerical results can be analyzed – statistics!
- Validation data available (must be carefully interpreted)
- Technology has been used to assess cleaning efficacy for over 35 years. (Food Safety, Aerospace, Clean-Room manufacturing)

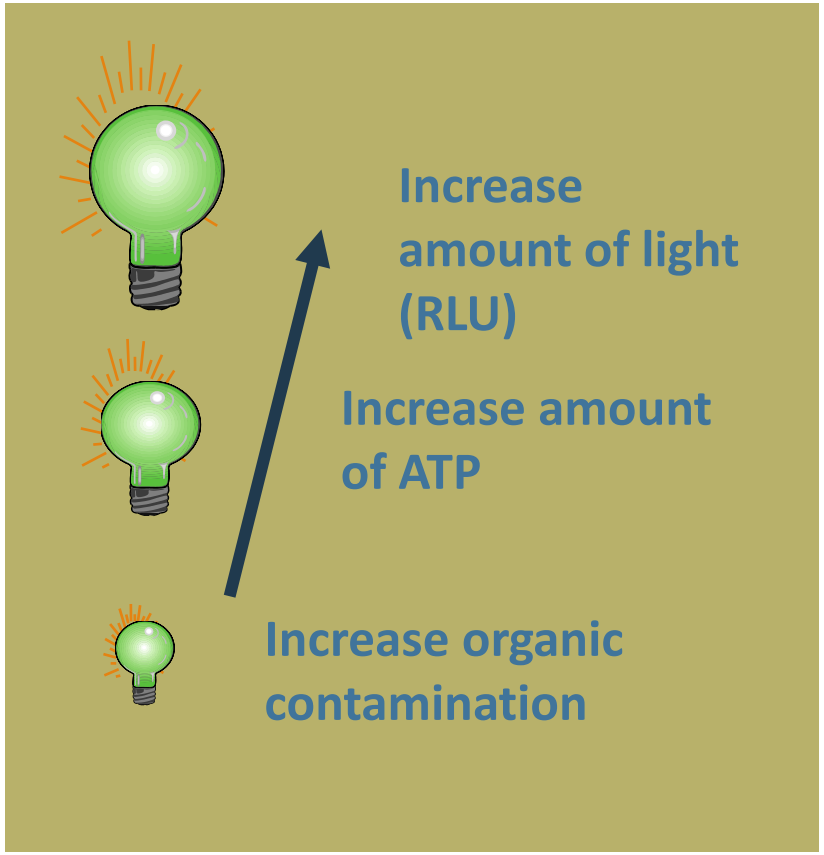
ATP Bioluminescence Technology

Converts ATP to a light signal

Fire-fly enzyme Luciferase uses ATP to produce Light



Simple Relationship



Benchmark for Clean

- The Pass/Fail benchmarks were developed to assess if a scope has been cleaned (soil removal) to an acceptable level.
  - Acceptable levels for ATP, protein, hemoglobin, carbohydrate, bioburden, endotoxin and sodium ion are defined in AAMI ST91

- *Pass/Fail benchmarks for any cleaning verification test are not a measure of the risk of pathogen transmission, nor does a "pass" guarantee that the scope is safe to use on a patient.*

- Ensure Pass/Fail thresholds have been validated for the technology used.

Quantitative or Qualitative Cleaning Verification Test

Things to consider

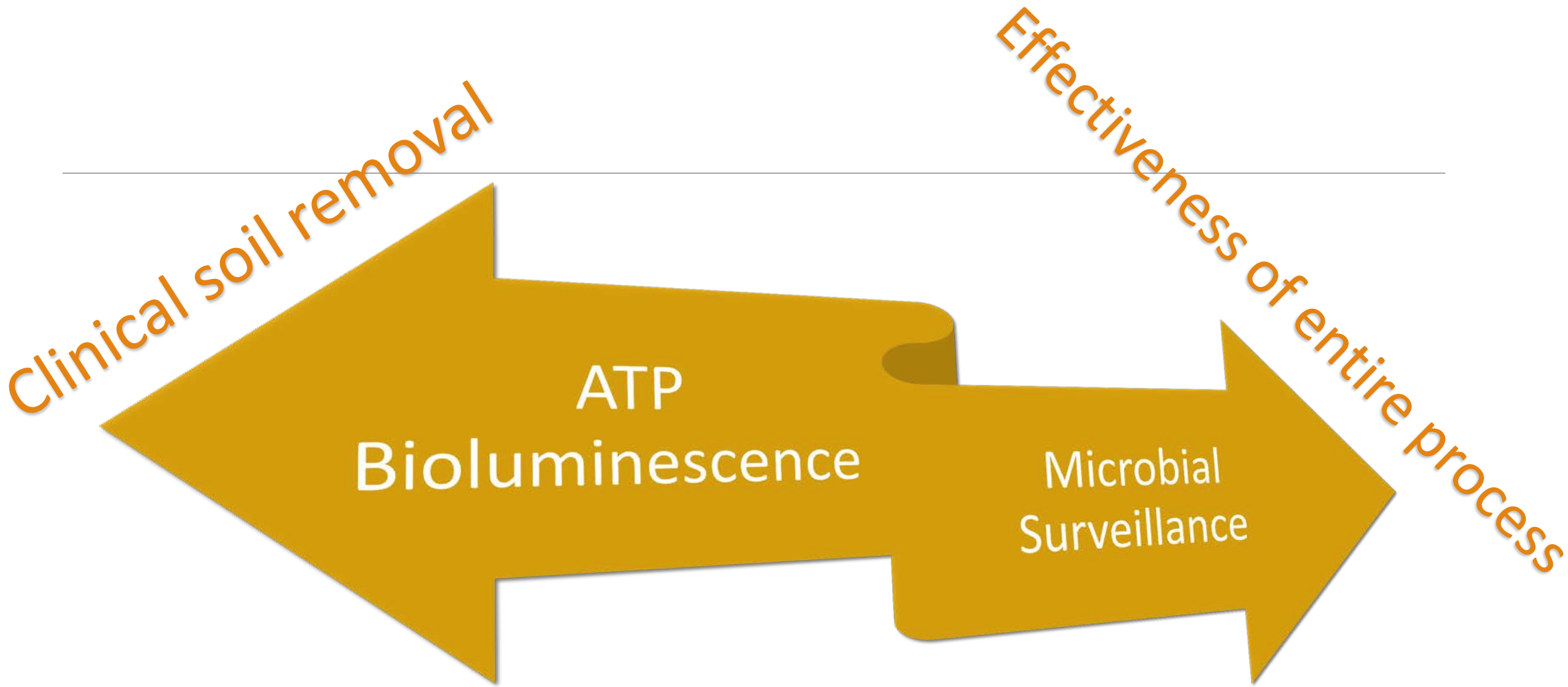
- Is there a validation study available?
- Are there studies that show the product can detect dirty scopes in a clinical setting?
- Do the claims make sense given the technology used?
- Ease of interpretation
- What are you getting for your time and money?

Standards and Guidelines Positions on Cleaning Verification

APSIC 2017, AAMI ST91 2015, AORN 2016, SGNA 2016 recommend the use/ assess the use of rapid cleanliness indicators for verification of efficacy of manual cleaning.

Discussion – Quality Control

1. Are current quality control practices acceptable for flexible endoscopes?
2. What are the factors that prevent better quality control?
3. Cleaning verification – how often should it be performed?
4. Use of lubrication aids – how does this impact cleaning effectiveness? How can policy be established to reduce/eliminate use?
5. What is needed for better training and competency assessment?


Clinical soil removal
Effectiveness of entire process
ATP
Bioluminescence
Microbial
Surveillance

Microbial Surveillance of Endoscopes

Guideline recommendations

- ESGE/ ESGENA– Minimum every three months
- ASGE/ Multisociety: Consider monthly for duodenoscopes
- GoSA: Varies based on scope type; monthly for high risk. Included monthly testing of AER and Water
- APSIC: Periodic surveillance

Periodic surveillance of duodenoscopes recommended by US CDC 2015, 2017

- Controversial
  - Lack of validated method and requires environmental culture
  - Questions on appropriate frequency
  - Questions on validity as method does not detect all pathogens
  - CDC Recommendation is 1x/mo or after 60 procedure

AORN 2016 and SGNA 2017

- Recommend to conduct a risk assessment and may be considered in event of an outbreak
- Can be used as a method for assessing quality of reprocessing or defects in endoscopes

AAMI 2015: No guidance; 2018 - TBD

Source: Guidelines cited

Specific Tests: Used for Investigations or Answering Very Specific Questions.

Microbiological Counts

- Viable microbial numbers
- Pathogen detection
- Effectiveness of entire process

Hemoglobin

- Blood

Culturing of Endoscopes: Limitations

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 sufficient for sampling duodenoscopes

- Biofilm bacteria must be cultured differently
- Bacteria exposed to disinfectants need special culture conditions

Should ATP measurements correlate with bacterial counts?

A common concern, a common misconception….

Non-culture methods: ATP Bioluminescence

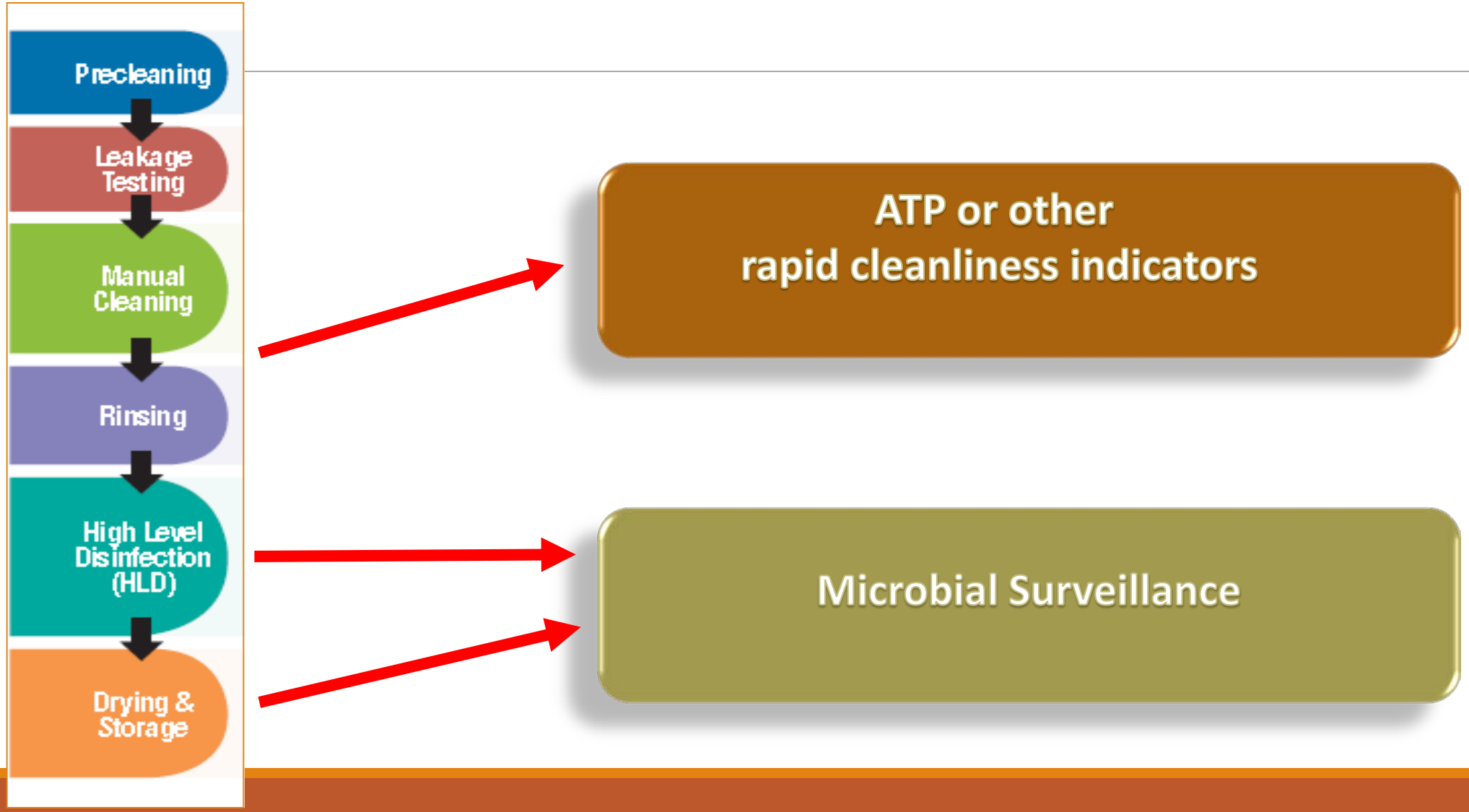
- ATP: measures cleaning effectiveness of reduction in soil to 'threshold' validated value
  - ATP measures organic contamination from <u>all</u> living sources
    - Microorganisms, Human cells, secretions, excretions, body fluids, food residue

Microbial culture:

- Does not 'correlate' to ATP
- Measures bacteria only
- Indication of effectiveness of entire disinfection or sterilization process

Correlation of ATP and Microbial Counts is not possible as they measure two different things and provide different pieces of Quality Control information.

Sequence of QC testing

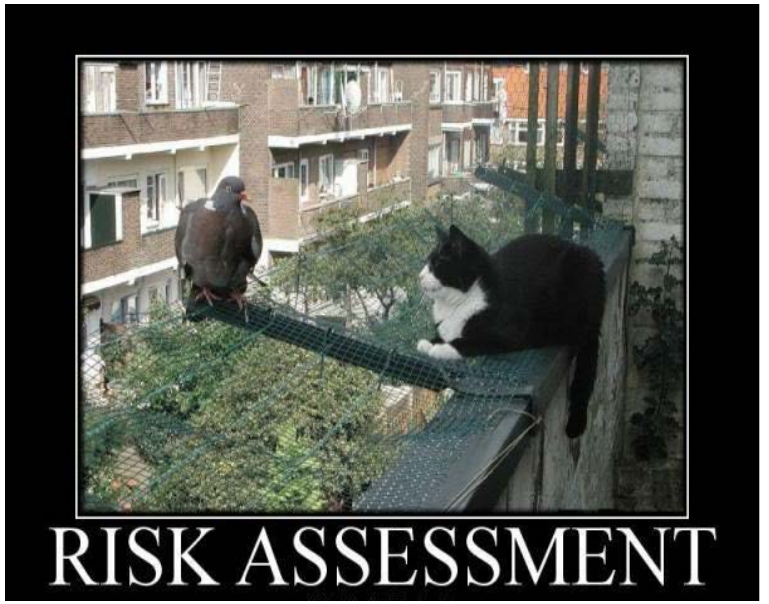


Recommendations

No longer consider Endoscopy as a low risk procedure

Implement QA programs

- Written policies
- Training/Competencies
- Regular Audits and continued oversight
- Make sure IFUs are up to date
- Informed consent for patients



Implement a monitoring program for manual cleaning

- Multiple sampling sites
- Multiple methods
- Every scope, every time

Implement periodic microbial surveillance for HLD procedures as an audit tool

Summary Points

- Patient-ready endoscopes are contaminated
- Viable microbes commonly survive and patient infection transmission occurs
- Patient outcomes have been catastrophic and public health is at risk due to superbugs
- Guidelines and instructions for use are too complex
- Employees rarely do or are able to follow the steps in guidelines and IFU
- Quality improvement is urgently needed

Thank you for your time and attention!

References - web

- CDC Threat Report: www.cdc.gov/drugresistance/threat-report-2013/
- FDA Safety Communication. Feb. 19, 2015 http://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm434871.htm
- FDA Supplemental Measures. Aug. 4, 2015 http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm454766.htm
- Gastroenterology and Urology Devices Panel Meeting May 14-15, 2015 http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/Gastroenterology-UrologyDevicesPanel/ucm445590.htm
- AAMI ST91 Flexible and semi-rigid endoscope reprocessing in health care facilities http://my.aami.org/store/SearchResults.aspx?searchterm=st91&searchoption=ALL
- CDC Interim Duodenoscope Protocol Mar.12, 2015 http://www.cdc.gov/hai/outbreaks/index.html

References (2)

- **Reprocessed Flexible Bronchoscopes: FDA Safety Communication - Risk of Infection Sept. 7, 2015** http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm462979.htm
- Alexandra M. Dirlam-Langlay, Cori L. Ofstead, Natalie J. Mueller, Pritish K. Tosh, Todd H. Baron, Harry P. Wetzler. **Reported gastrointestinal endoscope reprocessing lapses: The tip of the iceberg.** American Journal of Infection Control 2013 Dec;41(12):1188-94.
- Ofstead, Cori L., Wetzler, Harry, P., Alycea Snyder, Rebecca A. Horton, **Endoscope Reprocessing Methods: A Prospective Study on the Impact of Human Factors and Automation.** 2010 Gastroenterology Nursing. Vol 33, No. 4, pp. 304-311
- Alfa et al. 2006 American Journal of Infection Control 34, 561-570
- Bommarito, M., Thornhill, G., Morse, D. 2013. **A Multi-site Field Study Evaluating the Effectiveness of Manual Cleaning of Flexible Endoscopes using an ATP Detection System.** American Journal of Infection Control 41(6) p. S24**.**
- Alfa MJ, Fatima I, Olson N. 2013. **The adenosine triphosphate test is a rapid and reliable audit tool to assess manual cleaning adequacy of flexible endoscope channels.** Am J Infect Control.41:249-53.
- Sciortino CV Jr, Xia EL, Mozee A. 2004**. Assessment of a novel approach to evaluate the outcome of endoscope reprocessing.** Infect Control Hosp Epidemiol. 25:284-90.
- **Bernstein, B. et al. Dramatic Improvement in Endoscope Cleanliness Using a Commercial Bioburden Detection System and Implementation of a Modified Cleaning Algorithm.** Gastrointestinal Endoscopy, Vol.79 (5), Supplement. May 2014, Pages AB121 DDW 2014 ASGE
- Kovaleva, J., Peters, F.T., van der Mei, H.C., & Degener, J.E. (2013). **Transmission of infection by flexible gastrointestinal endoscopy and bronchoscopy.** *Clinical Microbiology Review*, 26(2), 231–254.

References (3)

- Bajolet O, Ciocan D, et.al. **Gastroscopy-associated transmission of extended-spectrum beta-lactamase-producing *Pseudomonas aeruginosa*.** J Hosp. Infect 2013 (83)
- Epstein L, Hunter J, et. Al. **New Delhi Metallo β-Lactamase-producing carbapenem-resistant *Escherichia coli* associated with exposure to duodenoscopes**. JAMA 2014. (312:1447-55
- Kovaleva J, Degener J., et.al. **Methylobacterium and its role in health care associated infection. J Clin Microbiol.** 2014 (52). 1317-21
- Wendelboe A, BaumbachJ., et.al. **Outbreak of cystoscopy related infections with *Pseudomonas aeruginosa*: New Mexico. 2007**. J Urol 2008. (N180). 588-92.
- Wendorf K, Kay M., et.al. **Endoscope retrograde cholangiopancreatography-associated AampC *Escherichia coli* outbreak.** Infect Control Hosp Epidemiol 2015. (#^). 634-42.
- Guy M, Vanhems P. , et.al. **Outbreak of pulmonary Pseudomonas aeruginosa and *Stenotrophomonas matlophilia* infections related to contaminated bronchoscope suction valve**s, Lyon, France. Euro Surveil. 2014. 2016:21.
- Ofstead CL, Wetzler HP, Heymann OL, Johnson EA, Eiland, JE, Shaw MJ. Longitudinal assessment of reprocessing effectiveness for colonoscopes and gastroscopes: Results of visual inspections, biochemical markers, and microbial cultures. *American Journal of Infection Control*, 2016; In press.
- Ofstead CL, Wetzler HP, Eiland, JE, Heymann OL, Held, SB, Shaw MJ. Assessing residual contamination and damage inside endoscopes over time. *American Journal of Infection Control*, September 2016; Epub ahead of print.
- Ofstead CL, Wetzler HP, Johnson EA, Heymann OL, Maust TJ, Shaw MJ. Simethicone residue remains inside gastrointestinal endoscopes despite reprocessing. *American Journal of Infection Control*, July, 2016; 44(11): 1237-40.
- O'Horo, J. C., Farrell, A., Sohail, M. R.*, et al.* (2016). Carbapenem-resistant Enterobacteriaceae and endoscopy: An evolving threat. *Am J Infect Control* **44**, 9: 1032-6.