

Using Data:

Keeping Endoscopy Patients Safe in the Age of the Superbug

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From the beginning...

“Information...if wisely used...would enable us to save life and suffering, and to improve the treatment and management of the sick”

— Florence Nightingale, 1858



“In God we trust. All others must bring data.”

W. Edwards Deming

Nurse Scientists As Advocates



Dorothea
Dix



Virginia
Henderson



Mary Eliza
Mahoney



Florence
Nightingale



Margaret

Patient Risk = Nursing Action



Types of Data

- Big Data: Complex data sets to describe the “big picture”
- Small Data: Consists of smaller, more usable and actionable sets of data to create change or improvement
- Healthcare data derived from governmental or regulatory agencies is big data
- Hospital quality data is generally small data

Evidence Based Medicine

- Term was first used in 1992
- Many nursing actions were based on anecdotal evidence - grounded in one's own experience or that of others
- Often easier to grasp anecdotal evidence than scientific evidence
- Bias exists based on what we can see or experience for ourselves

“It is a capital mistake to theorize before one has data.”

Sherlock Holmes

Anecdotal Evidence

- Milk of magnesia and heat lamp for treating decubiti
- Sponge bathing with alcohol and water to reduce fever
- Instilling saline into endotracheal tube to thin mucous before suctioning
- Total bedrest for a week after heart attack
- Milk-rich diet to treat gastric ulcers

Endoscopy Before Evidence

- Diagnostic ERCPs
- Colonoscopy for symptoms only
- Patients admitted for colon preps
- Cauterize everything
- Re-use everything
- Simethicone always added to colonoscopy flush water
- Endoscope-related infection transmission –
1 in 1.8 million procedures (Really?)

Olympus TJF-Q180V

Endoscopy centers must “insure that reusable medical devices are cleaned & reprocessed appropriately prior to use in another patient”

(ASGE/SGNA)



ERCP-Related MDRO Infections

- According to the CDC, 38 patients were exposed to CRE at Advocate Lutheran Hospital in Chicago while undergoing ERCP, between January and September, 2013.
- At Virginia Mason Hospital in 2013, 32 patients were exposed following ERCP.
- On Feb. 18, 2015 the University of California, Los Angeles Health System notified 179 patients of potential exposure to carbapenem-resistant *Enterobacteriaceae* during endoscopic procedures conducted at the Ronald Reagan UCLA Medical Center from Oct. 3, 2014, to Jan. 28, 2015.
- 3 direct deaths, 11 indirect deaths and 45 people infected from contaminated duodenoscopes, according to the US Food and Drug Administration.

What Is A “Superbug”

Superbug:

An informal term for a bacterium that has become resistant to antibiotics that usually are used to treat it, such as methicillin-resistant *Staphylococcus aureus* (MRSA) or any multidrug-resistant bacterium.

Today's Superbugs

- Carbapenem-resistant *Enterobacteriaceae* (CRE) **Most common superbug associated with ERCP. Incurs 50% mortality.**
- Methicillin-resistant *Staphylococcus aureus* (MRSA)
- ESBL-producing *Enterobacteriaceae* (extended-spectrum β -lactamases)
- Vancomycin-resistant *Enterococcus* (VRE)
- Multidrug-resistant *Pseudomonas aeruginosa*
- Multidrug-resistant *Acinetobacter*
- *E.coli* H30-Rx: The H30-Rx strain of antibiotic-resistant *E. coli* bacteria is the most resistant strain and has become a main cause of bacterial infections in the elderly worldwide over the past decade

Causes of Transmission

- Complex design of endoscopes, duodenoscopes and linear EUS scopes
- Inadequate cleaning of channels, elevator channel recesses and valve ports
- Rise in multi drug resistant organisms
- Presence of stones or sludge in biliary system which impedes drainage
- More elderly and immuno-compromised patients receiving endoscopic care

National Patient Safety Goal 7: Reduce the Risk of Healthcare Associated Infections (The Joint Commission 2018)

Healthcare Associated Infections What are they?

- ” Infection contracted by a patient while under medical care that was not present or incubating prior to that care and appears within 72 hours post care” .
- ◆ The most common negative outcome in healthcare delivery worldwide
 - ◆ Approximately 10% of patients will be infected while receiving health care
 - ◆ Factors involved differ according to setting and resources
 - ◆ Lack of procedures and absence of appropriate guidelines and policies are contributing factors

Essential Nursing Rationale

- Nurses share responsibility for disease prevention in our units
- In procedure areas such as the OR and Endoscopy it is imperative to follow proper cleaning procedures
- Nurses must insure a program exists to maintain proper reprocessing compliance, provide training, assess competence & ensure policies are followed by entire staff
- Nurses must work with their Infection Prevention colleagues to create metrics for verifying proper reprocessing practices
- Monitor the data and improve on deficiencies identified

FDA Advisory April, 2019

The FDA Continues to Remind Facilities of the Importance of Following Duodenoscope Reprocessing Instructions: FDA Safety Communication April 12, 2019

“If reprocessing instructions are not followed in every step of the process, tissue or fluid from one patient can remain in a duodenoscope when it is used on a subsequent patient. In rare cases, this can lead to patient-to-patient transmission of infection.”

FDA Advisory, continued

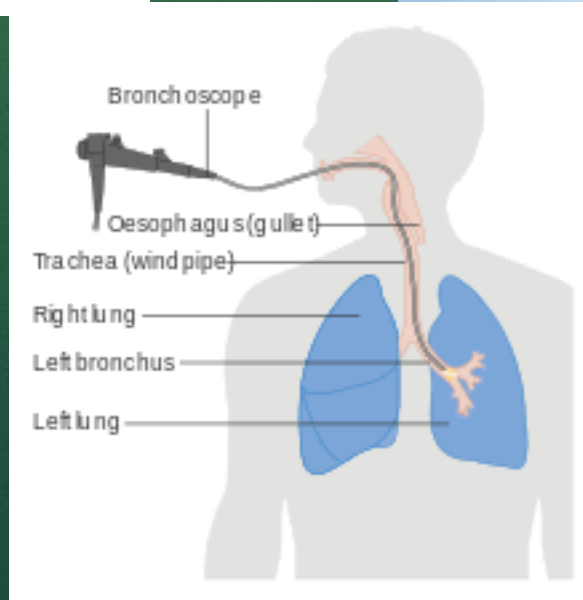
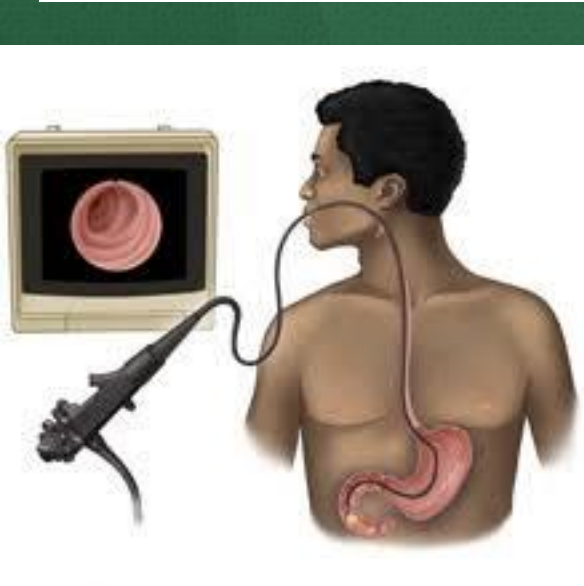
As of March 2019, scope manufacturers continue to collect samples for the Sampling and Culturing Study. Preliminary results as of March 2019 indicate higher than expected levels of contamination:

- “For high concern organisms, defined as organisms that are more often associated with disease, such as *E. coli*, and *Pseudomonas aeruginosa*, updated culturing results appear to show that up to 5.4% of properly collected samples test positive, which is an increase from the 3% contamination rate that was previously reported.”
- In 2018, 3 deaths were reported in the US related to duodenoscopes.

FDA Advisory 8/29/19

- “...the agency is recommending moving away from using duodenoscopes with fixed endcaps to those with disposable components that include disposable endcaps – or to fully disposable duodenoscopes when they become available.”
- “...we’re communicating with health care facilities now – so they can begin developing a transition plan to replace conventional duodenoscopes...”
- “...users frequently had difficulty understanding and following manufacturers’ reprocessing instructions and were not able to successfully complete reprocessing, which may leave the duodenoscopes contaminated.”

FDA Class 2 Medical Devices



[Click for a more detailed view](#)

Class II Medical Devices

- Class II medical devices are those devices that have a moderate to high risk to the patient and/or user. 43% of medical devices fall under this category. Most medical devices are considered Class II devices. Examples of Class II devices include powered wheelchairs and some pregnancy test kits.

Spaulding Classification

Developed in 1968, the Spaulding Classification categorized medical devices & type of disinfection required based on site of instrument use & perceived risk of infection transmission.

- ◆ Critical – exposed to vasculature, i.e. surgical equipment, scalpels, implants
- ◆ Semi-critical – exposed to mucous membranes, i.e. endoscopes, ET tubes (dental excluded)
- ◆ Non-critical – exposed to intact skin, i.e. thermometer, BP cuff

Spaulding Classification - Disinfection

- Critical – requires sterilization or prolonged contact with sporicidal chemical
- Semi-critical – requires high level disinfection (HLD) or short term contact with sporicidal chemical
- Non-critical – low to intermediate disinfection with hospital-based disinfectant

Recommendations for Insuring Cleanliness, (FDA 2015)

- Enhanced oversight & training for front-line staff
- Meticulous pre-cleaning & manual cleaning
- Adherence to scope IFU & use of proper brushes
- Record keeping of all phases of reprocessing
- Use of surveillance cultures
- Double reprocessing between patients
- ETO or liquid chemical sterilization

AORN

- AORN: “There is a need for rapid testing methods to detect residual soils and verify the adequacy of manual cleaning.”

Rapid Test Methods

- **Bioburden Assays: Scope-Check, EndoCheck, ChannelCheck – Detect the elements of biofilm - blood, protein & carbohydrate – within the endoscope channel after manual cleaning**



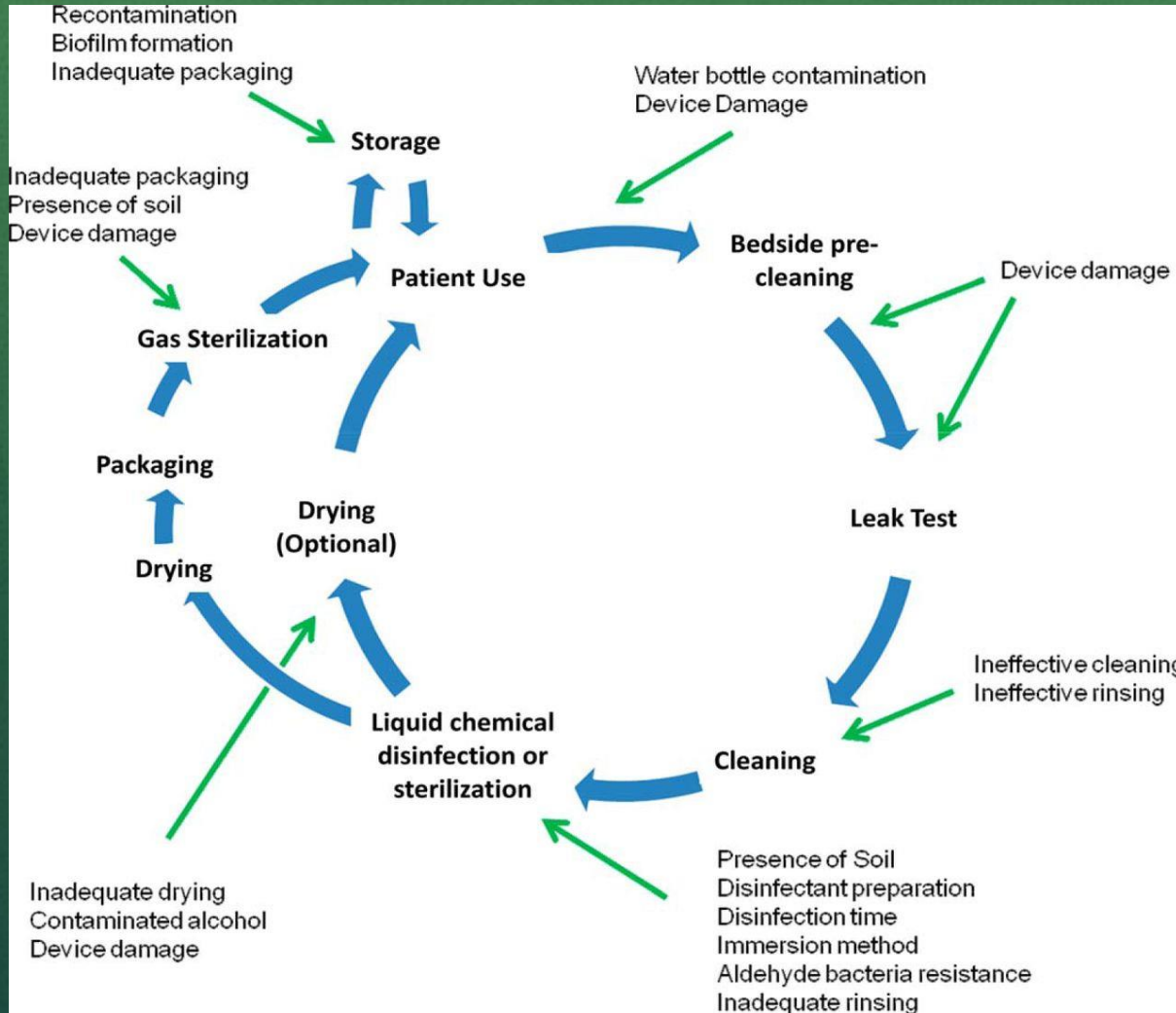
Rapid Test Methods

- **Adenosine Triphosphate (ATP)
Bioluminescence: Clean Trace, Hygiena,
ATP Complete**

- ATP is present in all microorganisms and human cells, providing a means of testing biological residue.
- *The FDA announced that it is aware that some health care facilities are using adenosine triphosphate, or ATP, test strips, to assess duodenoscope cleaning. These test strips claim to indicate the presence of live microbes inside of duodenoscopes. However, to date, the FDA is not aware of any legally marketed ATP test strips cleared by the agency for this use, which means the FDA has not reviewed them for effectiveness in assessing reprocessing.*



Scope Cleaning Challenges



Our Question

Will use of a bioburden assay test reveal opportunity for improvement in the manual endoscope cleaning process, thereby reducing risk of endoscope acquired infection?

Costs of Test Methods to BWFH

- Bioburden Assay Test Strips:
Healthmark ChannelCheck \$90 per
box of 200 strips
- ATP Bioluminescence:
3M Clean Trace Luminometer \$2700
Test Strips \$200 for box of 100 strips



Cost-Based Decision

Healthmark ChannelCheck

What Does Channel Check Do?

- ChannelCheck™ tests for three common organic soils at once: blood, protein and carbohydrates.
- Flush an individual channel with sterile water and recover that water.
- Dip the test strip in the recovered water for 5 seconds.
- Remove the strip, wait 90 seconds and then compare the color of the pads to the results chart. Should any of the pads indicate there is residual soil, reclean the device and then retest.

Data Collection

- Began in 2015 on small scale with duodenoscopes and linear EUS scopes
- In 2016 all scopes tested at least once per week
- Bioburden assay testing revealed that EGD and elevator channel scopes retain more residual soil than colonoscopes
- Reasons unclear for EGD scopes. Speculation: smaller channels, more viscous secretions, presence of bile

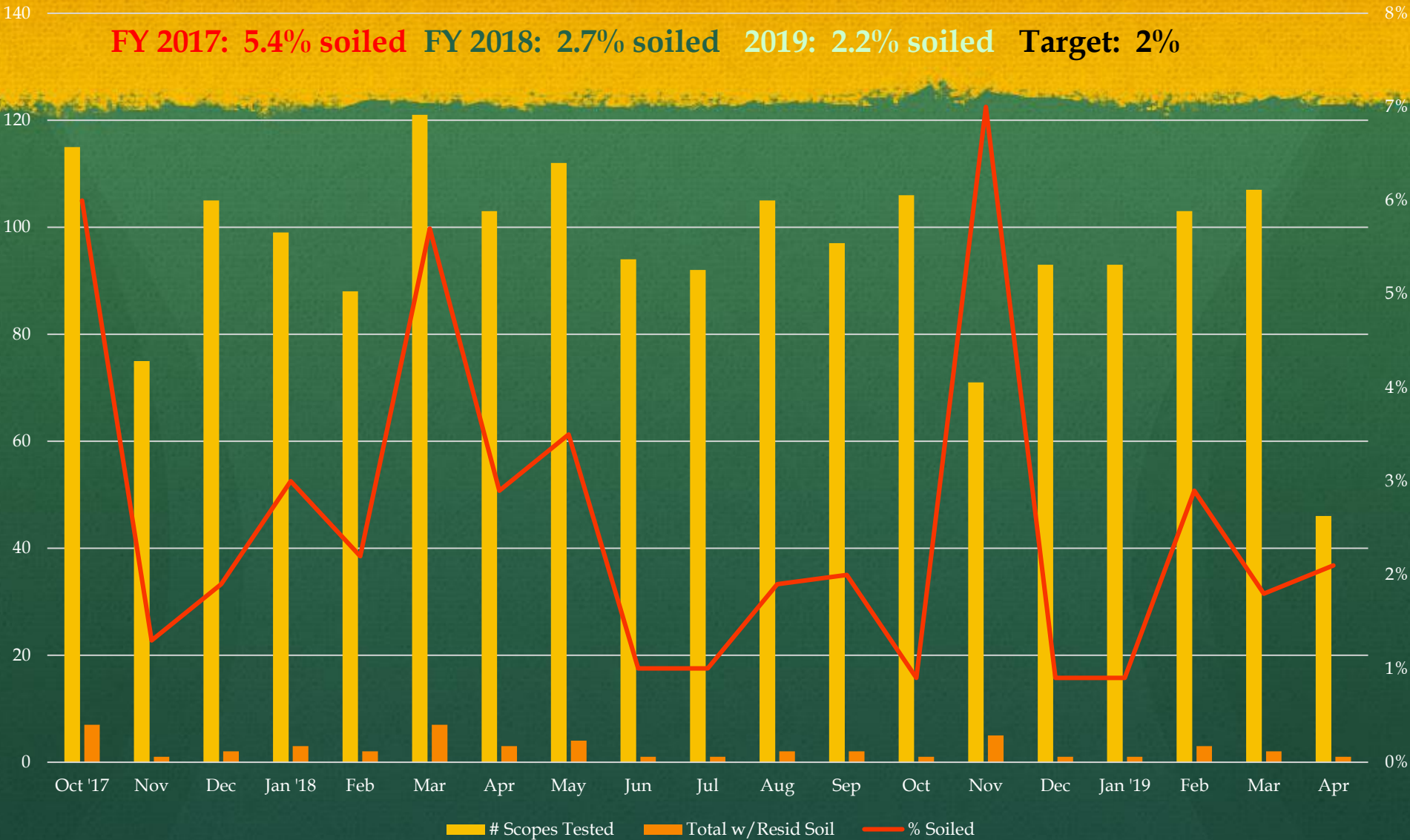
Our Results

Note: Tests done after manual cleaning, prior to HLD

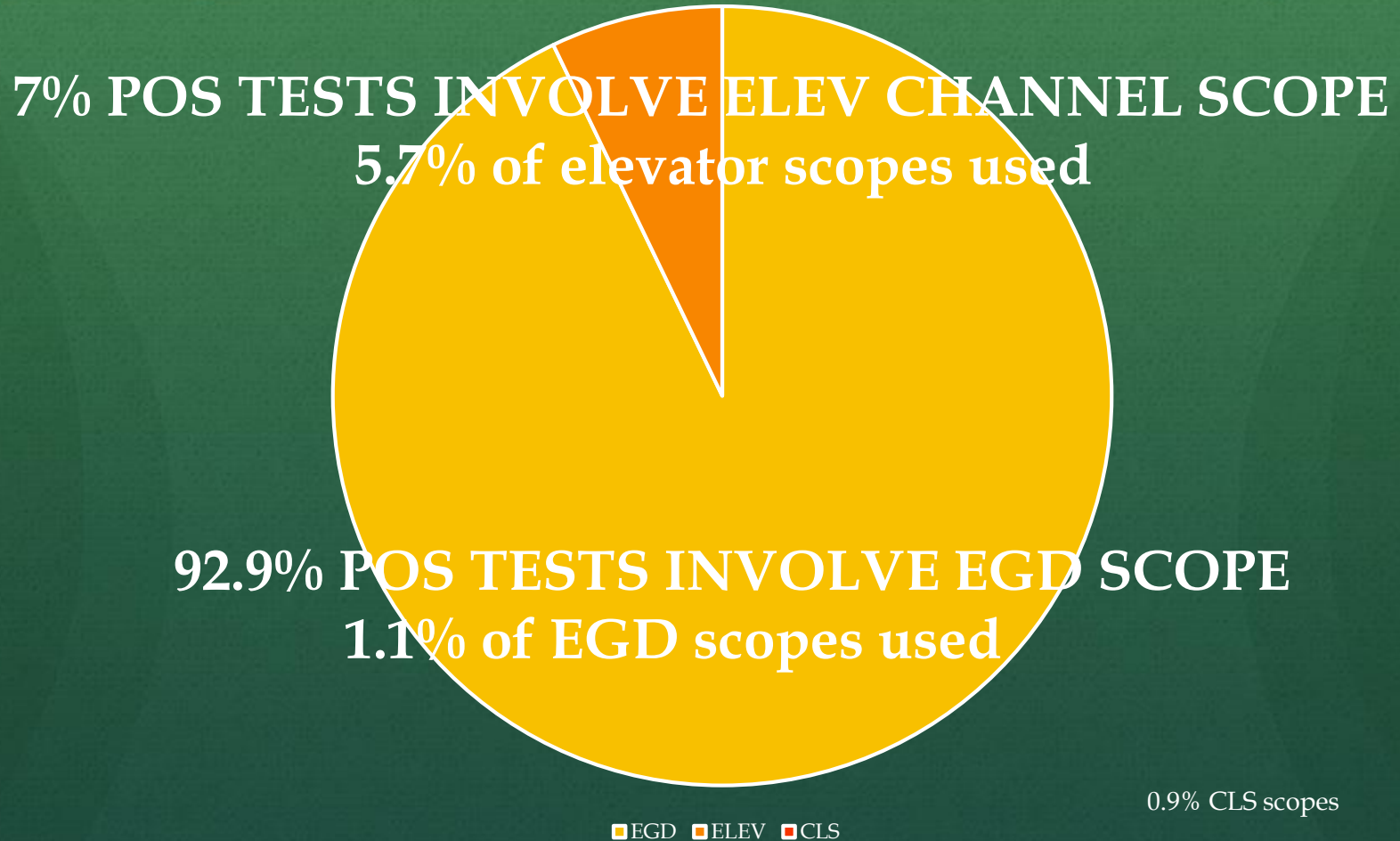
- 2015 - 8% (Elevator channel scopes)
- 2016 - 2017: 5.4%
- 2017 - 2018: 2.7%
- 2018 - 2019: 2.2%

RESIDUAL SOIL 10/17 - 4/19

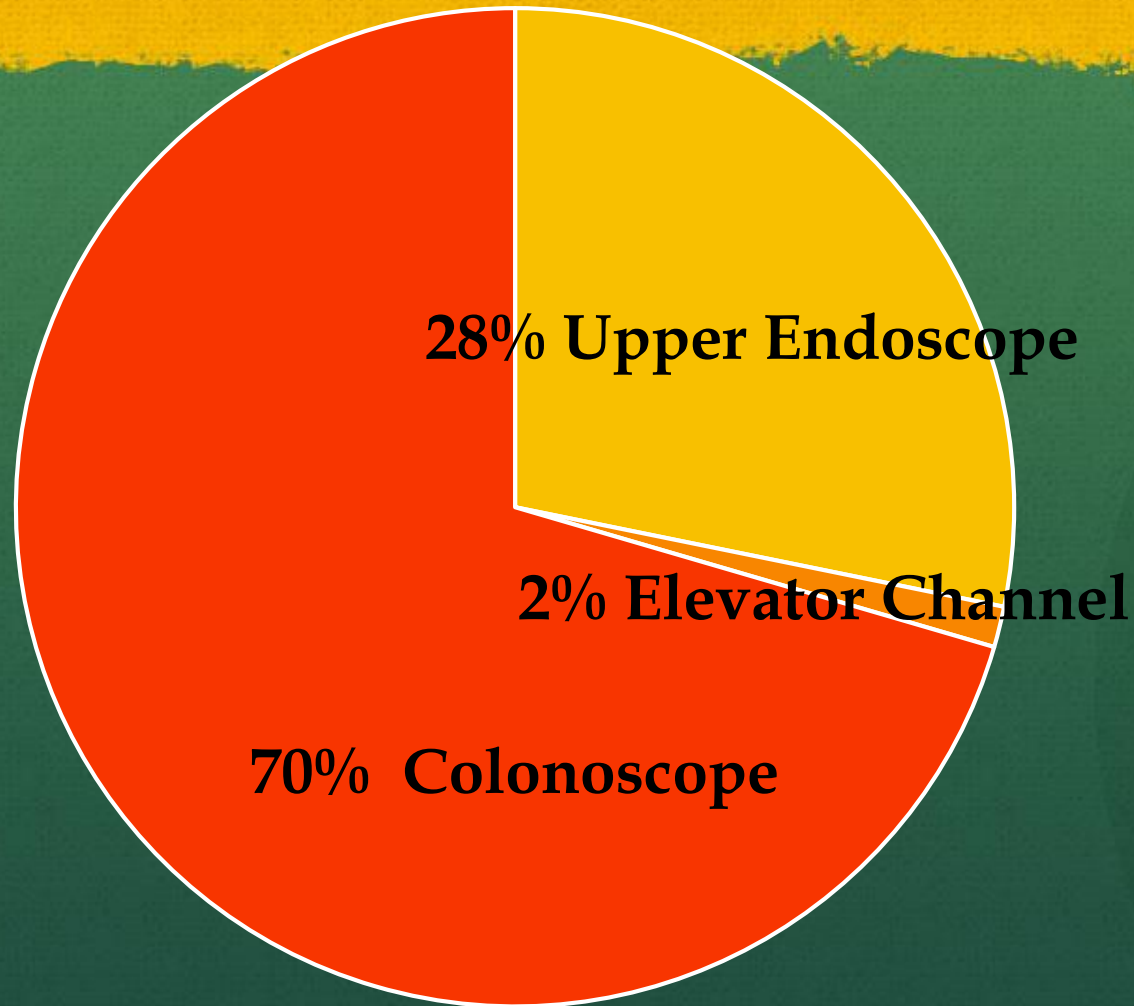
FY 2017: 5.4% soiled **FY 2018: 2.7% soiled** **2019: 2.2% soiled** **Target: 2%**



WHICH SCOPES TEST POSITIVE?



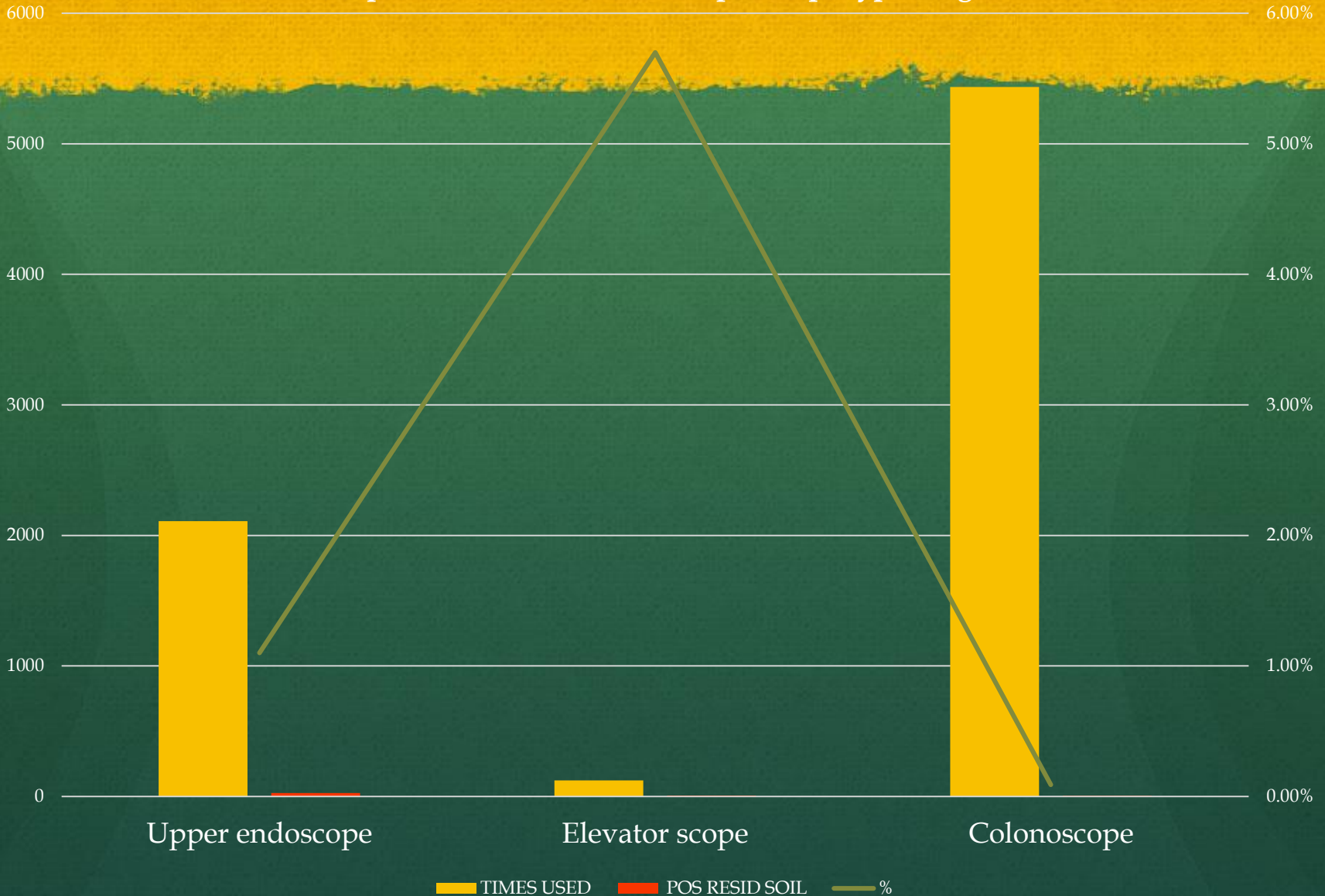
SCOPE TYPE USAGE



■ EGD ■ ELEV ■ CLS

Residual soil: scope type & usage

% positive residual soil tests per scope type usage



How the Data Helped

Able to reduce our percentage of residual soil from 5.4% to 2.2% by implementing the following changes:

- Additional training for techs with focus on elevator channel & EGD scopes
- Utilized clean water for rinsing channels, not water from sink
- Use of high velocity flush pump for flushing scopes, not suction
- Standardized pre-cleaning
- Focused attention on reprocessing

What About Culturing?

(According to the CDC)

- Duodenoscope surveillance sampling and culturing is a shared responsibility of multiple departments within a healthcare facility.
- Responsible departments should determine frequency of sampling and culturing..., clinical use of duodenoscopes while awaiting culture results, endoscopes to be sampled, ...endoscope handling after processing, how samples should be received in the laboratory, culture reporting format, identification of staff receiving culture results, training and proficiency assessment for sampling and culturing staff, duration of time to maintain culturing records, threshold limits for low/moderate-concern organisms, and frequency of review of this protocol. (No requirements. Decisions left to facility.)
- **CDC sampling protocol is 14 pages, 66 steps**

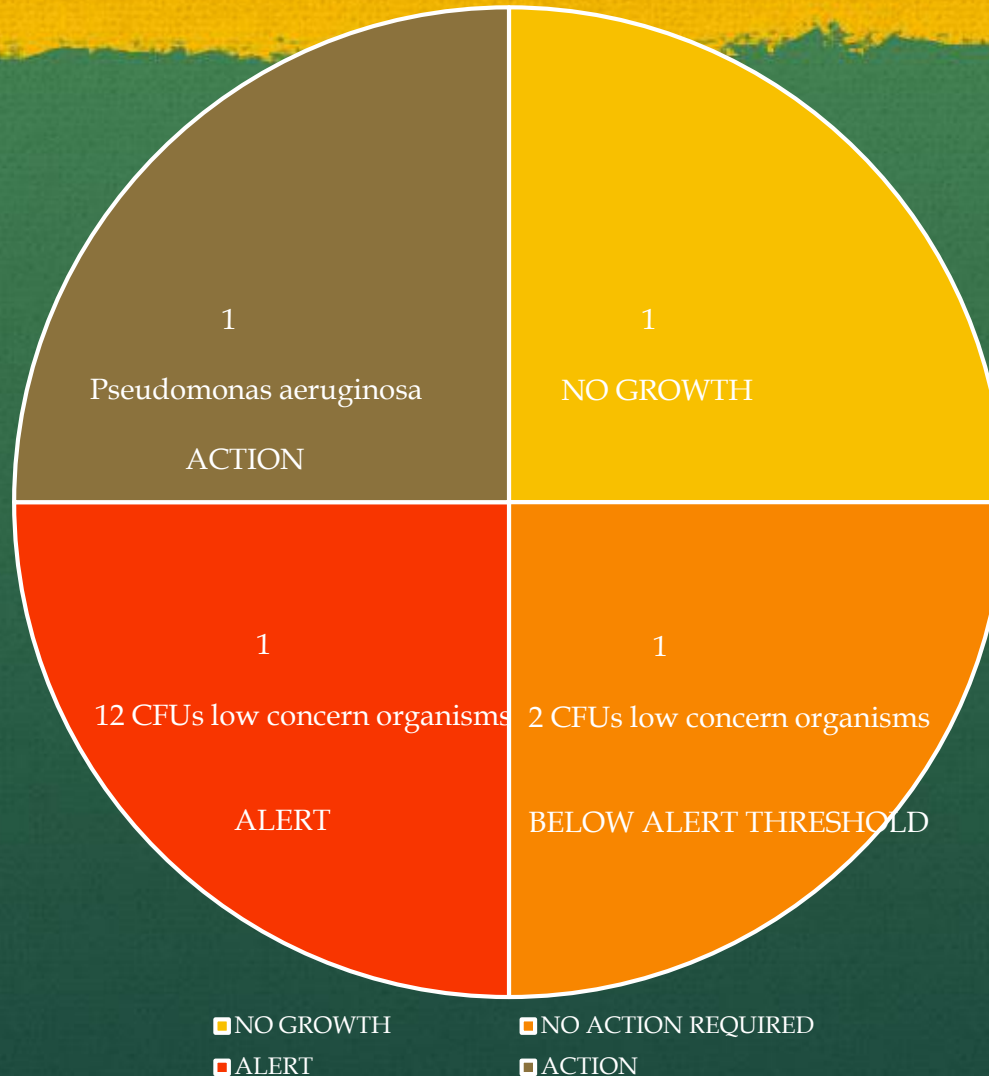
CDC Alert Definitions

- **ALERT:** Steps taken by a healthcare facility after growth of elevated numbers (e.g., 11 – 100 CFU) of low/moderate-concern organisms that is below the Action level (e.g., > 100 CFU) for those organisms. Growth of low/moderate-concern organisms at the Alert level may warrant a review of reprocessing, sampling, and culturing protocols.
- **ACTION:** A sample positive for any number of high-concern organisms or > 100 CFU of low/moderate-concern organisms. The presence of this type of contamination on a reprocessed endoscope may or may not lead to infection or colonization of patients by those organisms. **REQUIRES ACTION.**

CDC DEFINITIONS CONTINUED:

- **ACTION: POTENTIAL RESPONSES –**
 - Remove scope from use
 - Conduct a risk/safety management response including potential patient notification & follow up
 - Review reprocessing practices and re-train staff as needed
 - Review sampling & culturing procedures
- **HIGH-CONCERN ORGANISM:** Organisms that are more often associated with disease. Examples of high-concern organisms include Gram-negative rods (e.g., *Escherichia coli*, *Klebsiella pneumoniae* or other *Enterobacteriaceae* as well as *Pseudomonas aeruginosa*), Gram-positive organisms including *Staphylococcus aureus*, Beta-hemolytic *Streptococcus*, *Enterococcus* species, and yeasts.
- Samples from endoscopes are not clinical specimens from patients, they are not used for diagnostic purposes, and they are not used to certify an endoscope as sterile.

Culture Breakdown



Pseudomonas Aeruginosa

- *Pseudomonas aeruginosa*. *P. aeruginosa*, a Gram-negative opportunistic pathogen, is the most commonly reported microorganism responsible for transmission of infection during GI endoscopy and bronchoscopy. It is known for its preference for a moist environment (hospital water supply and wet endoscope channels after reprocessing)

Endoscopy ACTIONS

- Scope quarantined
- Reprocessing guidelines reviewed with scope techs
- Tech staff re-trained by manufacturers' field engineers
- Safety inspection performed
- Culturing process audited by O.R. educator for compliance with sampling protocol
- Presented to Infection Control Committee
- Petitioned Administration for drying pumps.

Beyond Post-Its: More “Endodata” for Patient Safety



ASGE/SGNA Endoscopy Quality Indicators

Determined by analysis of 4 questions:

- ◆ Is the indicator related to quality?
- ◆ Is it meaningful to measure?
- ◆ Is it feasible to measure?
- ◆ Are you able to comply with measure in own unit?

Quality Domains

The 5 domains for quality measurement:

- ◆ Patient experience
- ◆ Employee experience
- ◆ Efficiency and operations
- ◆ Procedure-related
- ◆ Safety and infection control

Joint ASGE/SGNA Indicators

Identified as “...compelling to measure or track for a high-quality endoscopy unit”:

- ◆ Unit documents regular education, training & QI for all staff on new equipment/devices & techniques
- ◆ Unit records, tracks & monitors procedure quality indicators for individual MDs and unit as a whole
- ◆ Reports are communicated to referring providers & patients (Quality Steering Committee, Quality Board)
- ◆ Process in place to track scopes from storage, use, reprocessing & back to storage

Indicators Relevant to Endoscopy Quality (ASGE/SGNA)

- Delivery & documentation of procedural sedation
- Pre-procedure nursing assessment completed
- Language & interpreter needs documented
- Patient education & method is documented
- Discharge instructions with provider emergency contact provided & documented
- Pain documented throughout all phases of care
- Rate of mislabeled/missing pathology specimens is tracked
- Process exists to insure that reusable medical devices are cleaned & reprocessed appropriately prior to use in another patient

Measures of Endoscopy Center Quality (ASGE, GI QUIK)

- Procedural sedation documentation compliance
- Use of reversal agents
- Cecal intubation
- Prep quality
- Adverse events
- Volume by procedure
- Adenoma detection rate
- Scope withdrawal time

Nursing Indicators Measureable in Endoscopy (NDNQI)

- Patient Falls/Falls Assessment
- RN Education /Certification
- RN Satisfaction Survey
- Voluntary Nurse Turnover
- Nurse Vacancy Rate
- Pain Assessment, Intervention, Reassessment
- IV Infiltration Rate

Make It Your Own

- Identify opportunities for improvement in your unit
- Consider the measure(s) that could facilitate improvement
- Form a question or hypothesis to guide your study
- Collect and analyze your data
- Use your data to improve practice in your unit

**“The goal is to turn data
into information, and
information into
insight.”**

Carly Fiorina

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