Evidence-Based Methods for Sterility and High Level Disinfection Assurance: The Path to High Reliability

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I have been in the Army for 24 years and a nurse for 15 years. I received a bachelor's degree in nursing from the Inter-American University of Puerto Rico, a master's degree from the Uniformed Services University of the Health Sciences, and a doctorate degree from The University of Alabama "*Roll Tide.*" I am a board-certified Acute Care & Critical Care Clinical Nurse Specialist with a focus on perioperative nursing and a Certified Operating Room Registered Nurse.

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Disclosures

- Dr. Jose Rodriguez & Dr. Kenneth Romito have no relevant financial or non-financial relationships to disclose relating to the content of this activity.
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Learning Objectives

At the conclusion of this activity, participants will be able to:

1. Explain the business and clinical impact associated with contaminated surgical instruments.
2. Identify the recommended elements of an effective endoscope reprocessing program.
3. Summarize how clinical audits work, including the strengths and weaknesses of the process.
4. Describe how clinical audits can help improve reprocessing practices to increase quality and safety.
5. Select three common cleaning verification technologies used during the audit process and recommended elements for an effective system.

Learning Objectives Cont.

At the conclusion of this activity, participants will be able to:

6. Illustrate how adenosine triphosphate (ATP)-based technology works and aligns with recommended elements.
7. Outline how ATP-based technology, when integrated to a quality control program, helps improve quality and safety.

Overview

- Endoscope reprocessing is a complicated processes with no safety nets
- Critical tasks with no safety nets benefit from programs to promote high reliability
- Audits are useful in areas where critical task compliance is low
- The cost of hospital acquired infections should be avoided at all costs
- Program evaluation and development related to medical device reprocessing requires leadership support

Overview

- Unaided visual inspection of cleaned instruments can result in the retention of bioburden and contaminated instruments.
- Adenosine triphosphate (ATP)–based technology uses a reaction between ATP and luciferase-luciferin to assess the cleanliness of environmental surfaces and surgical instruments.
- This quality improvement project used ATP-bioluminescence technology for the rapid (i.e. 15-second) validation of surgical instrument cleanliness.
- The ATP-based technology was effective in detecting contaminated instruments and identifying irregularities in the processes for cleaning surgical instruments. Results showed that 13.5% of cannulated instruments failed the ATP assay for cleanliness, with most of these occurring after manual cleaning.

The Audit Science

Introduction

- Exposure to contaminated endoscopes can be **life threatening**
- 2015 CDC ***"Call to Action"*** to evaluate High-Level Disinfection (HLD) across the nation
- Surgeons General **mandate** to evaluate HLD programs in the Military Healthcare System (MHS)
- Achieving **high reliability**: Repetitive audits with leadership buy-in and feedback to stakeholders

(Centers for Disease Control and Prevention, 2015; DHA, 2017)

Los Angeles Times

latimes.com

UCLA SAID it discovered the outbreak late last month while running tests on a patient. This week, it began to notify patients who were treated from October to January and offer them medical tests.

SUPERBUG INFECTS PATIENTS AT UCLA

Tainted scopes may have exposed 179 at hospital

By Chad Terhune

Nearly 180 patients at UCLA's Ronald Reagan Medical Center may have been exposed to potentially deadly bacteria from contaminated medical scopes, and two deaths have already been linked to the outbreak.

The Times has learned that the two people who died are among seven patients that UCLA found were infected by the drug-resistant superbug known as CRE — a number that may grow as more patients get tested. The outbreak is the latest in a string of similar incidents across the country that has top health officials scrambling for a solution.

UCLA said it discovered the outbreak late last month while running tests on a patient. This week, it began to notify 179 other patients who were treated from October to January and offer them medical tests. By some estimates, if the infection spreads to a person's bloodstream, the bacteria can kill 40% to 50% of patients.

At issue is a specialized endoscope inserted down the throats of about 500,000 patients annually to treat cancers, gallstones and other ailments of the digestive system.

Deadly superbug

WHAT ARE CRE BACTERIA?

CRE, which stands for carbapenem-resistant Enterobacteriaceae, is a family of germs difficult to treat because of high levels of resistance to antibiotics.

WHO GETS INFECTED?

Patients whose care requires devices such as ventilators and urinary or intravenous catheters and patients taking long courses of certain antibiotics are most at risk.

HOW DANGEROUS ARE THESE GERMS?

If the infection spreads to the bloodstream, CRE can kill 40% to 50% of its victims.

Sources: CDC.gov; Atlanta Journal-Constitution, Los Angeles Times

These duodenoscopes are considered minimally invasive, and doctors credit them for saving lives through early detection and treatment. But medical experts say some scopes can be difficult to disinfect through conventional cleaning because of their design, so bacteria are transmitted from patient to patient.

These instruments are not the same type used in more routine endoscopies and colonoscopies.

The procedure in question is known as ERCP, or endoscopic retrograde cholangiopancreatography. The superbug is carbapenem-resistant Enterobacteriaceae.

UCLA said it immediately notified public health authorities after discovering the bacteria in one patient and tracing the problem to two of these endoscopes. The university said it had been cleaning the scopes "according to standards stipulated by the manufacturer," and it changed how it disinfects the instruments after the infections occurred.

Dale Tate, a university spokeswoman, said "the two scopes involved with the infection were immediately removed and UCLA is now utilizing a decontamination process that goes

[See Superbug, A10]

(Terhune, 2015)

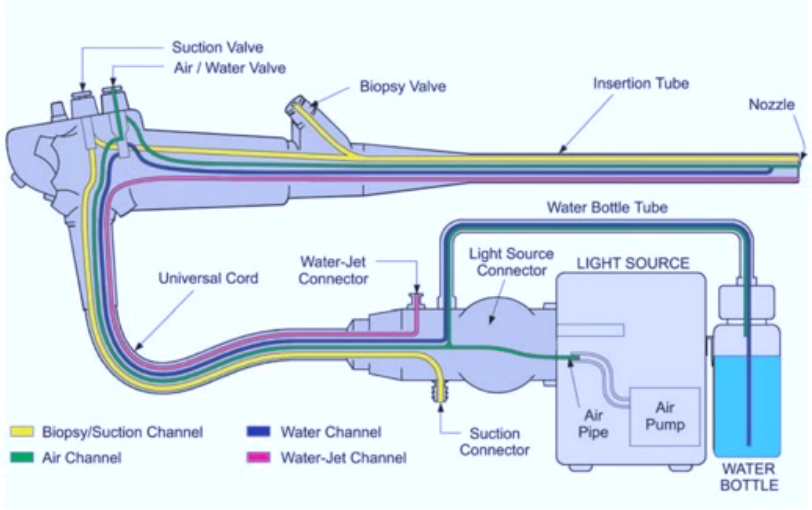
Significance

Over 18 million flexible endoscope procedures performed annually in the U.S.

Endoscope design is complex which makes cleaning a complicated, multi-step process

There are **NO** **safety nets**, if one action is missed or incorrectly performed, patients are at risk!

(FDA, 2015; Peery et al., 2012)



OLYMPUS EVIS EXERA TJF TYPE 160VF/160F REPROCESSING MANUAL

(olympusamerica.com, n.d.)

Significance *(cont.)*

Infection rate of 1-1.6 per 1000 procedures

Healthcare Acquired Infections (HAI) are considered ***"Never Events"***

Costs for HAIs are ***$16.6 billion annually***

Not reimbursed by Centers for Medicare and Medicaid Services

Organizational Impact: delayed return to duty, ↑cost, ↓quality, and ↓safety

(Centers for Medicare and Medicaid Services, 2006; FDA, 2015; Hassan et al., 2012)

System Question

At Walter Reed National Military Medical Center (WRNMMC), will an evidence-based **audit process** for a **program evaluation** of HLD, compared to current practice, support a **high reliability organization's** (HRO) goal to achieve **quality, safety, and continuous process improvement**?

(WRNMMC, n.d.)

Focus Areas

Identified **current state** of HLD practices at WRNMMC and performed a **gap analysis**

Performed **4 recurring audits** and developed **evidence-based recommendations** for improved practice

Conducted **longitudinal synthesis** of audit findings demonstrating organizational progress towards becoming a **high reliability organization**

Top Photo: (Hygiena.com, n.d.) Middle Photo: (Romito, n.d.) Bottom Photo: (Galusaustralis.com, n.d.)

Project Design

Assessment of HLD policies, practices, and equipment at WRNMMC

65 total steps evaluated across 6 Phases of High Level Disinfection (HLD):

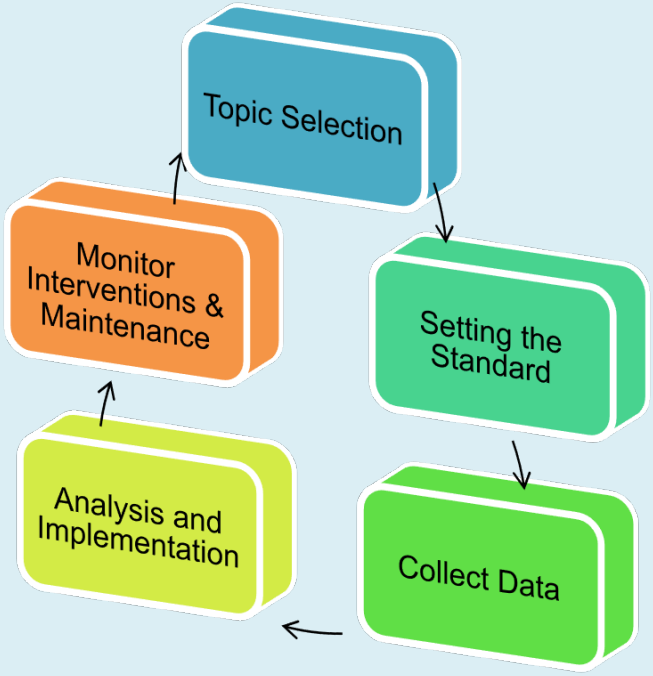
- Point of Use Cleaning
- Leak Testing
- Manual Cleaning
- HLD/ Rinsing
- Drying & Storage
- Record Keeping

5 Clinics | 4 Audits | 11 Months

6 Culture of Safety and 10 Leadership Risk Assessment questions

Donabedian's Lasting Framework for Healthcare Quality

Structure



Audit Quality Loop

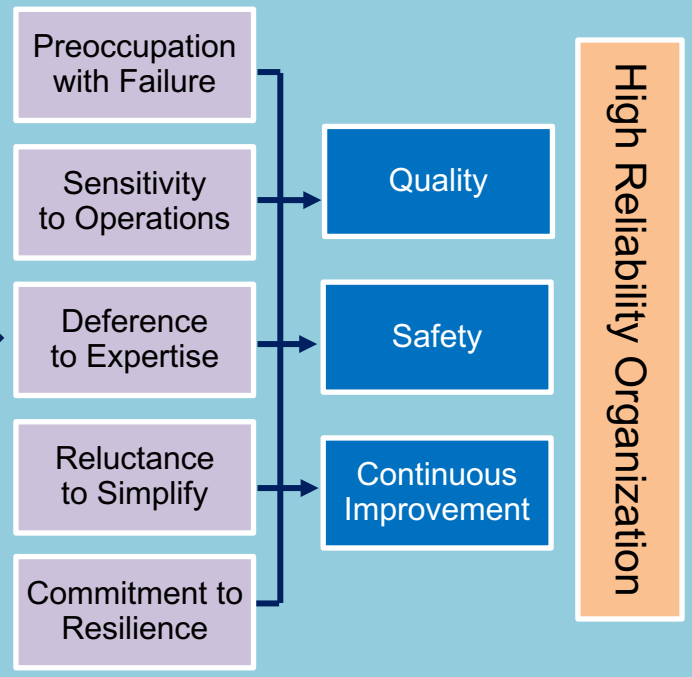
(Esposito & Canton, 2014)

Process

CDC Framework for Program Evaluation

(CDC, 2017)

Outcome

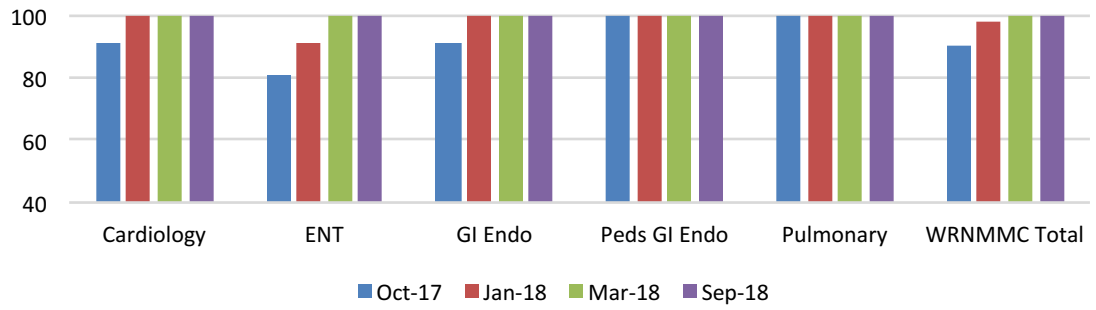


HRO Principles→ HRO Goals→ HRO

(Chassin & Loeb, 2013)

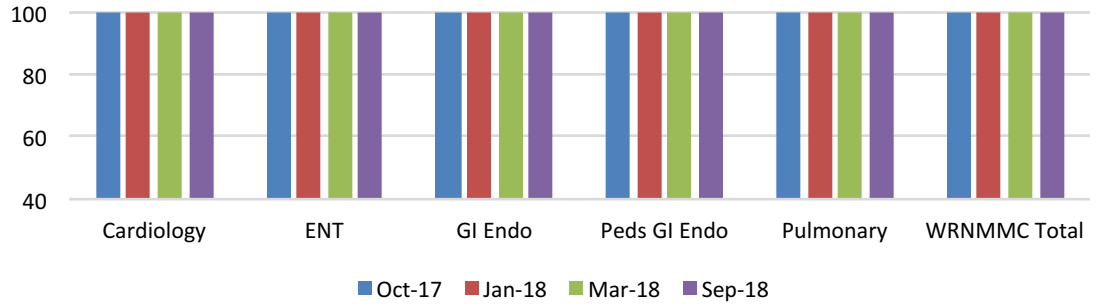
Analysis of Results

Point of Use



- Initial audit score 90.8%
- 4 Deficiencies
- 4 Corrections
- 9.2% Improvement
- **Final audit score 100%**

Leak Testing

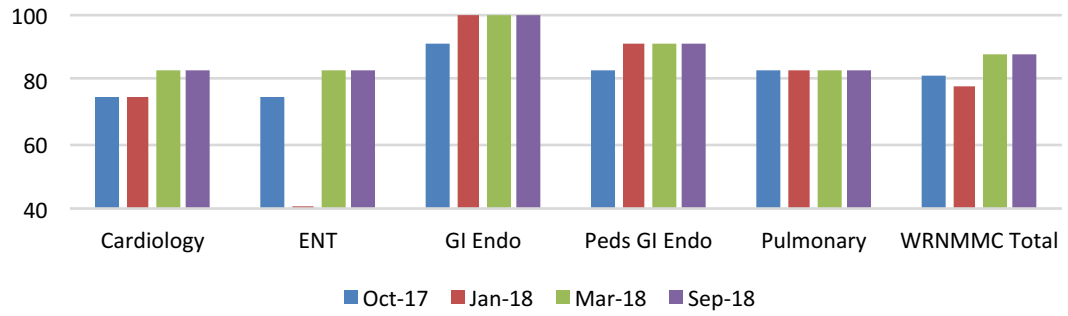


- Initial audit score 100%
- Final audit score 100%
- **100% Sustainment**

(Romito & Fedderson, 2019)

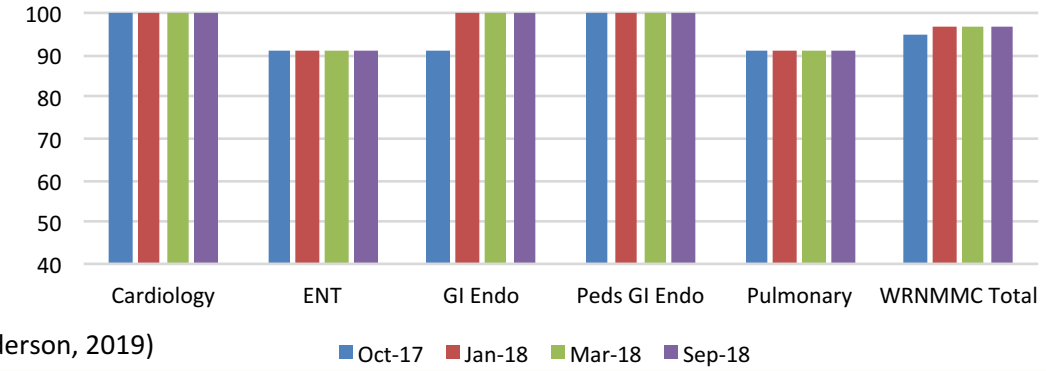
Analysis of Results *(cont.)*

Manual Cleaning



- Initial audit score 81.4%
- 14 Deficiencies
- 7 Corrections
- 6.6% Improvement
- **Final audit score 88%**

HLD and Rinsing



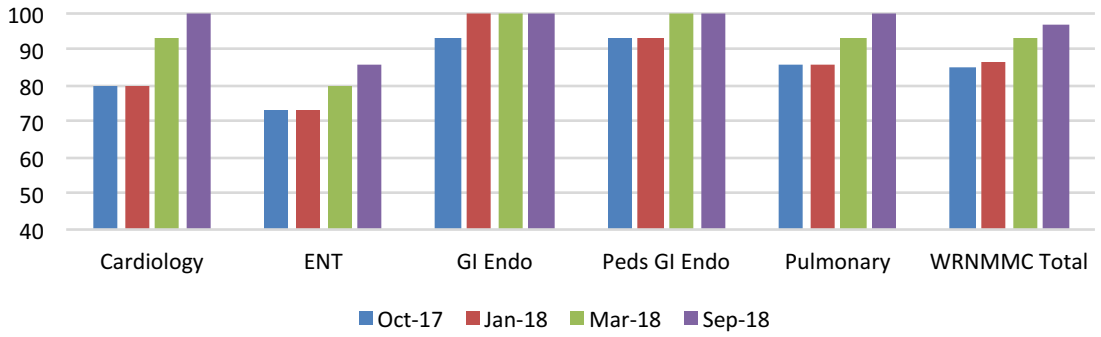
(Romito & Fedderson, 2019)

- Initial audit score 94.6%
- 3 Deficiencies
- 1 Correction
- 1.8% Improvement
- **Final audit score 96.4%**

***NOTE**: New AERs purchased OCT 2018 - this action resulted in the correction of remaining deficiencies*

Analysis of Results *(cont.)*

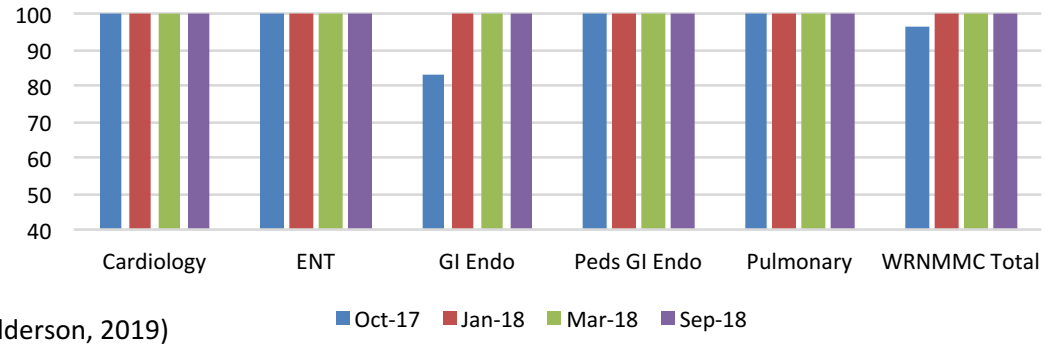
Drying and Storage



- Initial audit score 85%
- 12 Deficiencies
- 9 Corrections
- 12.2% Improvement
- **Final audit score 97.2%**

**NOTE: New storage cabinets purchased OCT 2018 – this resulted in the correction of remaining*

Record Keeping



(Romito & Fedderson, 2019)

- Initial audit score 96.6%
- 1 Deficiency
- 1 Correction
- 3.4% Improvement
- **Final audit score 100%**

Impact

HRO Goals	Initiatives Implemented Across the Organization	Impact
Quality	***Organizational Structure Improvement***	21 Areas
	*HLD Committee Formation; HLD Education & Training	
	Closure of Stone Center; HLD Tracers	
Safety	***Policy Changes***	24 Areas
	*Standardized HLD Policies; *Endoscope Storage	
	HLD Training & Education	
	Leadership/Culture of Safety	18 Areas
	*Leadership Engagement	
Continuous Process Improvement	***Standardization***	29 Areas
	Transportation Equipment; Purchased New AERs	
	Enzymatic Sponges	
	Process Improvement	43 Areas
	*Workflow Charts; Binders	
	*Room Pressure Monitoring; HLD Fluid Temperatures	
	Spill Kits	
	22 Total Initiatives	135 Areas

(* = 2 initiatives)

Impact Cont.

WRNMMC

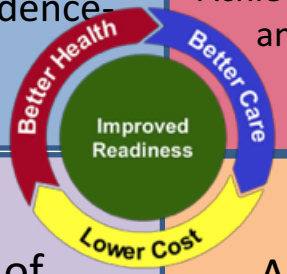
MHS/DHA

Global Implementation

96.9% compliance rate at WRNMMC → Command Chartered HLD Committee → Full time HLD Committee Chair hired

Better Care: Achieved by implementing evidence-based, standardized HLD practices

Better Health: Achieved by creating an environment and culture by which safe endoscopic procedures are free of contamination exposure



Lower Costs: Achieved by avoidance of cost-related HAIs

Increased Readiness: Achieved by rapid return to duty following endoscopic procedures

Global Surgical Conference 1st place for Evidence Based Practice → Recognized by AORN as *"Best Practice"* → Featured on AORN website

Adenosine Triphosphate-Bioluminescence Technology as an Adjunct Tool to Validate Cleanliness of Surgical Instruments

Introduction

- Advancement in surgical instrument design has improved perioperative care and outcomes. (O'Sullivan et al., 2019; Bel & Carret, 2015)
- New designs pose great challenges to cleaning processes.
- Bioburden is often left behind in surgical instruments. (AAMI, 2017)
- Bioburden compromise the effectiveness of the sterilization process. (AAMI, 2017)
- Bioburden increases the risk for surgical site infections (SSI).

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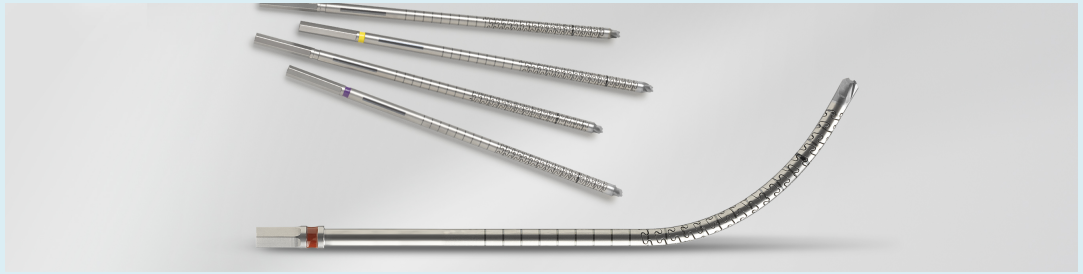
Background and Significance

- Surgical site infections (SSI) account for 31% of hospital acquired infections and $3.3 billion dollars in hospitalization costs. (Zimlixhman et al., 2013)
- 8,205 deaths occur because of SSIs. (Russo, 2018)
- Microbial contamination leads to bioburden buildup and prevents effective sterilization. (AAMI, 2017)
- Visual inspection has not been a reliable method. (AAMI, 2017)
- More objective and sensitive methods are needed to validate the cleanliness. (AAMI, 2017)
- Adenosine triphosphate (ATP) technology is a viable and affordable solution.

(NBC News, 2012)

Background and Significance Cont.

(https://www.smith-nephew.com/)



(https://www.zimmerbiomet.com/)

(https://www.intuitive.com/)

Evidence Review

- In 2009, 10,000 veterans underwent endoscopic procedures performed with contaminated endoscopes. (govinfo.gov, 2019)
- In 2009, a study regarding SSIs after orthopedic procedures discovered that seven patients developed SSIs in their joints due to contaminated surgical instruments. (Tosh et al., 2011)
- US Food and Drug Administration recommended surgical processing facilities consider assistive technology to validate instrument cleanliness. (FDA, 2014)

Evidence Review Cont.

- Visual inspection of surgical instruments, is not an effective method. (Doll & Bearman, 2018)
- ATP-based method is an alternative for rapidly verifying the cleaning processes.
- ATP-bioluminescence vs. visual inspection study: ATP-based assay is a sensitive and rapid tool. (Huang et al., 2015)
- ATP-based technology is a rapid and inexpensive alternative. (Sethi et al., 2017)
- ATP-based method is practical in the validation of cleaning processes. (FDA, 2014)

(www.bamc.health.mil, 2017)

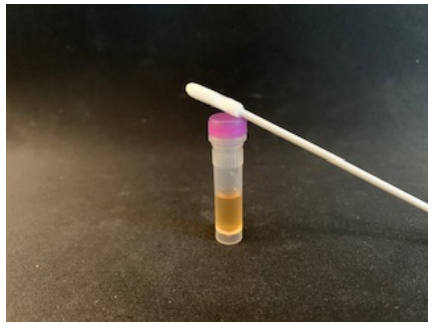
Recommended Practice Guidelines

Five recommended markers per the Association for the Advancement of Medical Instrumentation (AAMI) ST-79:

1. *Hemoglobin*
2. *Protein*
3. *ATP*
4. Carbohydrates
5. Lipids

(AAMI, 2017)

Protein



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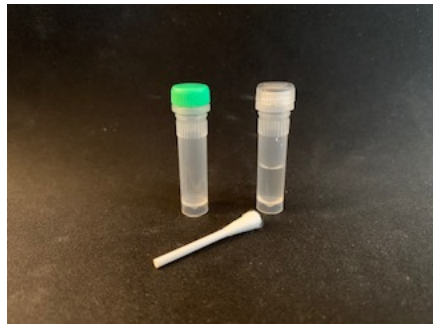
Hemoglobin



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ATP

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Criteria For Cleaning and Verification Tests

- Rapid
- Easy to perform
- Sensitive
- Accurate
- Repeatable
- Free of interfering substances
- Robust
- Allows for quick testing right after cleaning
- Will not damage or require recleaning of the device

(AAMI, 2017)

AORN's Position

The Association of Perioperative Registered Nurses (AORN) recommends healthcare organizations "to evaluate and incorporate existing technologies, such as ATP-bioluminescence, ***to objectively*** evaluate manual and mechanical cleaning processes." (AORN, 2018)

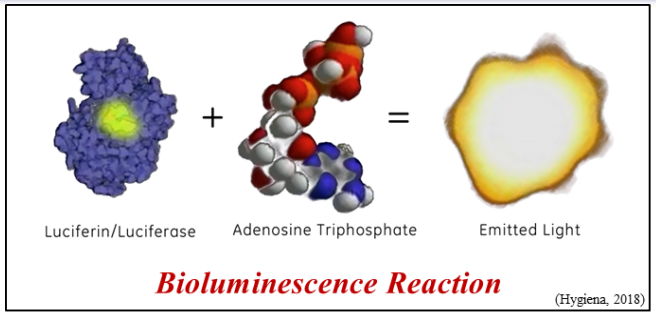
Project Setting

- Walter Reed National Military Medical Center (WRNMMC)
  - 47 technicians and 1 registered nurse
  - 16 are certified registered central services technicians (CSST)
- 18 operating rooms (avg. caseload of 1,200 per month)
- 8,000 surgical trays processed monthly

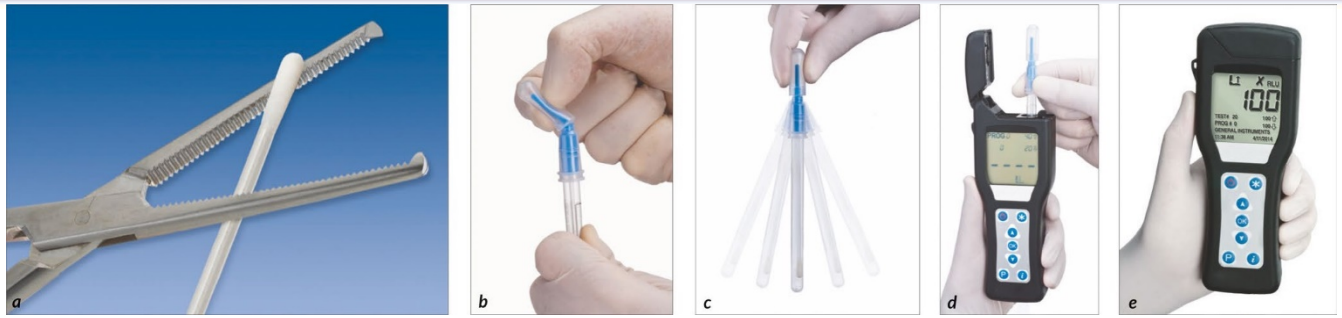
Project Goals

This quality improvement project (QIP) sought to investigate if ATP-bioluminescence can serve as an adjunct technology to visual inspection by increasing bioburden detection in cannulated surgical instruments.

Adenosine Triphosphate Technology



(Hygiena, 2018)



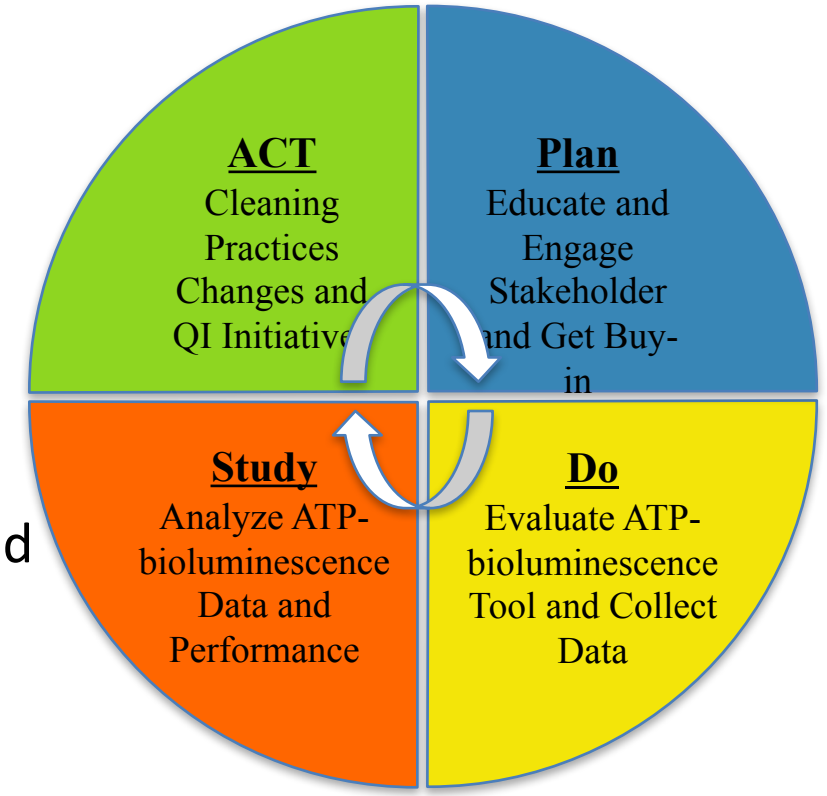
(Ruhof, 2019)

- Advantages
  - Easy to perform
  - Digital
  - Affordable
  - Rapid
  - Repeatable
  - Sensitive
  - Robust

- Disadvantages
  - Narrowed Spectrum
  - Looses detectability over time
  - Requires hardware and software
    - Up-front investment
  - Variable benchmarks

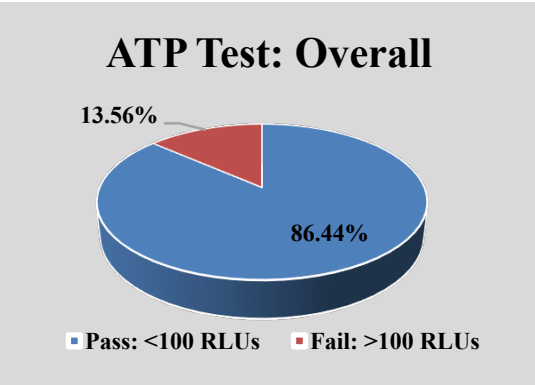
Project Design

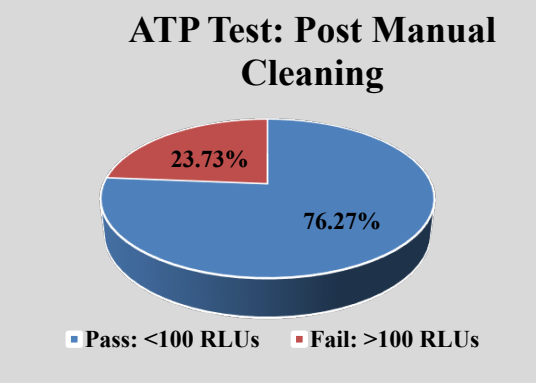
- Tool: ATP-based assessment tool
- Sample technique: convenient sample
- Sample size: 118 surgical instruments
- Benchmark: 0-100 relative light units (RLUs)
- Data collection:
  - Author conducted testing
  - Instructions for use (IFU) for testing were followed
  - Post manual and automated testing
  - Lumens measured to determine diameter

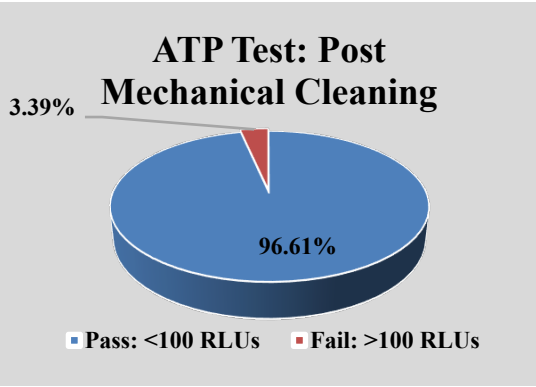


Impact of ATP at WRNMMC: Results

- The ATP system identified 16 contaminated instruments (13.56%).
- The contamination rate after mechanical cleaning was significantly lower when compared to after manual cleaning (p=0.0022).
- These results suggest that ATP technology is an effective tool and highlight the importance of mechanical cleaning.
- Hand power drills and suction tips were the two most common types of instruments with the highest testing failures (3.39% and 5.80%).







ATP at WRNMMC: Discussion

- ATP-based technology can effectively detect bioburden
- Sensitive, simple to perform, and provides40 immediate results
- Data collected during this project was used to identify issues with cleaning practices
- ATP-based technology is cost effective and feasible
- A solution to minimize health care–related costs of SSIs and optimize patient and staff member safety

Implications for Practice

- ATP bioluminescence showed to be an effective adjunct technology to visual inspection.
- ATP-bioluminescence technology is a viable and affordable solution.
- Future studies should focus on the identification of standardized benchmarks.

(www.health.mil)

Where Next?

- Standardization
- Application to other clinical areas
  - OR
  - Endoscopic Suite
  - In-patient units
  - Environmental Services
- Hemoglobin vs. Protein vs. ATP

Key Takeaways

ATP-bioluminescence Technology:

- Possesses the characteristics needed to rapidly assess the cleanliness of surgical instruments and cleaning protocols.
- The results suggest that it is a rapid, affordable, and effective method.
- Showed its greatest potential after manual cleaning, which highlights the importance of mechanical cleaning, and the integration of a cleaning verification method such as ATP-bioluminescence in facilities that lack mechanical cleaning capabilities.
- Assisted in the detection of gaps in knowledge and cleaning protocols.
- Can be used to support and enhance education and training programs.

Questions

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