

2019

**APIC Applied
Learning
Conference**

Addressing and Improving Device Reprocessing at Your Facility:

**Let's not let what we *can't* do
get in the way of what we *can*!**

APIC EDUCATION

Judie Bringhurst



2019

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Disclosures: Judie Bringhurst MSN RN CIC

- Faculty: Judie Bringhurst MSN RN CIC
- Relationships with commercial interests:
 - Consultant: Cogentix
 - Honorarium: Medivator/Cantel

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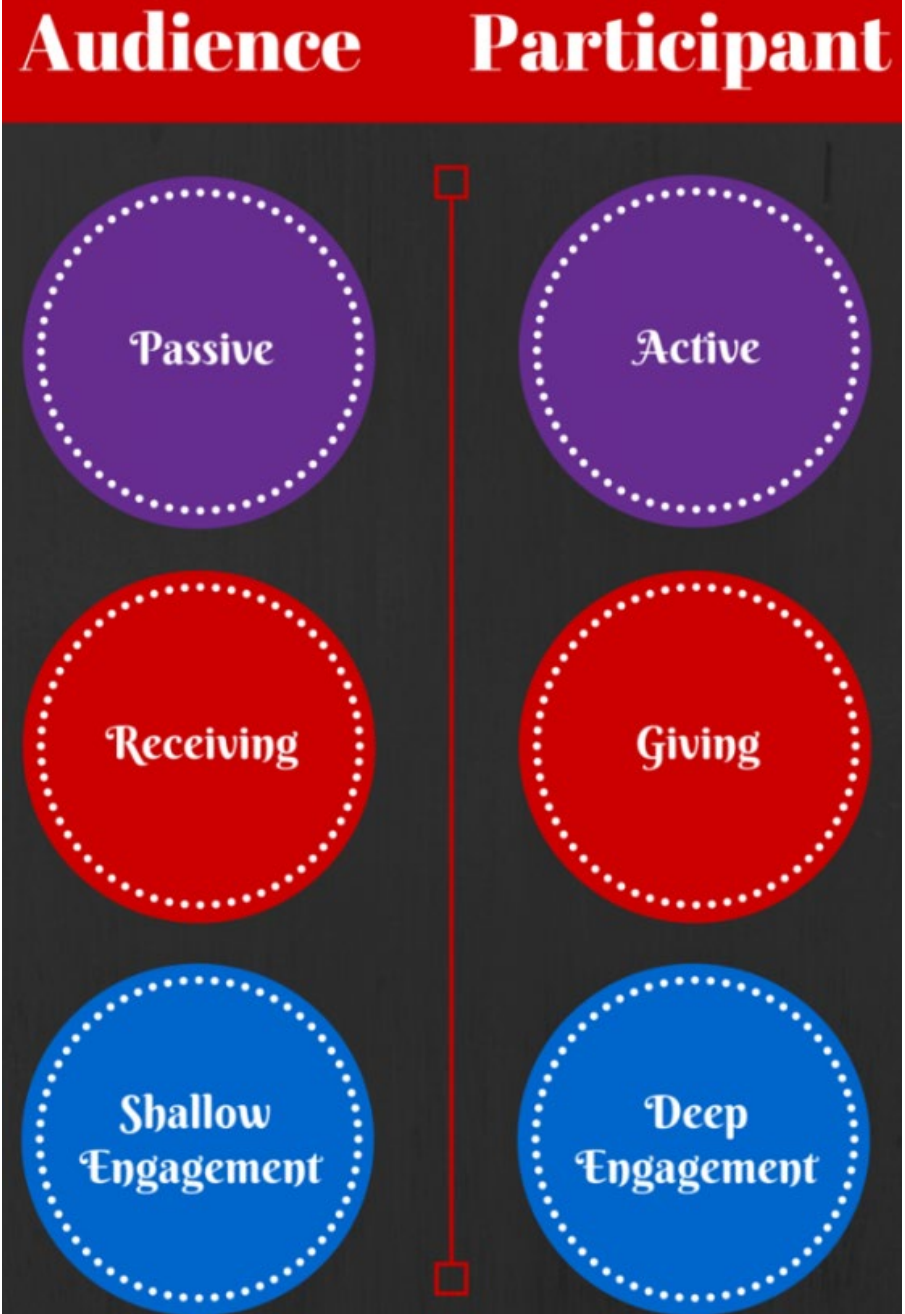
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Learning Outcomes: Springboard to Your Conference

- Workshops and General Sessions
 - Endoscopes
 - Collaboration
 - Emerging Technologies
 - Sterile Processing Department
 - Microbiology
 - Antibiotic Stewardship
 - APIC's Competency Model
- Let's get started!

But first...







Raise your hand if you have some areas of concern related to
reusable device reprocessing at your facility.

Index Card Activity #1



What is your # 1 most pressing concern related to reprocessing reusable medical devices at your facility?

A True Tarheel Story of Persistence and Determination

- Needed a new scope reprocessing room for GI Procedures
- Over 3 years, meetings with all stakeholders including scope room staff to design new room
- Plans completed and submitted to North Carolina Division of Health Services Regulation (CMS in NC) and approved
- Bids went out...bids came in...
- WAY over \$\$ set aside for this project...
- Project placed on hold indefinitely...
- Unacceptable say we!
- I saw a senior VP in the hallway one day...and I showed him this...



He funded the project within days...

And

Now we have this...



This is OUR watch and we cannot do
nothing.

Don't let what you cannot do interfere
with what you can do.

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”

**NOTHING IN THE WORLD CAN TAKE
THE PLACE OF PERSISTENCE. TALENT
WILL NOT; NOTHING IS MORE COMMON
THAN UNSUCCESSFUL MEN WITH
TALENT. GENIUS WILL NOT;
UNREWARDED GENIUS IS ALMOST A
PROVERB. EDUCATION WILL NOT; THE
WORLD IS FULL OF EDUCATED
DERELICTS. PERSISTENCE AND
DETERMINATION ARE OMNIPOTENT.**

CALVIN COOLIDGE

Let's dig in!

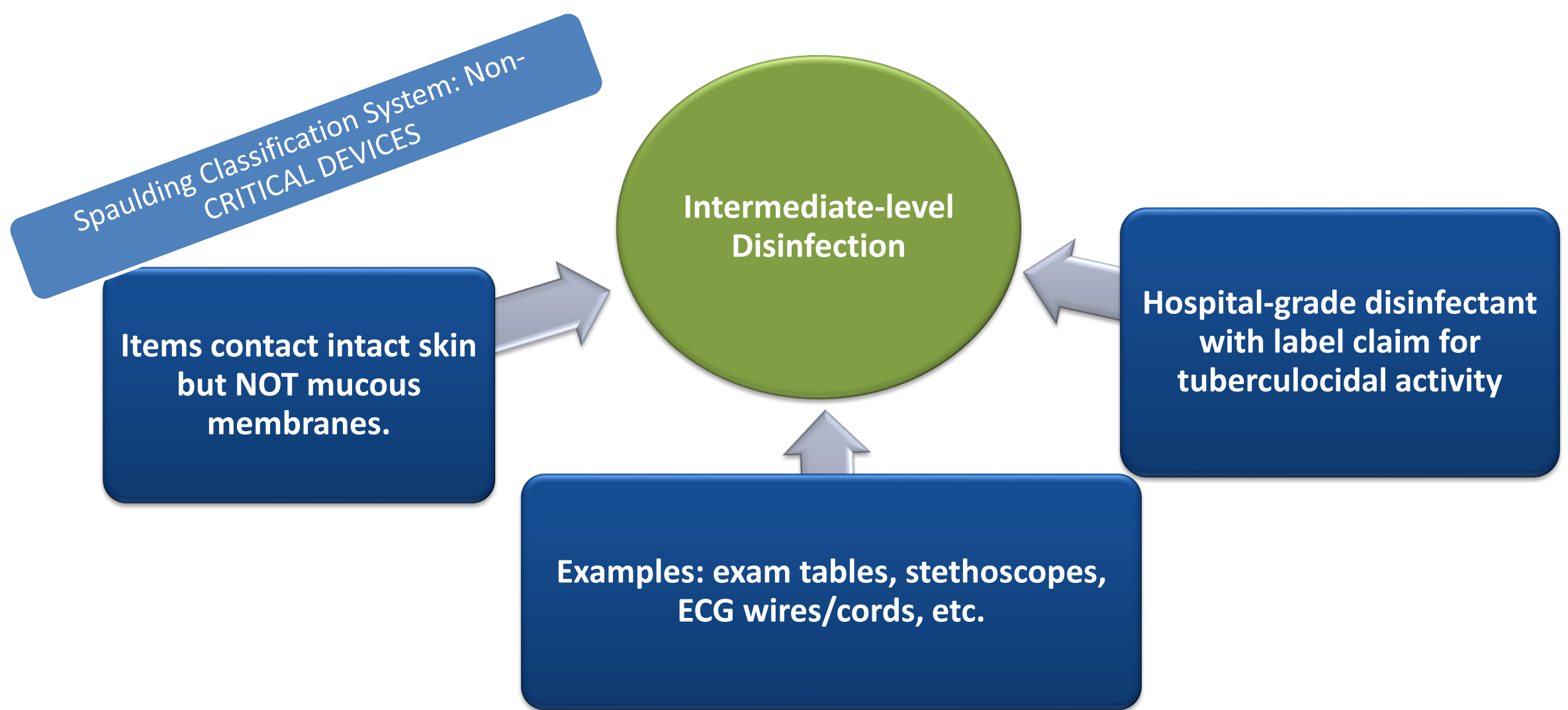
E. H. Spaulding, 1968

- Spaulding Classification Scheme
- All major societies and healthcare advisory institutions subscribe
 - AAMI: Association for the Advancement of Medical Instrumentation
 - ASGE: American Society of Gastroenterologists
 - SGNA: Society of Gastroenterology Nurses and Associates
 - CDC: Centers for Disease Control and Epidemiology
- Clear, logical approach to disinfection and sterilization
- Three categories:
 1. **non-critical**
 2. **semi-critical**
 3. **critical**
- Items categorized on the basis of the degree of risk of infection involved in their ***use***
 - Example: scissors vs. scissors

Non-critical devices: Items that come in contact with intact skin but not mucous membranes or normally sterile tissue

Examples:

- Exam tables
- Stethoscopes
- BP cuffs
- OR tables
- EKG wires/cords
- Bedpans

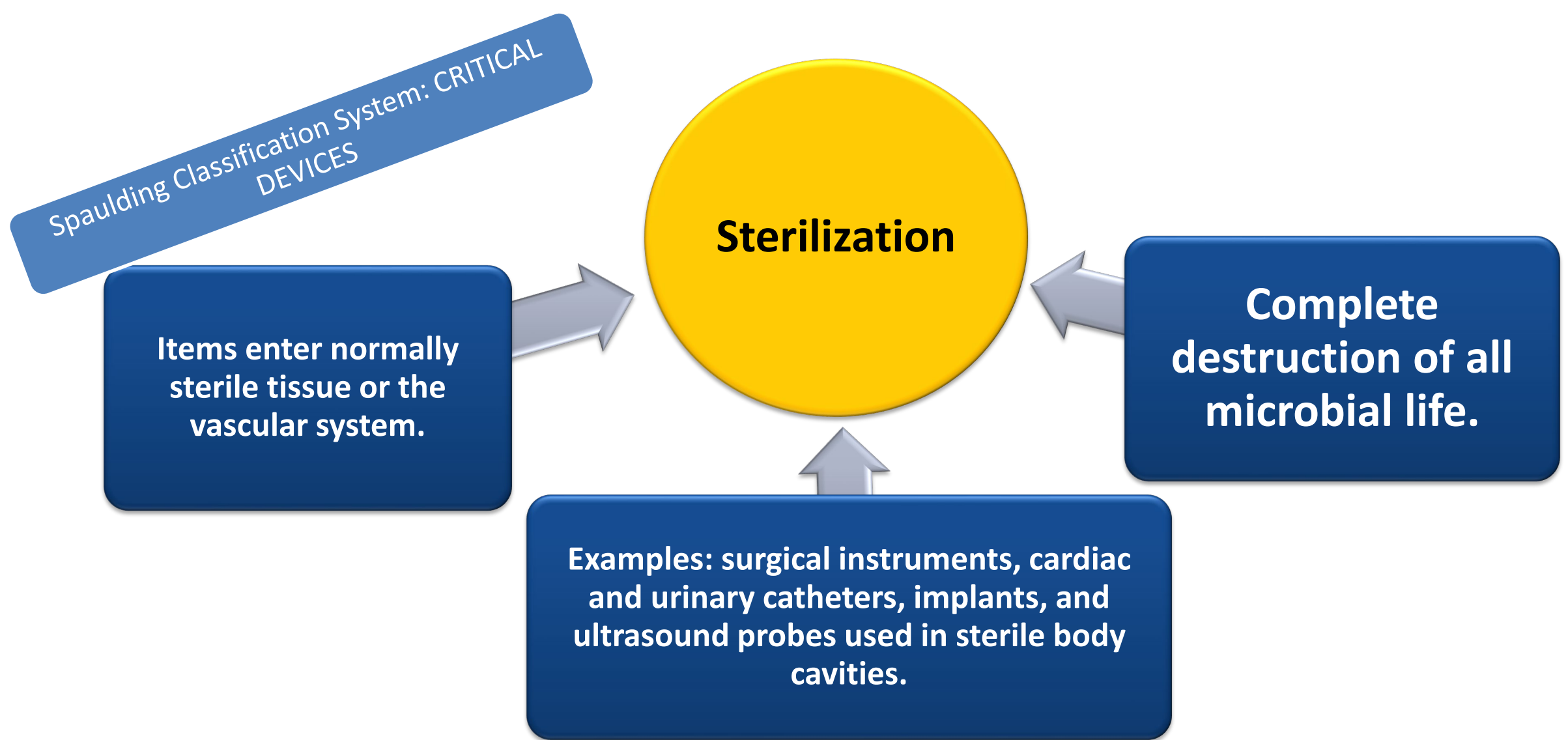


Virtually no risk has been documented for transmission of infectious agents to patients through noncritical items when they are used as noncritical items; however, potentially could contribute to secondary transmission by contaminating hands of health-care workers or by contacting medical equipment that subsequently contacts patients.

Critical devices: “...objects that enter normally sterile tissue or the vascular system.”

Examples:

- Surgical instruments
- Cardiac catheters
- Implants
- Ultrasound probes used in sterile body cavities



Critical items confer a high risk for infection if they are contaminated with **any** microorganism.

Steam Sterilization: Enormous Margin of Safety

- 100 quadrillion (10^{-17}) margin of safety
- Sterilization kills 1 trillion spores *in addition to* the washer/disinfector which removes or inactivates 10-100 million microbes.

There is a 1:100 quadrillion chance of the item NOT being sterile
(that's a "1" with 17 zeros after it)

Generally speaking, and particularly compared to HLD, I don't worry about steam sterilization practices – well, I don't lose sleep over steam sterilization.



Semi-critical devices: “...contact mucous membranes or nonintact skin.”

Examples:

- Anesthesia equipment
- Gastrointestinal endoscopes
- Bronchoscopes
- Laryngoscope blades
- Cystoscopes

Spaulding Classification System:
Semi-CRITICAL DEVICES

Items contact mucous
membranes or nonintact
skin.

High Level Disinfection

Complete elimination of
all microorganisms in or
on an instrument, except
for small numbers of
bacterial spores.

Examples: some endoscopes,
laryngoscope blades,
cystoscopes, ultrasound
probes.

High-Level Disinfection: No Margin of Safety for GI Endoscopes

- Margin of safety with endoscope reprocessing minimal or non-existent for two reasons:
- **Microbial load**
 - GI endoscopes contain 10^{7-10}
 - Cleaning results in 2-6 $\log_{10}$ reduction
 - High-level disinfection results in 4-6 $\log_{10}$ reduction
 - Results in a total 6-12 $\log_{10}$ reduction of microbes
- **Complexity of endoscope**
- **Humans**

I do worry
about high-level disinfection practices.



In fact

High-level disinfection

is

the problem with instrument reprocessing today
– inpatient and outpatient.

1950 vs 2013, Formula One Racing

https://www.youtube.com/watch?v=RRy_73ivcms

Human error and outbreaks

TABLE 3. Documented Completion of Steps During Manual Cleaning With High-Level Disinfection Reprocessing

Observed Activity	Steps Completed (%) (n = 69)
Leak test performed in clear water	77
Disassemble endoscope completely	100
Brush all endoscope channels and components	43
Immerse endoscope completely in detergent	99
Immerse components completely in detergent	99
Flush endoscope with detergent	99
Rinse endoscope with water	96
Purge endoscope with air	84
Load and complete automated cycle for high-level disinfection	100
Flush endoscope with alcohol	86
Use forced air to dry endoscope	45
Wipe down external surfaces before hanging to dry	90

Ofstead, C.L., Wetzler, H.P., Snyder, A.K., Horton, R.A. (2010). Endoscope Reprocessing Methods. A Prospective Study on the Impact of Human Factors and Automation. *Gastroenterol Nurs*, 33(4), 304-11.

Transmission of Infection by Endoscopy

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

Scope	Outbreaks	Micro (primary)	Pts Contaminated	Pts Infected	Cause (primary)
Upper GI	19	Pa, H. pylori, Salmonella	169	56	Cleaning/Disinfection (C/D)
Sigmoid/Colonoscopy	5	Salmonella, HCV	14	6	Cleaning/Disinfection
ERCP	23	Pa	152	89	C/D, water bottle, AER
Bronchoscopy	51	Pa, Mtb, Mycobacteria	778	98	C/D, AER, water
Totals	98		1113	249	

Based on outbreak data, if we could eliminate deficiencies associated with cleaning, disinfection, AER, contaminated water and drying, we would eliminate about 85% of the outbreaks.

RECENT ENDOSCOPY-RELATED OUTBREAKS OF MRDO WITHOUT REPROCESSING BREACHES

Rutala WA et al. Virulence, 2016

MDRO	Scope	No.	Recovered From Scope	Molecular Link	Reference
<i>P. aeruginosa</i> (VIM-2)	Duodenoscope	22	Yes, under forceps elevator	Yes	Verfaillie CJ, 2015
<i>E. coli</i> (AmpC)	Duodenoscope	35	Yes (2 scopes)	Yes	Wendorf, 2015
<i>K. pneumoniae</i> (OXA)	Duodenoscope	12	No	Yes	Kola A, 2015
<i>E. coli</i> (NDM-CRE)	Duodenoscope	39	Yes	Yes	Epstein L, 2015
<i>K. pneumoniae</i>	Duodenoscope	15	No	Yes	Kim S, 2016
<i>K. pneumoniae</i>	Duodenoscope	34	Yes	Yes	Marsh J, 2015
<i>E. coli</i>	Duodenoscope	3	No	Unknown	Smith Z, 2015
<i>K. pneumoniae</i>	Duodenoscope	13	Yes	Yes	Carbonne A, 2010

Under-reporting of Transmission Associated with Endoscopy

In a CDC survey, 1/3 of respondents reported that their institutions have not used any surveillance methods to identify possible bacterial transmission following certain endoscopic procedures.



Why? Device complexity (industry) and reprocessing complexity (human factors)

- Device Complexity
 - AERs, Endoscopes
 - Validation
- Humans are humans...
 - 111-page reprocessing instructions

Simply stated, HLD may be too complicated to be safe.

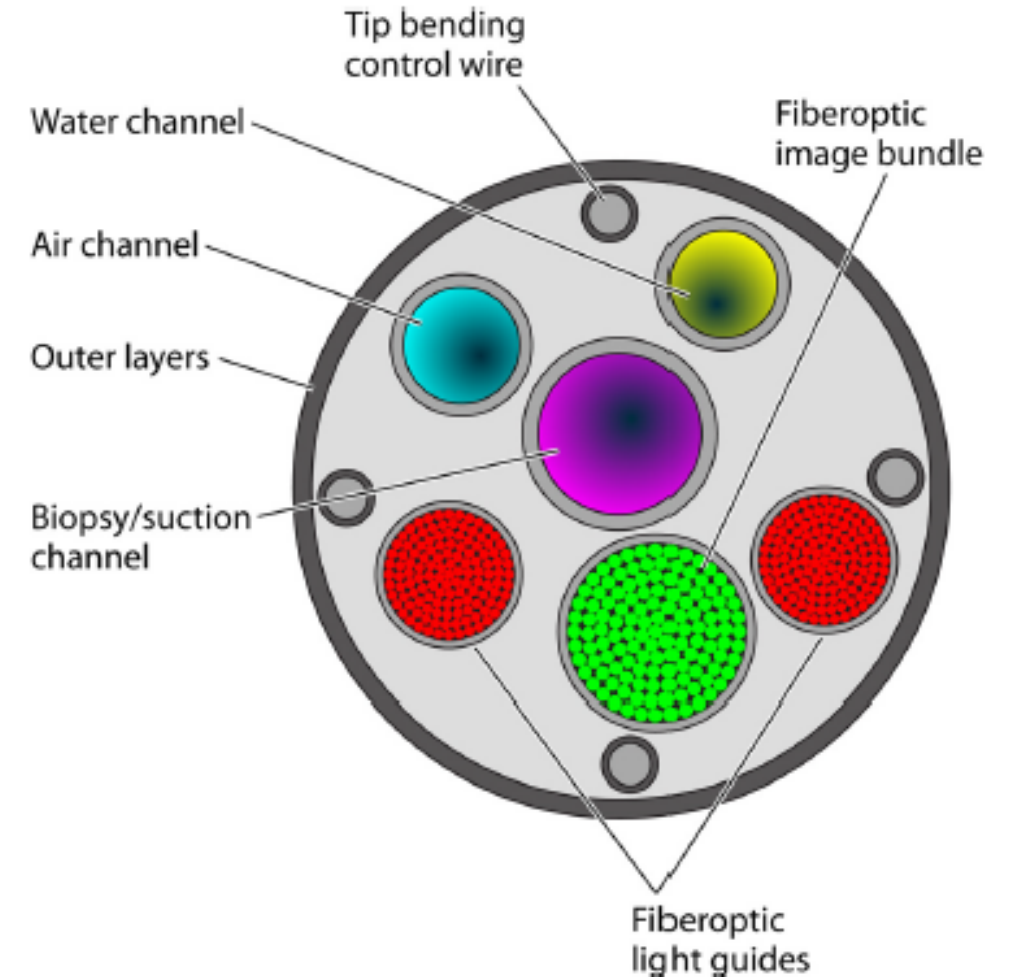
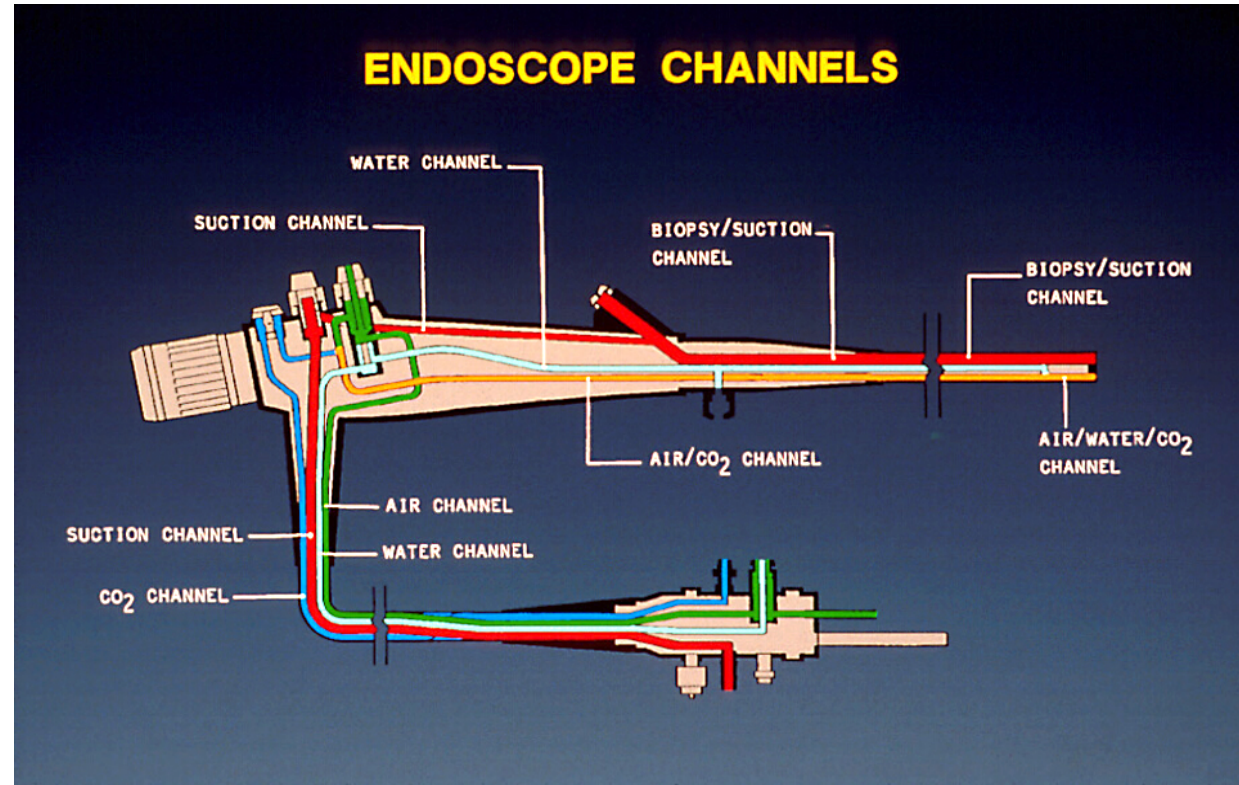


FIG 1 Schematic drawing of a cross section of a flexible endoscope showing the complex design and multiple internal channels (inner diameter, 2.8 to 3.8 mm).

A predisposition for disinfection failures

Rutala WA, Weber DJ. Infect Control Hosp Epidemiol 2015;36:643-648

- Heat labile
- Long, narrow lumens
- Right angle bends
- Rough or pitted surfaces
- Springs and valves
- Damaged channels may impede microbial exposure to HLD
- Heavily contaminated with pathogens, 10^{7-10}
- Cleaning (4-6 $\log_{10}$ reduction) and HLD (4-6 $\log_{10}$ reduction) essential for patient safe instrument



Instructions for use (IFU) complexity (human factors)

Table of Contents for Olympus Q180V

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- Tested 45 patient-ready endoscopes at 3 hospitals
- Fluid detected in 22 (49%)
- Microbial growth detected in 71% to include *Stenotrophomonas maltophilia*, *Citrobacter freundii*
- Substantial defects observed in all 45 endoscopes
 - Discoloration
 - White or black residue
 - Scratches
 - Gouges
 - Non-intact channel lining
 - Debris inside endoscopes
 - Damaged distal ends
 - Insertion tube buckling
 - Dented channels
- Concluded inadequate reprocessing, damaged endoscopes and insufficient drying contributed to retained fluid and contamination



Retained fluid droplets

692

C.L. Ofstead et al. / American Journal of Infection Control 46 (2018) 689-96

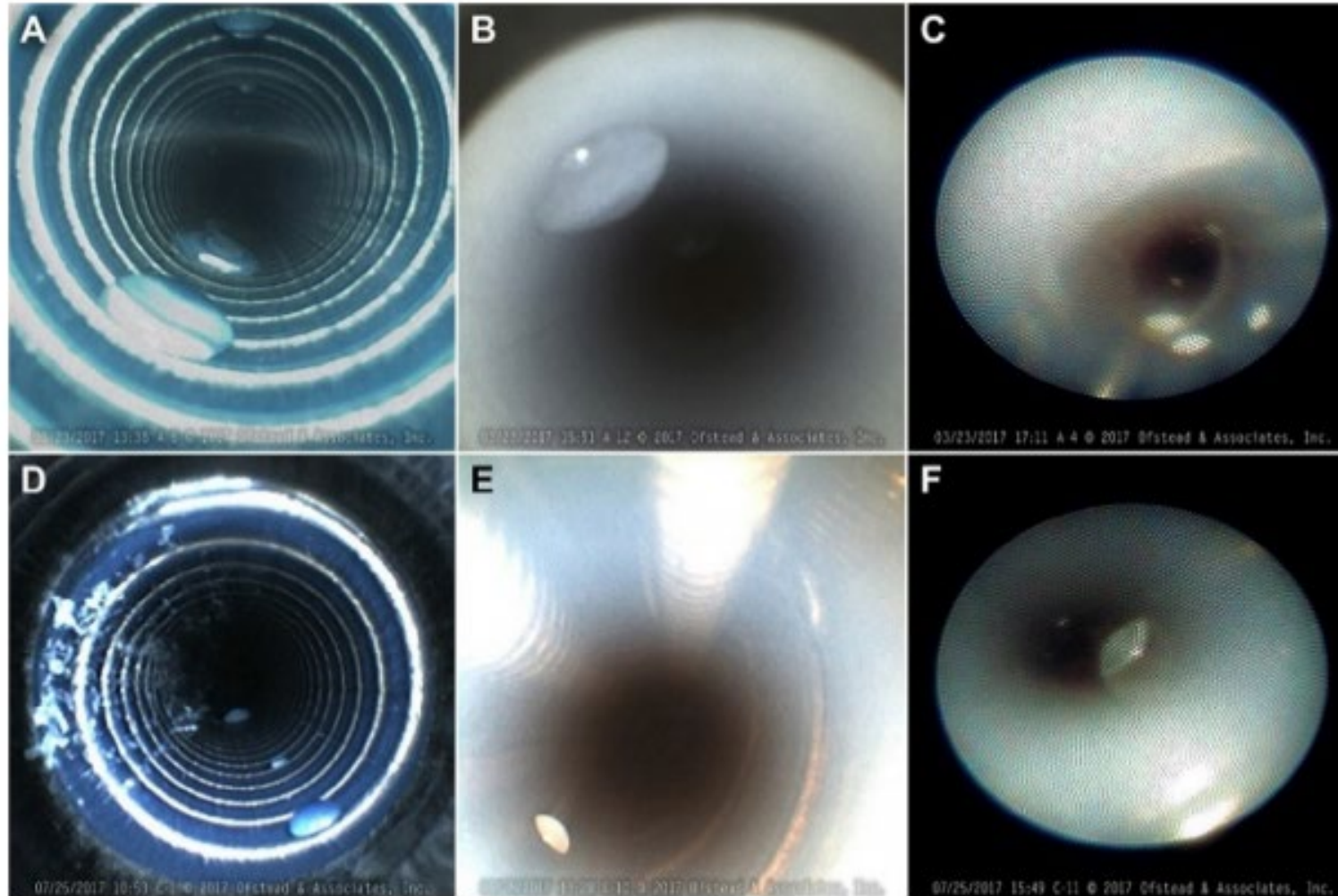


Fig 1. Retained fluid droplets found inside endoscope channels. (A) Gastroscope A-6; (B) Colonoscope A-12; (C) Cystoscope A-4; (D) Gastroscope C-1; (E) Duodenoscope C-10; and (F) EUS Radial Endoscope C-11.

Residues, damage



Fig 2. Residues observed on external surfaces of endoscopes. (A) Oily residue near biopsy port of pediatric colonoscope A-10; (B) dried “water spots” on control handle of cystoscope B-17; and (C) whitish-blue, powdery residue under control handle knobs of gastroscope B-5.

Residual moisture and waterborne pathogens inside flexible endoscopes: Evidence from a multisite study of endoscope drying effectiveness

Cori L. Ofstead MSPH, Otis L. Heymann BA, Mariah R. Quick MPH, John E. Eiland RN, MS, Harry P. Wetzler MD, MSPH

AJIC 46 (2018)

Visible Defects

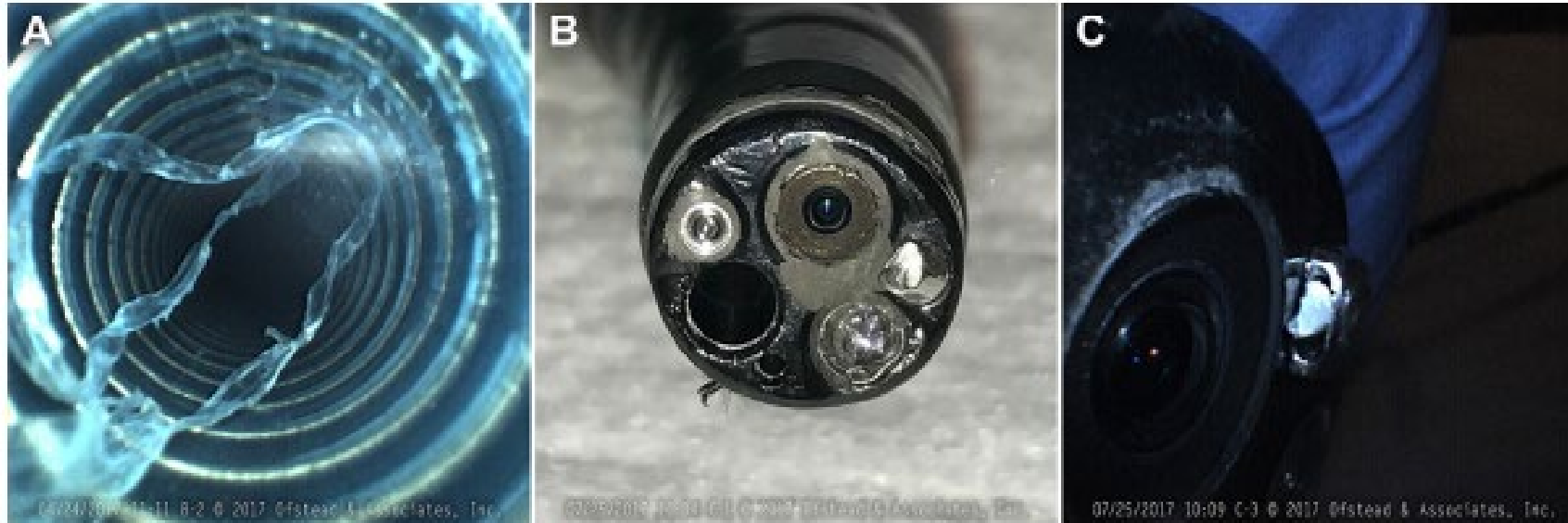


Fig 4. Visible defects observed during visual inspections. (A) Non-intact channel lining in gastroscope B-2; (B) damaged distal end with exposed metal mesh fibers protruding from gastroscope C-1; and (C) white debris protruding from the water jet outlet on the distal end of gastroscope C-3.

Residual moisture and waterborne pathogens inside flexible endoscopes: Evidence from a multisite study of endoscope drying effectiveness

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AJIC 46 (2018)



“Reprocessing guidelines describe drying as critically important, but there is no consensus among experts and guideline-issuing bodies on best practices for endoscope drying and storage.”



Everybody's Talking Now...



But changes have been slow...

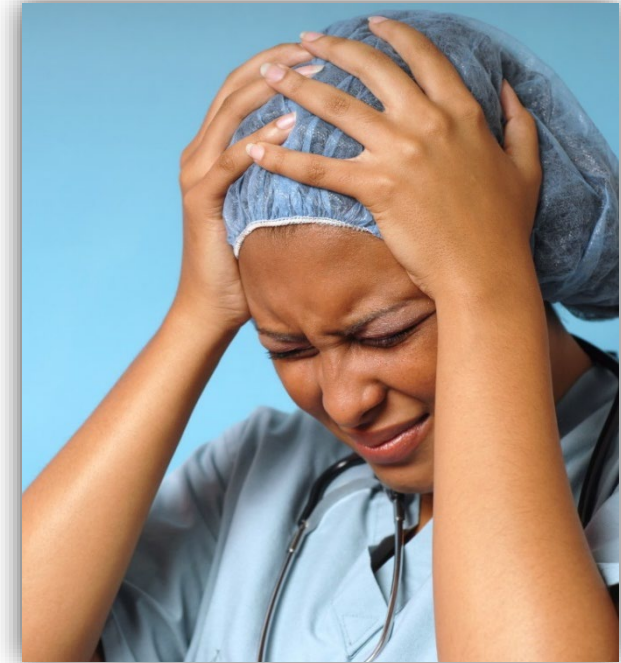
Lack of Standardization in the Industry

No Standardization in the
Instrument Reprocessing Industry



Enzymatic Detergents - No Standardization

- Different ratios of detergent to H₂O
- Automated dispensing systems
 - Are they REALLY accurate?
 - Are we checking accuracy?
- Some require certain H₂O temperatures for efficacy
- All must be precisely measured
- All require specific and different soak times
- None are disinfectants – a risk to staff!!



HLD Soak Times and Usage: No Standardization

- Most glutaraldehyde is a 20 minute soak time (unheated)
- Revital-ox Resert[®] is an 8 minute soak time
- OPA is a 12 minute soak time
- Rapicide[®] HLD glutaraldehyde is only FDA approved to be used heated in an automated endoscope reprocessor (AER)
- Peracetic acid can only be used as parts A and B in an AER



Test Strips: No Standardization

Staff may not leave the instrument processing room during wait times

- Cidex[®] glutaraldehyde strips
 - 75 seconds – pass = purple, fail = orange
- Cidex[®] OPA strips
 - 90 seconds – pass = purple, fail = teal
- Revital-Ox[®] strips
 - 60 seconds – pass = dark blue, fail = mottled
- Rapicide[®] PA strips
 - 30 seconds – pass = black, fail = shades of gray/black



Validation



Device Validation



- Are HLD chemicals validated by device manufacturer?
- Is the device validated by the manufacturer of the HLD chemical?
- Does the device have lumens?
- Is the sterilizer or AER validated to be efficacious with those lumens?
 - Length, diameter play a role
 - Are there hookups or adapters that must be used to perfuse lumens?
 - Are the correct hookups in use?
- Your device manufacturer must supply you with validation documents

Device/Hook-up Validation

MEDIVATORS

DSD/SSD Hookup Support

For AER Models: DSD-201, DSD-201LT, DSD-91E
SSD-102, SSD-102LT, SSD-100
DSD EDGE

Select the Endoscope...

Manufacturer

Type

Model

Select Scope Manufacturer ▼

Select Scope Type ▼

Select Scope Model ▼

Retrieve Hookup Info

Enter Endoscope Model Number with Keyboard

[Back to MEDIVATORS Support Home](#)

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Chemical Validation

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Products >>> Device Matrix >> Resert > Step 1

Revital-Ox™ RESERT® High Level Disinfectant Device Compatibility Matrix



The information in the device guide identifies those cleaned, immersible, reusable, semi-critical medical devices and accessories that have been tested to confirm materials compatibility by STERIS' Device Testing Program and/or the device manufacturer with Revital-Ox Resert High Level Disinfectant. The devices shown in the guide are **ONLY** a representation to confirm materials compatibility with a wide range of medical devices. Therefore, not all compatible devices will be listed.



Revital-Ox™ RESERT® High Level Disinfectant

Quick Search — Device by Model Number

SEARCH 

OR

Step-Through Guided Search

Step 1

Step 2

Step 3

Select Manufacturer

Aircraft Medical Limited
Aloka
B-K Medical
Boston Scientific
Care Fusion
Cogentix Medical
ConMed
Custom Ultrasonics
DeVilbiss Healthcare
ESAOTE

Select Device Name

Select Device Name

Select Model Number

Select Model Number

NEXT 



- Rigid bronchoscopes HLD'd via Steris System 1e by *NON-central sterile* staff with *no training* in HLD
- Bronchoscope manufacturer had not validated these scopes to be safely reprocessed in the Steris System 1e (SS1e) – an automated endoscope reprocessor (AER)
- SS1e manufacturer had not validated these scopes to be safely reprocessed in their AER
- Staff believed their practice was safe...
- “...it’s not a sterile site anyway...”

Portals of entry

- Routes through which pathogens enter their new host(s)
- Can be sterile tissue
- Can be non-sterile tissue
- To cause an infection, microbes must enter our bodies via a portal
- We have four:
 1. Respiratory tract
 2. GI tract
 3. Urogenital tract
 4. Breaks in the skin or mucous membrane

(There are 5 portals of entry on the front of the face)



Sept and Oct, 2015 Regulatory Recommendations: Health Care Facilities Need to Immediately Review Medical Device Reprocessing Procedures

Train Staff, Audit Adherence to Steps, Provide Feedback on Adherence

This is an official
CDC HEALTH UPDATE

Distributed via the CDC Health Alert Network
October 2, 2015, 08:00 EST (08:00 AM EST)
CDCHAN-00383

CDC/FDA Health Update about the Immediate Need for Healthcare Facilities to Review Procedures for Cleaning, Disinfecting, and Sterilizing Reusable Medical Devices

As a follow-up to [HAN 00382](#) (distributed September 11, 2015), the Centers for Disease Control and Prevention (CDC) and U.S. Food and Drug Administration (FDA) are providing this update to rescind the following recommendation: If healthcare facilities contract maintenance and repair of these devices to third-party vendors, healthcare facilities should verify that these vendors are approved or certified by the manufacturer to provide those services. We are making this change because there are currently no formal standardized programs or processes through which all manufacturers certify third-party vendors. We are also further clarifying that healthcare facilities which hire contractors to perform device reprocessing should verify that the contractor has an appropriate training program (i.e., consistent with what would be required in the healthcare facility) and that the training program includes the specific devices used by the healthcare facility.



September 5, 2018

Sterile Processing and Infection Preventionists,

Infection Control (IC) standard IC.02.02.01—which requires hospitals to reduce the risk of infections associated with medical equipment, device and supplies—continues to be among the standards most commonly cited as noncompliant. In 2017, 72 percent of surveyed hospitals and critical access hospitals were found to be noncompliant with this standard.

After a careful evaluation of high-level disinfection (HLD) and sterilization process steps, The Joint Commission has refined its scoring, effective September 1, 2018, to focus on the process steps that pose the highest risk to patients if they fail. These scoring revisions (see table below) are intended to help hospitals hone in on the highest-risk process steps to become more compliant with IC.02.02.01.

We will continue to score IC.02.02.01 as noncompliant whenever manufacturer instructions are not followed. And, over the next several months, we will closely monitor the revisions to ensure consistent scoring.

The Joint Commission looks forward to working with your hospital to improve compliance with IC.02.02.01 through the scoring revisions. If you have any questions, please contact the [Standards Interpretation Group](#).

Sincerely,

Sylvia Garcia-Houchins, MBA, RN, CIC
Director, Infection Prevention and Control
Division of Healthcare Improvement
The Joint Commission

FDA recommends health care facilities and manufacturers begin transitioning to duodenoscopes with disposable components to reduce risk of patient infection

In continued efforts to protect patient safety, FDA orders new postmarket studies for manufacturers, requests real-world contamination rates in duodenoscope labeling and warns about certain test strips illegally marketed to assess duodenoscope cleanliness

For Immediate Release:

August 29, 2019

Today, the U.S. Food and Drug Administration is recommending (<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pss.cfm?s=a>) that duodenoscope manufacturers and health care facilities transition to different types of duodenoscopes that may pose less risk to patient safety. Specifically, because of challenges with cleaning these devices for reuse (reprocessing) and persistent high levels of contamination, 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. Disposable designs simplify or eliminate the need for reprocessing, which may reduce between-patient duodenoscope contamination as compared to reusable, or fixed endcaps.

GI Endoscopes: Shift from Disinfection to Sterilization

Rutala, Weber. JAMA 2014. 312:1405-1406

EDITORIAL

Editorials represent the opinions of the authors and *JAMA* and not those of the American Medical Association.

Gastrointestinal Endoscopes A Need to Shift From Disinfection to Sterilization?

William A. Rutala, PhD, MPH; David J. Weber, MD, MPH

More than 10 million gastrointestinal endoscopic procedures are performed annually in the United States for diagnostic purposes, therapeutic interventions, or both.¹ Because gastrointestinal endoscopes contact mucosal surfaces, use of a contaminated endoscope may lead to patient-to-patient transmission of potential pathogens with a subsequent risk of infection.¹

In this issue of *JAMA*, Epstein and colleagues² report findings from their investigation of a cluster of New Delhi metallo- β -lactamase (NDM)-producing *Escherichia coli* associated with gastrointestinal endoscopy that occurred from March 2013 to

July 2013 in a single hospital in northeastern Illinois. During the 5-month period, 9 pa-

First, endoscopes are semicritical devices, which contact mucous membranes or nonintact skin, and require at least high-level disinfection.^{3,4} High-level disinfection achieves complete elimination of all microorganisms, except for small numbers of bacterial spores. Because flexible gastrointestinal endoscopic instruments are heat labile, only high-level disinfection with chemical agents or low-temperature sterilization technologies are possible.³ However, no low-temperature sterilization technology is US Food and Drug Administration (FDA)-cleared for gastrointestinal endoscopes such as duodenoscopes.

Second, more health care-associated outbreaks and clusters of infection have been linked to contaminated endoscopes than to any other medical device.^{3,5} However, until now,



Related article page 1447

Current Enhanced Methods for Reprocessing Duodenoscopes

Rutala WA, Weber DJ. Infect Control Hosp Epidemiol 2015;36:643-648

Doing nothing is not an option: Hospitals performing ERCPs should do one of the following (priority ranked):

- Ethylene oxide sterilization after high level disinfection with periodic microbiologic surveillance
- Double high-level disinfection with periodic microbiologic surveillance (UNC Hospitals) **
- High-level disinfection with scope quarantine until negative culture
- Liquid chemical sterilant processing system using peracetic acid (rinsed with extensively treated potable water) with periodic microbiologic surveillance
- High-level disinfection with periodic microbiologic surveillance

**more recent evidence is showing double HLD has no added killing power against pathogens

Modified Spaulding Classification Scheme?

Rutala, Weber Am J Infect Control. 2016;44:e1-e7

CRITICAL - objects which **directly or secondarily (i.e., via a mucous membrane such as duodenoscope)** enter normally sterile tissue or the vascular system or through which blood flows should be sterile.

“Although the scheme remains valid, there are some examples of disinfection studies with viruses, mycobacteria, and protozoa that challenge the current definitions and expectations of high- and low-level disinfection.”

“In HPV16 authentic viruses, only hypochlorite (4.86 log₁₀ reduction) and the 1.2% PAA-silver-based disinfectant (5.15 log₁₀ reduction) were able to produce .99.99% reduction in infectivity. All other disinfectants showed slight or no reduction in infectivity,” (Meyer et al, Jnl Antimicrobial Chemotherapy, 2014, 69, table 1).

Susceptibility of high-risk human papillomavirus type 16 to clinical disinfectants

Jordan Meyers^{1†‡}, Eric Ryndock^{2†}, Michael J. Conway^{2§}, Craig Meyers^{2*} and Richard Robison¹

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Received 7 October 2013; returned 18 November 2013; revised 31 December 2013; accepted 6 January 2014

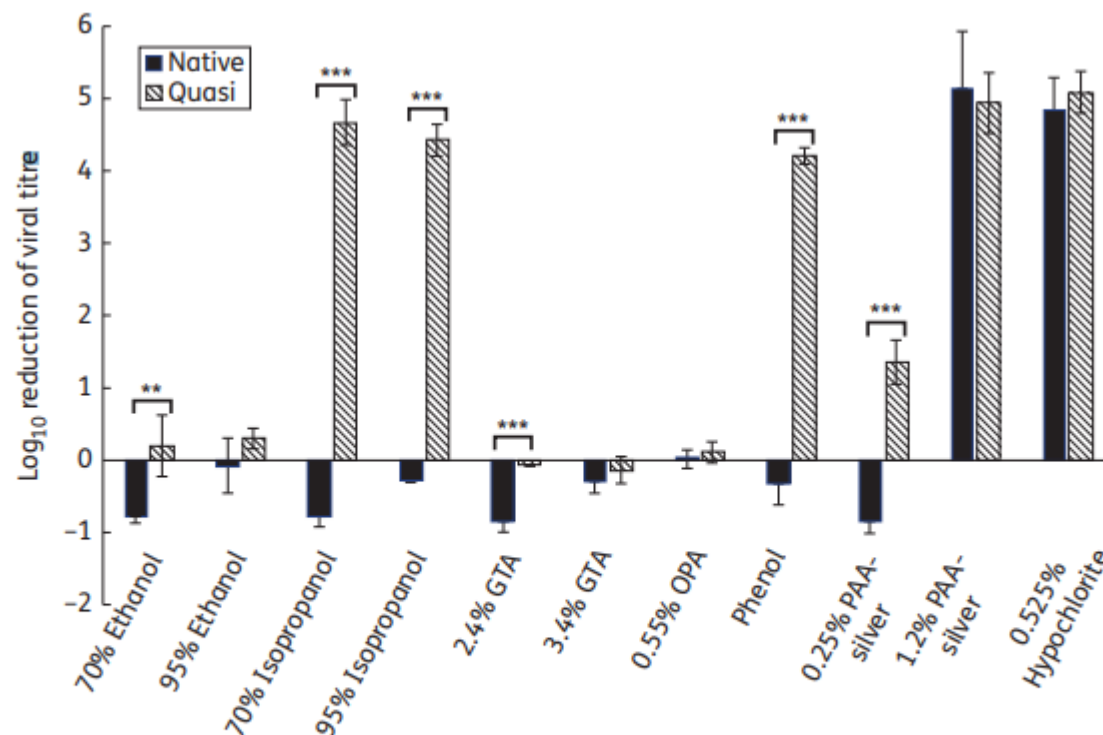


Figure 1. Susceptibility of HPV virions to clinical disinfectants. Both authentic virus and quasivirus were incubated with the indicated disinfectants for a contact time of 45 min. Disinfectants were neutralized and the virus was added to HaCaT cells for infection. Data shown are the averages of at least five independent experiments, with errors shown as the standard deviations of all experiments. ** $P < 0.01$. *** $P < 0.001$.

Reprocessing Channeled Endoscopes

Rutala, Gergen, Bringhurst, Weber. ICHE. 2016;37:228-231

Exposure Method	CRE (K. pneumoniae) Inoculum before HLD (glutaraldehyde)	CRE (K. pneumoniae) Contamination after HLD
Passive HLD (immersed, not perfused)	3.2x10 ⁸ 1.9x10 ⁹ 4.1x10 ⁸	3.1x10 ⁸ 4.6x10 ⁸ 1.0x10 ⁸
Active HLD (perfused HLD into channel with syringe)	3.0x10 ⁸ 9.2x10 ⁸ 8.4x10 ⁸	0 0 0

- Pathogens must have exposure to HLD for inactivation
- Immerse channeled flexible scope into HLD will not inactivate channel pathogens
- Completely immerse the endoscope in HLD and **ensure all channels (e.g., hysteroscopes, cystoscopes) are perfused**
- Air pressure in channel stronger than fluid pressure at fluid-air interface

It's not all AERs and endoscopes in our hospitals and outpatient facilities

- Endocavitary probes
- Dental devices: various mouthpieces and trays for impressions
- Transesophageal echocardiogram probes
- Ophthalmology semi-critical devices: Gonio lenses, tonometer tips
- Intubation laryngoscopes
- Vaginal specula
- Ophthalmic specula
- And bazillions of steam-sterilizable instruments

The Nation's Largest Patient Population?

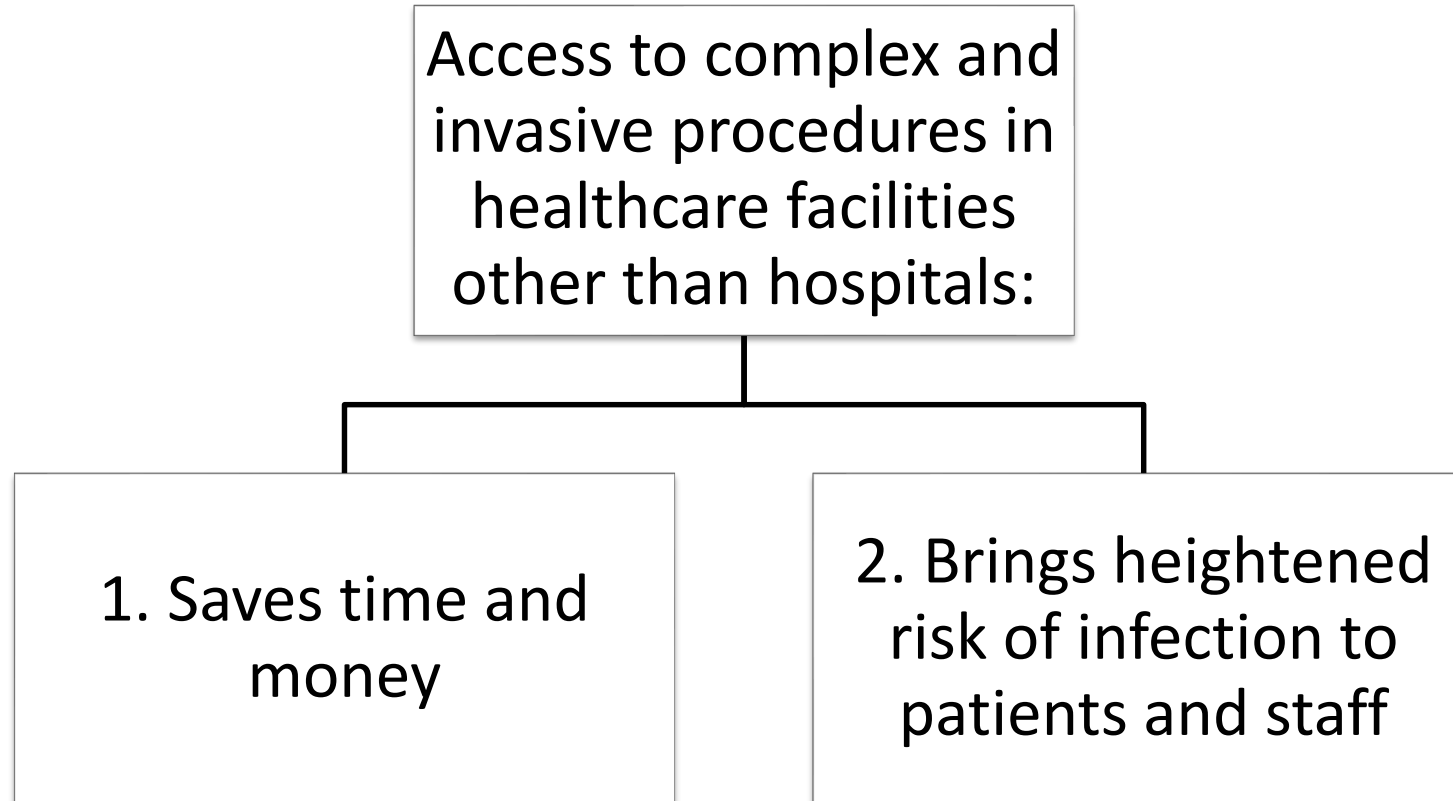
Guess... out loud!

Outpatient Care!

More patients obtain healthcare in specialty clinics and physicians' offices in the United States than in hospitals.

- 990 million ambulatory care visits to US physician offices (most specialties)
 - 85% of all adults in the US had contact with a health care professional in the past year
 - 93% of children in the US had contact with a health care professional in the past year
- 126 million outpatient hospital visits (CDC 2011)
-  UNC Health Care: 2.5 million arrived visits in 2016

Instrument Processing in Outpatient Care Facilities



Three Main Problems with Instrument Reprocessing in Out Patient Care:

Problem # 3: Physical Space Problems

- Improvements achieved without renovation

Problem #2.: Training and Education Problems Related to High-level Disinfection

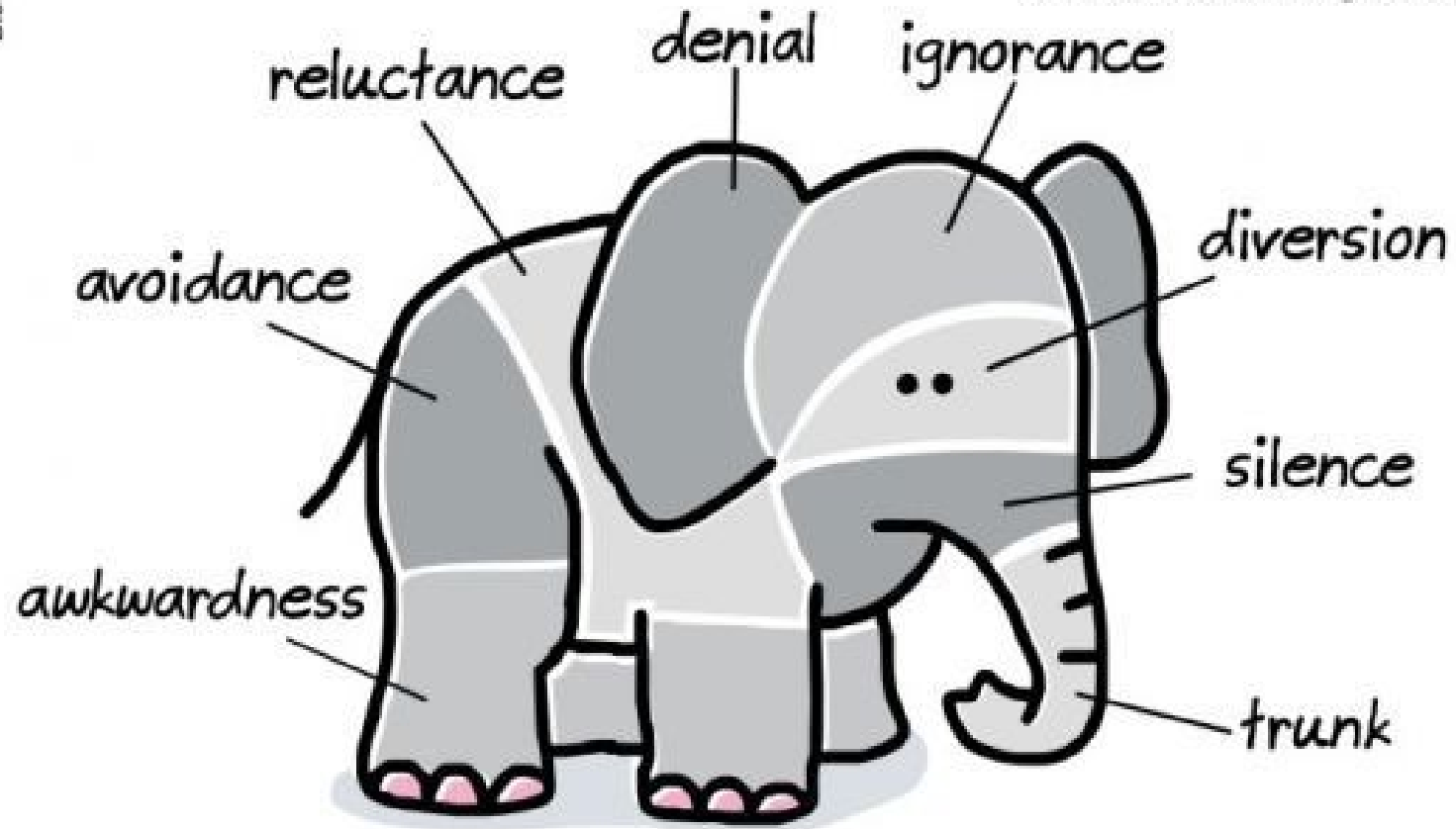
- IFUs/Validation
- Industry standardization
- HLD Education

Problem #1: ...is... guess!

Lack of Infection Prevention Presence

PARTS OF THE ELEPHANT IN THE ROOM

© John Atkinson, Wrong Hands



© John Atkinson, Wrong Hands • gocomics.com/wrong-hands • wronghands1.com

Outpatient facilities often exhibit
Magnified
physical plant challenges.



Double Sinks: Both clean or both dirty.

Infection Prevention helped
them figure this out.



- No sink at all
- Storage of endocavitary probes in processing room

Infection Prevention helped them make it safer: switched to accelerated hydrogen peroxide HLD chemical that only requires one rinse...

Before Infection Prevention Assistance... a Hot Mess!

Critical: rooms must have a dirty-to-clean flow *to the best of our ability to make it so.*

(This is a “clean-to-dirty-to-clean-to-dirty-to-dirty-to-dirty, dirty, dirty, dirty-to-clean” set up.)



After Infection Prevention Assistance – it's all rainbows and unicorns!



They decluttered and established a “dirty-to-clean” flow (mostly).

Infection Prevention helped them figure this out.



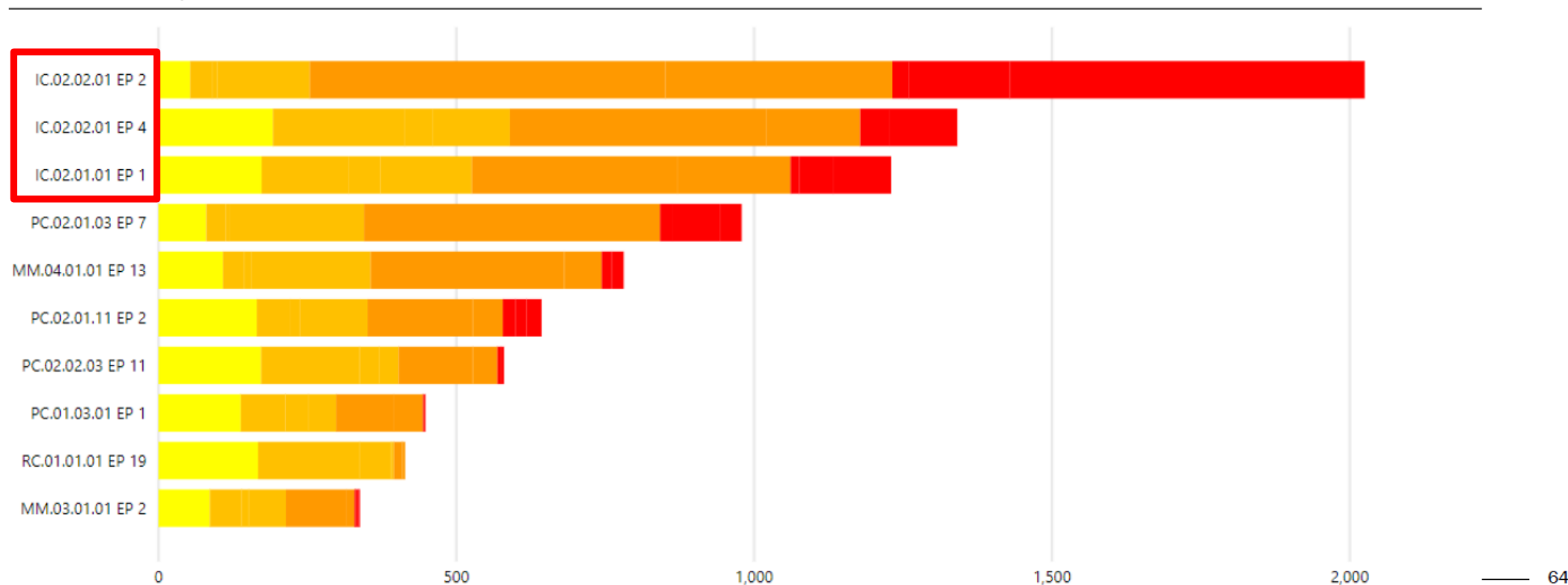
Most Frequently Cited Clinical* Elements of Performance (EPs)



Top 10 Most Frequently Cited Clinical EPs

*For Full and Initial **Hospital** surveys from 01/01/2018 through 09/30/2018 (n=1006)*

DISTRIBUTION OF SAFER SCORES BY STANDARD



*Clinical EPs include all chapters in the Hospital Accreditation manual except for the Environment of Care and Life Safety Code Chapters.

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Most Frequently Cited Clinical EPs:

Example Observations* (cont.)



IC.02.02.01 EP 2 –The hospital implements infection prevention and control activities when doing the following: Performing intermediate and high-level disinfection and sterilization of medical equipment, devices, and supplies.

- Not following manufactures guidelines or chosen evidence based guidelines such as Centers for Disease Prevention and Control (CDC), Association for advancement of Medical Instrumentation (AAMI), and/or Association for peri-Operative Registered Nurses (AORN) .
- Dirty instruments were not kept moist after the procedure in accordance with manufacturer instructions or, in the absence of instructions, with the facilities chosen evidence based guideline or national standard.
- Did not develop a process for assuring compliance with manufacturer instructions for all elements of reprocessing (e.g., extended soaking of endoscope if not reprocessed within time specified by manufacturer , did not rinse with three fresh water rinses as instructed by manufacturer).
- Results for Biological indicators used to monitor immediate use steam sterilization (IUSS) were not being logged.

*Note: Example observations are provided for the Top 3 most frequently cited EPs. Example observations contain observations found to be cited anywhere from low-risk to high-risk areas.

Most Frequently Cited Clinical EPs:

Example Observations*(cont.)



IC.02.02.01, EP 4 - The organization implements infection prevention and control activities when doing the following: Storing medical supplies and devices.

- An expired laryngeal mask airway (LMA) was found.
- Dirty items and clean patient supplies were stored together.
- Vaginal ultrasound probes were not protected from contamination during storage.
- CO2 detectors were found to be expired.
- The storage rack containing instrument trays with clean instruments did not have a protective covering on the bottom shelf.

*Note: Example observations are provided for the Top 3 most frequently cited EPs. Example observations contain observations found to be cited anywhere from low-risk to high-risk areas.

Most Frequently Cited Clinical EPs:

Example Observations*



IC.02.01.01, EP 1 -The hospital implements its infection prevention and control activities, including surveillance, to minimize, reduce, or eliminate the risk of infection.

- Presence of surfaces that were dirty and/or not cleanable (e.g., foam, torn, missing laminate).
- Not following manufacturer instructions, including performing routine quality control and maintenance of equipment.
- Failed to use appropriate disinfectants or water temperature (e.g., patient care surfaces, food services, laundry).
- Linen cart did not have an impervious bottom.
- Documentation was lacking to confirm that the walls, ceiling and storage shelves were cleaned monthly for compliance to Secondary Engineering controls in the Chemotherapy pharmacy.

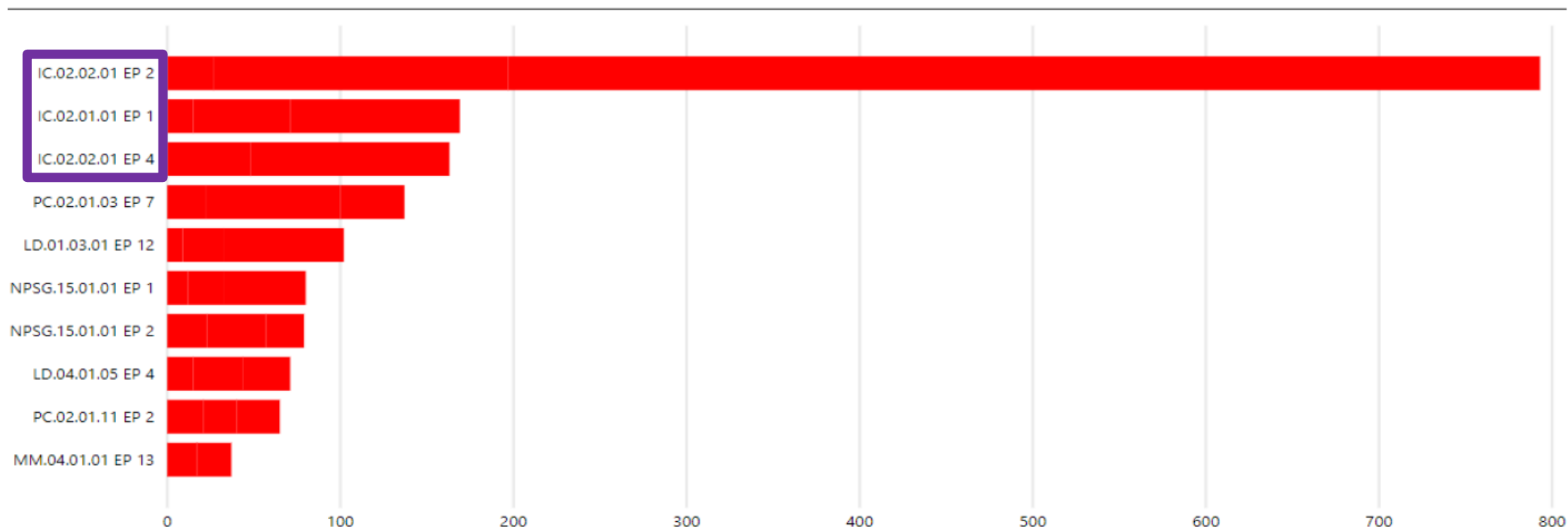
*Note: Example observations are provided for the Top 3 most frequently cited EPs. Example observations contain observations found to be cited anywhere from low-risk to high-risk areas.

Most Frequently Cited High Likelihood to Harm* Clinical** EPs



Top 10 High Risk Most Frequently Cited Clinical EPs
For Full and Initial Hospital surveys from 01/01/2018 to 09/30/2018 (n=1006)

DISTRIBUTION OF SAFER SCORES BY STANDARD



*High Likelihood to harm on the SAFER Matrix is defined as *harm could happen at any time*. The deficient practice could directly lead to harm without the need for other significant circumstances or failures. If the deficiency continues, it would be likely that harm could happen at any time to any patient (or did actually happen).

**Clinical EPs include all chapters in the Hospital Accreditation manual except for the Environment of Care and Life Safety Code Chapters.

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Most Frequently Cited High Likelihood to Harm



Clinical EPs: Example Observations* (cont.)

IC.02.02.01 EP 2 –The hospital implements infection prevention and control activities when doing the following: Performing intermediate and high-level disinfection and sterilization of medical equipment, devices, and supplies.

- Instruments were not cleaned and sterilized in accordance with manufacturer instructions:
 - Time, temperature and or pressurization was not monitored
 - Instruments not disassembled during terminal cleaning or sterilization
- Endoscope was not cleaned or high level disinfected in accordance with manufacturer instructions:
 - All steps were not followed (e.g., no leak testing, inadequate rinse)
 - Incorrect products used for cleaning (e.g., wrong size brush)
 - High level disinfectant temperature or concentration not monitored

*Note: Example observations are provided for the Top 3 most frequently cited High Likelihood to Harm EPs.

Most Frequently Cited High Likelihood to Harm The Joint Commission

Clinical EPs: Example Observations* (cont.)

IC.02.01.01, EP 1 -The hospital implements its infection prevention and control activities, including surveillance, to minimize, reduce, or eliminate the risk of infection.

- Dishwasher temperatures were not monitored with each cycle.
- HEPA Filters are absent from the Pharmacy Chemo Clean Room and the Ante Clean Room.
- In the operating room and surgery suite, it was observed that clean items and equipment were co-mingled with dirty equipment.
- There were no routine surveillance cultures of the clean room.
- Personnel did not wear or did not remove PPE in a way that would prevent exposure.

*Note: Example observations are provided for the Top 3 most frequently cited High Likelihood to Harm EPs.

Most Frequently Cited High Likelihood to Harm



Clinical EPs: Example Observations* (cont.)

IC.02.02.01, EP 4 - The organization implements infection prevention and control activities when doing the following: Storing medical supplies and devices.

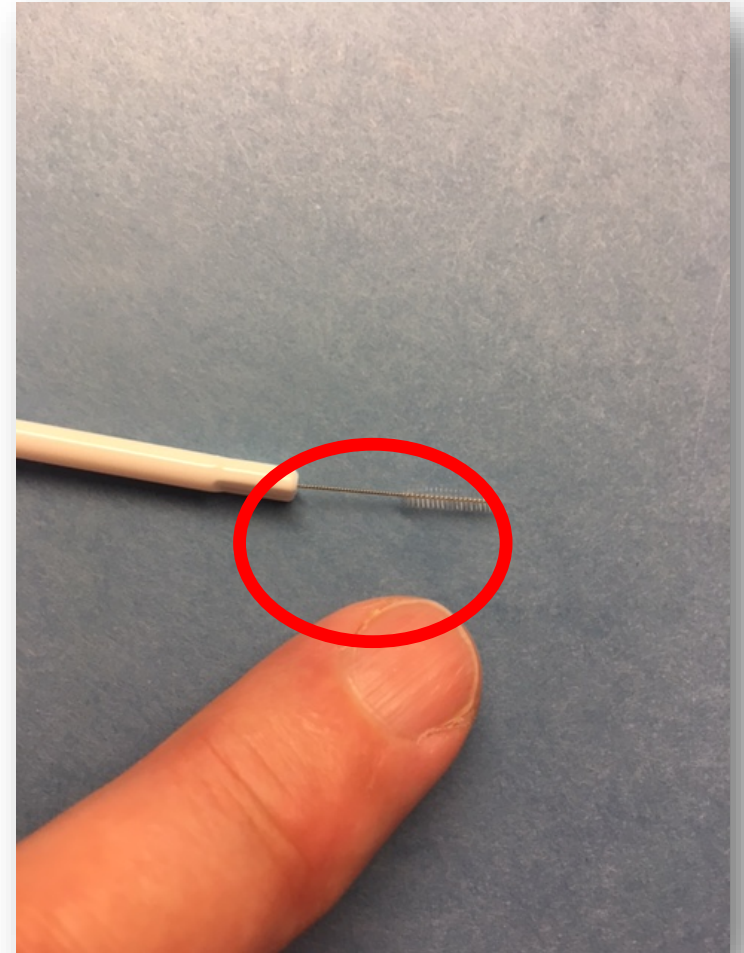
- Airway exchange devices and bougies in the operating rooms were stored in a location that was dirty or staff accessed them with soiled hands.
- Bronchoscopes were stored inside carrying (shipping) cases which are not cleanable.
- In the SICU storage area there were three wire racks being used to store sterile supplies. Wrapped supplies were being crushed by heavier trays and the rack did not have an impermeable barrier on the bottom shelf.

*Note: Example observations are provided for the Top 3 most frequently cited High Likelihood to Harm EPs.

Industry: Defining the Reusable Medical Device Problem

- GI endoscopes/bronchoscopes- every 2-3 years outbreak resulting in minor refinements that we are told will “fix” the problem; a few years latter another outbreak with life-threatening infections. This has continued for 40 years, we cannot continue to do the same thing repeatedly and expect a different result; must transition to sterilization.
- 8 MDRO outbreaks without breaches in endoscope reprocessing; editorials (e.g., Rutala, Weber. JAMA 2014) and FDA Panel (May 2015) recommend sterilization

Slide courtesy of William Rutala



Olympus's 2017 solution to the ERCP cleaning problem



Index Card Activity #2

Now, is your # 1 most pressing concern related to reprocessing reusable medical devices at your facility the same as it was in activity 1?



When the tidal
wave of change
comes, don't fight
the current.
Start looking
for a surf board.

~~~~~  
~~~~~

Behappy.me

First: HLD Education for all of us!

American
National
Standard



ANSI/AAMI
ST91:2015

Flexible and semi-rigid
endoscope processing in
health care facilities



Multisociety guideline on reprocessing flexible GI endoscopes: 2016 update

Prepared by: REPROCESSING GUIDELINE TASK FORCE

Bret T. Petersen, MD, FASGE, Chair, Jonathan Cohen, MD, FASGE, Ralph David Hambrick, III, RN, Navtej Buttar, MD, David A. Greenwald, MD, FASGE, Jonathan M. Buscaglia, MD, FASGE, James Collins, RN, Glenn Eisen, MD, MPH, FASGE

This article was reviewed and approved by the Governing Board of the American Society for Gastrointestinal Endoscopy (ASGE).

CMS: Infection Control Worksheet

Two multi-page documents specifically for inspecting infection prevention practices in acute care and ambulatory surgical facilities.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850



Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 15-43-ASC

DATE: June 26, 2015

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Advanced Copy - Update to Ambulatory Surgical Center (ASC) Infection Control Surveyor Worksheet (ICSW)

Memorandum Summary

- **ASC Infection Control Surveyor Worksheet Revisions:** The Centers for Medicare & Medicaid Services (CMS) has made minor revisions to the Infection Control Surveyor Worksheet, Exhibit 351 of the State Operations Manual (SOM) for assessing compliance with the Medicare ASC Infection Control Condition for Coverage (CfC).
- **Change:** Revisions were made to bring the worksheet into alignment with current accepted standards of practice; reflect recently released guidance; and improve the clarity of certain questions. The worksheet is used by State and Federal surveyors on all survey activity in

HIGH-LEVEL DISINFECTION

Practices to be Assessed	Was Practice Performed?	Surveyor Notes
A. Semi-critical equipment is high-level disinfected or sterilized	☐ Yes ☐ No ☐ N/A	
B. Is high-level disinfection performed on site? (If NO, Skip to "F")	☐ Yes ☐ No ☐ N/A	
(A "No" answer does not result in a citation, since ASCs are permitted to provide for high-level disinfection off-site, under a contractual arrangement.)		
(Surveyor to confirm there is a contract or other documentation of an arrangement for off-site sterilization by viewing it)		
a. If answer to B was YES, please indicate method of high-level disinfection:	☐ Manual ☐ Automated ☐ Other (please specify):	
C. Items are pre-cleaned according to manufacturer's instructions or, if the manufacturer does not provide instructions, evidence-based guidelines prior to high-level disinfection	☐ Yes ☐ No ☐ Unable to observe	

High-Level Disinfection (HLD) and Sterilization BoosterPak



 The Joint Commission

Updated June 2017

June, 2017

HICPAC Sample Audit Tool: Reprocessing Flexible Endoscopes

Purpose: Facilities can use this sample Audit Tool document as a template to develop their own audit tool specific to their endoscopes and evidence-based reprocessing practices. This sample tool is designed to be used in conjunction with the Competency Verification Tool. Facilities are encouraged to use these tools together to verify competency and audit current practice as well as to ensure that their practices are consistent with “Essential Elements of a Reprocessing Program for Flexible Endoscopes – Recommendations of the Healthcare Infection Control Practices Advisory Committee.”

Auditor: _____

Audit Item
<u>Precleaning</u>
Precleans the flexible endoscope
Discards the cleaning solution
Transporting

HICPAC Sample Competency Verification Tool: Reprocessing Flexible Endoscopes

HICPAC Sample Competency Verification Tool: Reprocessing Flexible Endoscopes

Purpose: Facilities can use this sample Competency Verification Tool as a template to develop their own tool to assess the competency of personnel tasked with processing all types of reusable flexible endoscopes and accessories. This sample tool is designed to be used in conjunction with the Audit Tool. Facilities are encouraged to use the tools together to verify competency and audit current practice as well as to ensure that their practices are consistent with “Essential Elements of a Reprocessing Program for Flexible Endoscopes – Recommendations of the Healthcare Infection Control Practices Advisory Committee.”

Name: _____ Date: _____

DEM = Demonstration S = Skills Laboratory RWM = Review of Written or Visual Materials/Policy V = Verbalization
 DO = Direct Observation SBT = Scenario-based Training P&P = Procedure Review (Specify P&P #s _____) O = Other: _____
 DA = Documentation Audit CS = Controlled Simulation KAT = Knowledge Assessment Test

Competency Statements/Performance Criteria	Verification Method [See legend above]	Not Met [Explain why]
<u>Precleaning</u> 1. <u>Precleans</u> flexible endoscopes and accessories at the point of use as soon as possible after the endoscope has been removed from the patient (or the procedure is completed) and before organic material has dried on the surface or in the channels of the endoscope.	☐ DEM ☐ S ☐ RWM ☐ V ☐ DO ☐ SBT ☐ P&P ☐ Other ☐ DA ☐ CS ☐ KAT	

Remember this?

Table of Contents for Olympus Q180V

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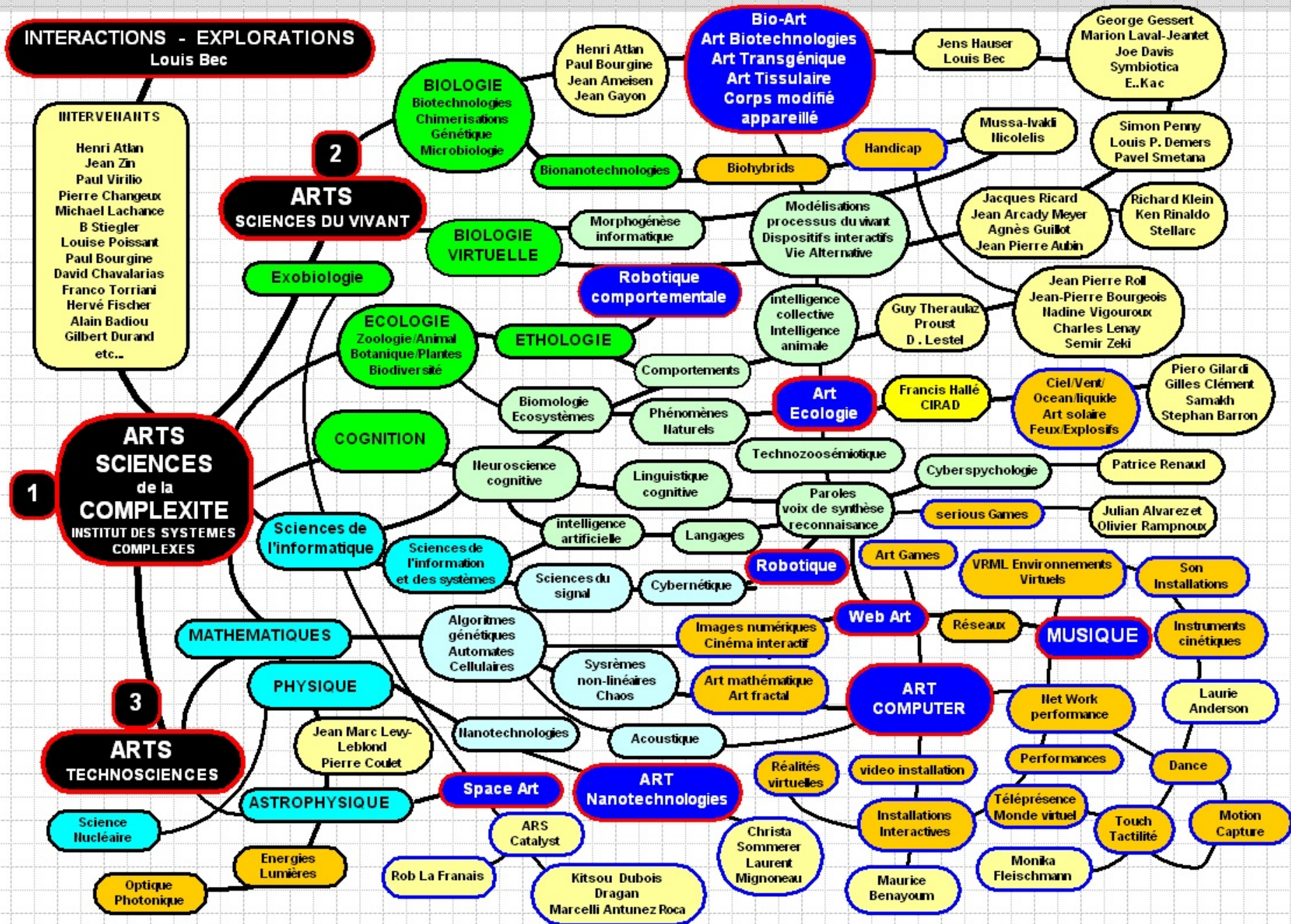
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111 pages?

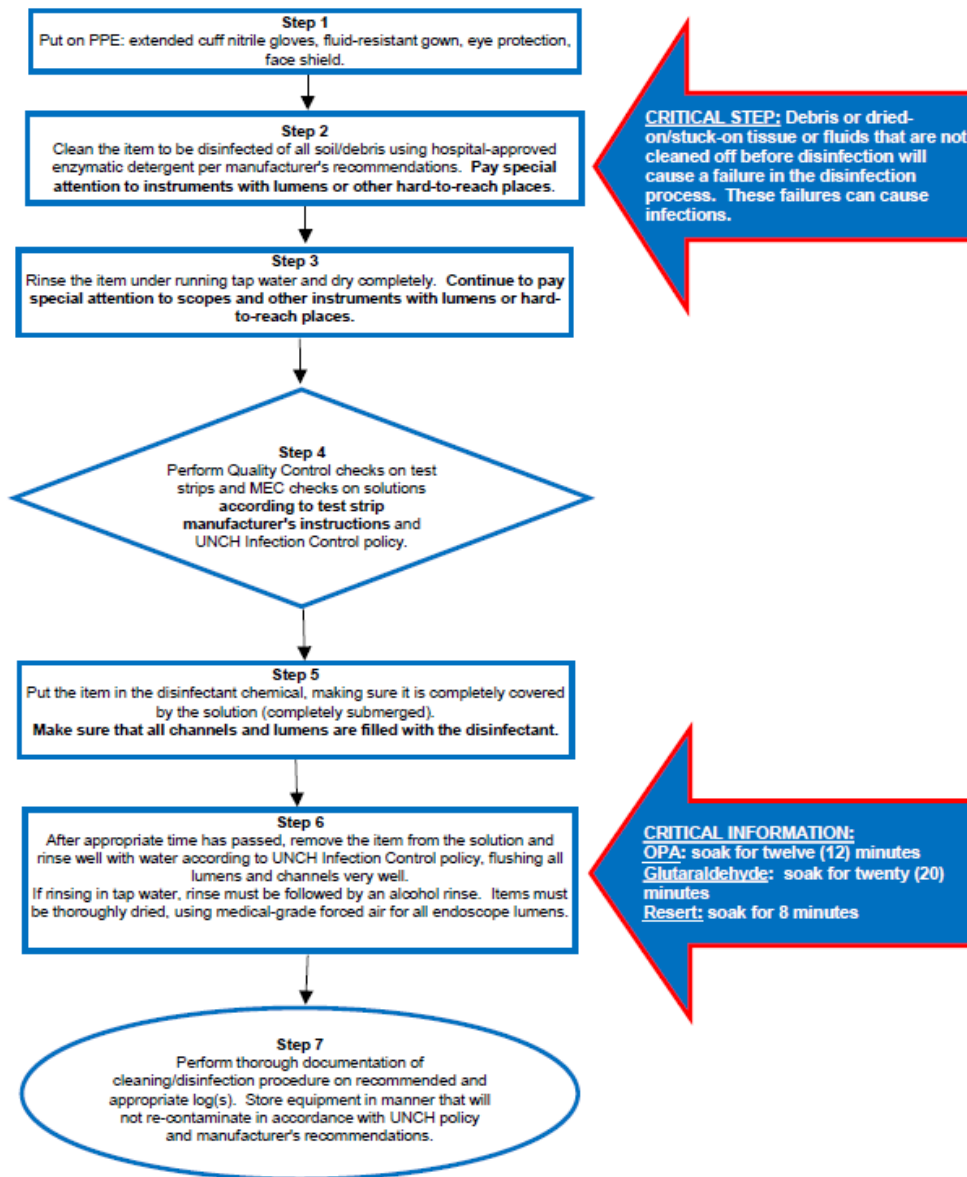
The quest...



...for a simplified HLD algorithm



Steps for High Level Disinfection of Equipment Using Glutaraldehyde, OPA, or Resert®



UNCH's HLD Workshop and Refresher Class

UNC Infection Prevention Policy:

1. Initial 3-hour workshop required for any staff with HLD responsibilities – NOT a train-the-trainer class
2. Yearly 1-hour refresher class required (Webex available)



High Level Disinfection (HLD) Workshop



Upcoming Workshops:

February 16, 2016 at HBH from 9:00am-12:00pm
Hillsborough Hospital Conference Room: HBT 11002

March 15, 2016 at HBH from 9:00am-12:00pm
Hillsborough Hospital Conference Room: HBT 11002

April 19, 2016 at HBH from 1:00pm-4:00pm
Hillsborough Hospital Conference Room: HBT 11002

May 17, 2016 at HBH from 9:00am-12:00pm
Hillsborough Hospital Conference Room: HBT 1002

At this workshop you will:

- ◆ Learn how to high-level disinfect semi-critical devices
- ◆ Understand your responsibilities related to HLD
- ◆ Learn the pitfalls of inadequate high-level disinfection
- ◆ Learn about OSHA regulations related to high level disinfectants
- ◆ Earn 3 nursing contact hours!

Online Registration

CLICK HERE

Please register online at:
<https://survey.unch.unc.edu/TakeSurvey.aspx?SurveyID=5568>
Please email Judie Bringhurst, MSN, RN CIC
for additional information at
judie.bringhurst@unchealth.unc.edu

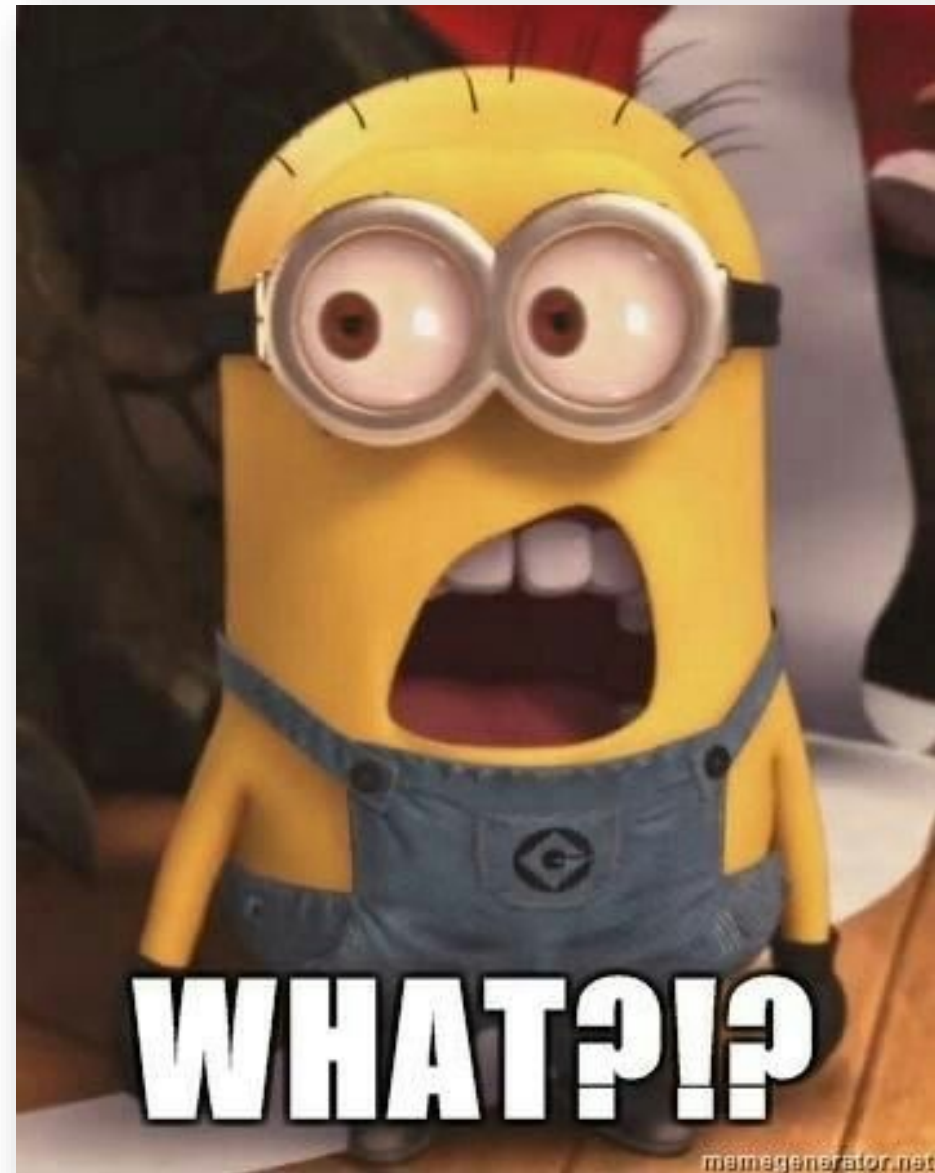






**Computer-based
training does not
work for HLD!**

But it's better than nothing.



Second: single use, sterile devices

Sterile, single use endoscopes – bronchoscopes, GI endoscopes, nasopharyngeal endoscopes, cystoscopes, ureteroscopes, duodenoscopes with single use disposable tips – All FDA cleared.

We ask our providers who may exhibit some skepticism: “Is the image and/or function good enough?” and then leave it up to them, after adequate education regarding HLD, which to choose for their patients.

We LOVE physicians that are willing to trial some of these new devices!



Third: HLD Monitoring and Quality Improvement:
Instrument reprocessing checklists and
competencies

Instrument Processing Checklist with Answers 2018	
Instrument Reprocessing	
All reusable equipment is high-level disinfected or sterilized according to manufacturer's instructions and/or evidence-based guidelines and according to UNC Cleaning, Disinfection, and Sterilization of Patient-Care Items policy.	
Please continually reassess all instruments being reprocessed by HLD or sterilization to see if there are disposable substitutes	
All elements in the instrument reprocessing sections are consistent with the UNCH Cleaning, Disinfection, and Sterilization Policy, IC 0008	
The Standards	How to Achieve the Standards

Multiple sections:

1. Decontamination/pre-cleaning
 2. High-level disinfection
 3. Sterilization
 4. Trophon
 5. General decontamination/HLD/Sterilization
- Finely detailed and **specific to products in use at UNCH.**
 - At least 2 surveys using the checklist are performed in every HLD area per year.
 - Areas have 30 days to address areas that require improvement and must do so in writing.
 - Serious deficits are not only corrected immediately but that information is forwarded to their Associate Vice President.

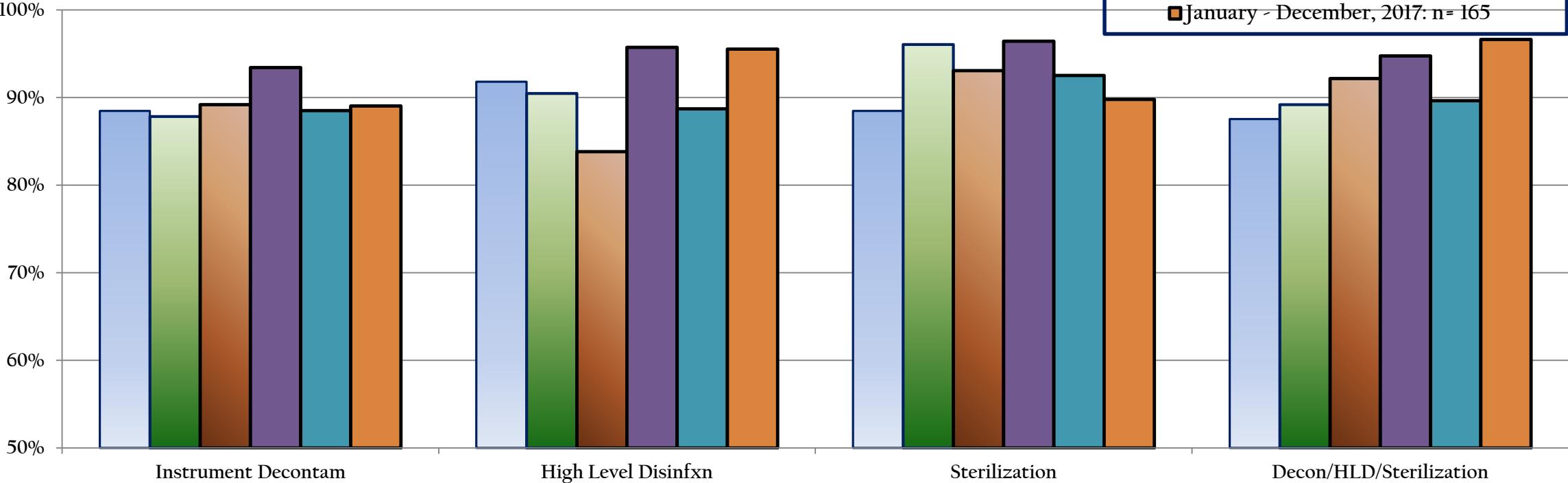
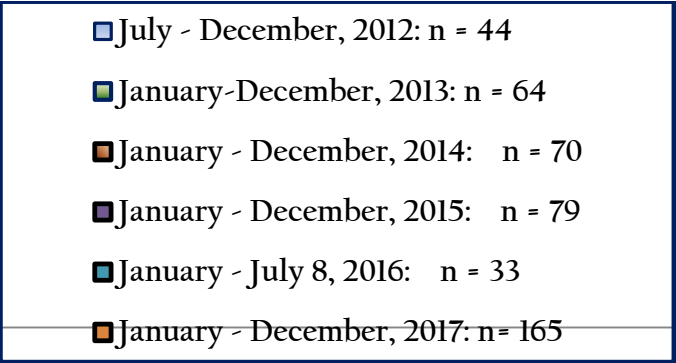
Instrument Reprocessing Survey Report 2018

Survey Date:			Infection Preventionist:
Area:			Area AICL:
Area Manager:			Total Infection Prevention Compliance: #DIV/0!

Standard	Met	Opportunity for Improvement	N/A	Notes
13. Instrument Decontamination/pre-cleaning				
a. Items are thoroughly pre-cleaned and decontaminated with enzymatic detergent according to manufacturer instructions and/or evidence-based guidelines prior to high level disinfection or sterilization.				
b. Enzymatic detergents - measured.				
c. Enzymatic detergents - measuring tools.				
d. Enzymatic detergents - basins/tubs marked.				
e. Enzymatic detergents - digital timer.				
f. Transporting used (dirty) equipment to instrument reprocessing area.				
g. Manufacturer's instructions for cleaning and/or disinfection for every item reprocessed.				
	0	0		
Percent Met	#####			
14. High Level Disinfection				
a. Medical instrument and devices are visually inspected for residual soil and re-cleaned as needed before high-level disinfection.				
b. HLD equipment (e.g., AER) is maintained according to manufacturer instructions and/or evidence-based guidelines.				
c. Chemicals used for HLD are prepared according to manufacturer instructions, UNC infection control policy, and evidence-based guidelines - only use approved products.				
d. Chemicals used for HLD are prepared according to manufacturer instructions, UNC infection control policy, and evidence-based guidelines - instructions read and followed.				
e. HLD expiration date must be affixed to original containers and secondary containers.				
f. Containers of HLD chemicals must be labeled with chemical name, hazard information and expiration date.				
g. Containers of HLD chemicals must be covered.				
h. Items that undergo HLD are dried before re-use.				
i. HLD logs are in order - daily entry.				

**UNCH Outpatient Care Facilities
Infection Prevention Rounds Data
July, 2012 - December, 2017**

Pooled Means



Checklists and Competencies...

HICPAC Competency:
12 pages

HICPAC Sample Competency Verification Tool: Reprocessing Flexible Endoscopes

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Checklists and Competencies...

HICPAC Auditing Tool: 3 pages

HICPAC Sample Audit Tool: Reprocessing Flexible Endoscopes

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Auditor: _____ **Date:** _____

Audit Item	Yes	No	Comments/Action
Precleaning			
Precleans the flexible endoscope at the point of use.			
Discards the cleaning solution and cloth after use.			
Transporting			
Transports the contaminated endoscope and accessories to the endoscopy processing room as soon as possible after use.			
Ensures the container or cart is labeled with a biohazard legend.			
Leak Testing			
Performs leak testing before manual cleaning if indicated.			
Manual Cleaning			
Uses a freshly prepared cleaning solution and does not add additional products to the water unless recommended by the manufacturer.			

Essential Guidance: CDC

Essential Elements of a Reprocessing Program for Flexible Endoscopes – Recommendations of the Healthcare Infection Control Practices Advisory Committee



Preface

The Healthcare Infection Control Practices Advisory Committee (HICPAC) is a federal advisory committee chartered to provide advice and guidance to the Centers for Disease Control and Prevention (CDC) and the Secretary of the Department of Health and Human Services (HHS) regarding the practice of infection control and strategies for surveillance, prevention, and control of healthcare-associated infections, antimicrobial resistance and related events in United States healthcare settings. **At the July 2015 HICPAC Meeting, CDC asked HICPAC for guidance on ways to improve facility-level training and ensuring competency for reprocessing endoscopes.** To develop recommendations for HICPAC to consider, a HICPAC workgroup was



Thousands of known human infections (and thousands more unknown) are associated with failures in HLD – either human or engineering failures.

All health care personnel are responsible for giving solvable issues our attention immediately.

Industry is responsible for immediately creating engineering controls on devices that make it difficult to infect a patient...such as single use, sterile devices and sheaths.

We, Infection Preventionists, are responsible for continuing the pressure on industry to do so.



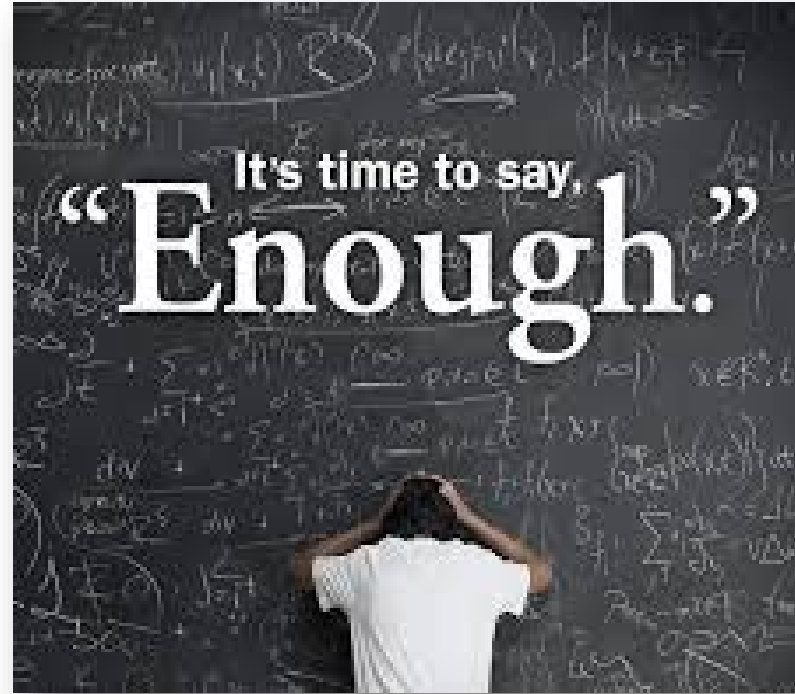
There has never been a time in which we must partner with industry like we must partner today

- Infection Prevention must be engaged with industry at a level not seen before
- Industry must be engaged with Infection Prevention at a level not seen before

Peter the Pushy Salesperson and the Infection Preventionist



Antidote: Educated IPs



Where we go from here and
Our First Step after today
(like, on **Monday**)

**Step One...GEMBA: go to the place
of the action:**

**Tuck ANY HLD Guideline under your arm
and**

**walk into
your scope processing room, your instrument
processing room, your instrument processing
closet and start a conversation.**



- **Your instrument reprocessing sites need** your attention, knowledge and assistance. (They may not know that yet!)
 - Documented patient safety issues take priority over all else in healthcare.
 - Document, document, document and then let leaders know what you find.

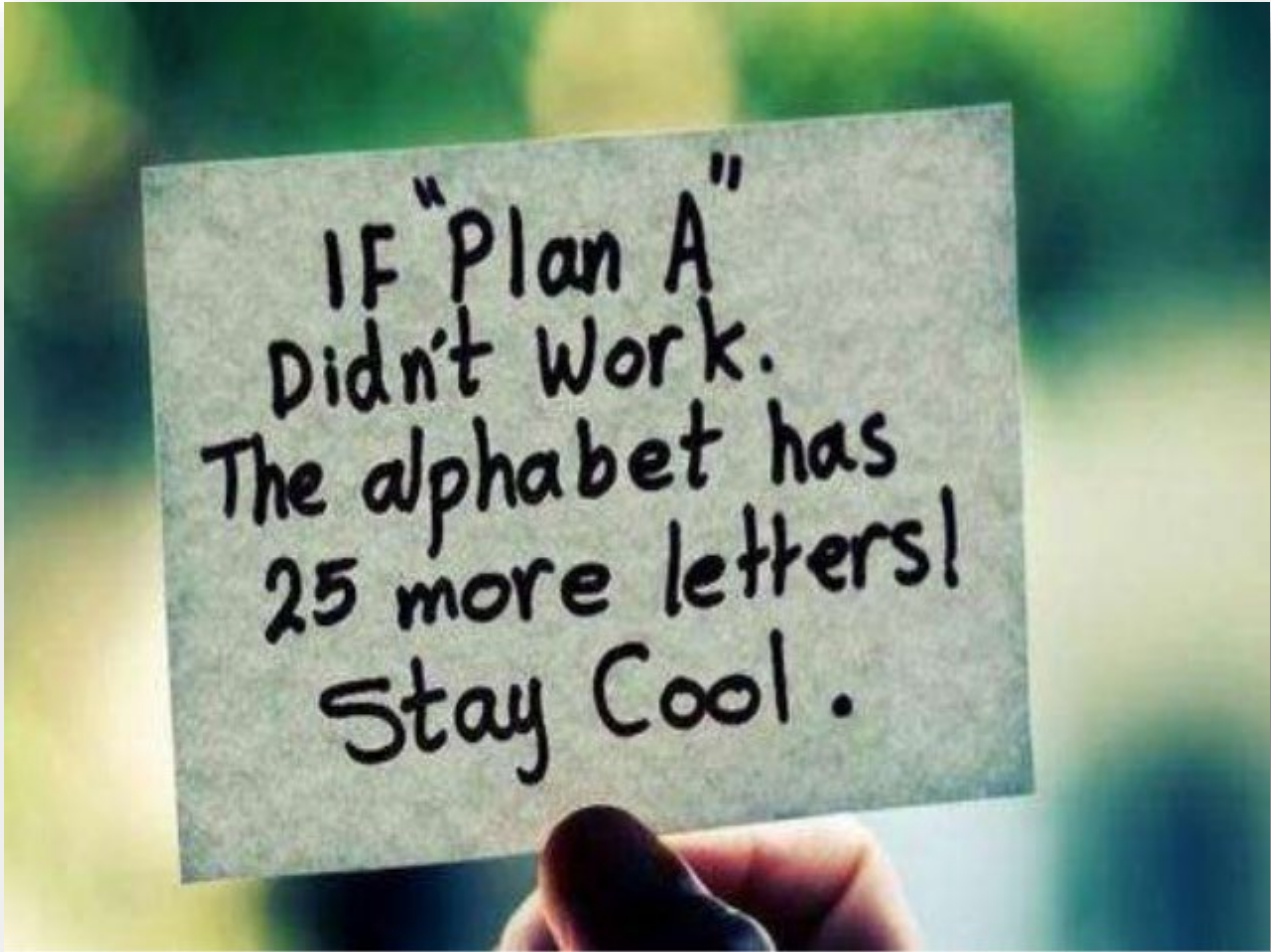
It was a mistake for me to assume people who HLD everyday
know the right way to do it.

Guarantees

- **We *CANNOT*** always make it perfect or even consistent with regulations and guidelines.
- **We *CAN* always** make it better and safer for our patients and our staffs. **I personally guarantee that.**
- Just start your first visit...the rest will happen for you automatically.

Take a phased approach to correction.

- Take time to research your findings in the evidence-based literature and guidelines
- Document your researched findings with citations
- Plan your actions based on the evidence and national evidence-based guidelines
- Inform area leaders
- Assist your staff with fixing the most dangerous practices first
- Move forward with other fixes in order of priority

A close-up photograph of a person's hand holding a small, rectangular piece of off-white paper. The paper has handwritten text in black ink. The background is a soft-focus green, suggesting an outdoor setting with foliage. The lighting is natural and bright.

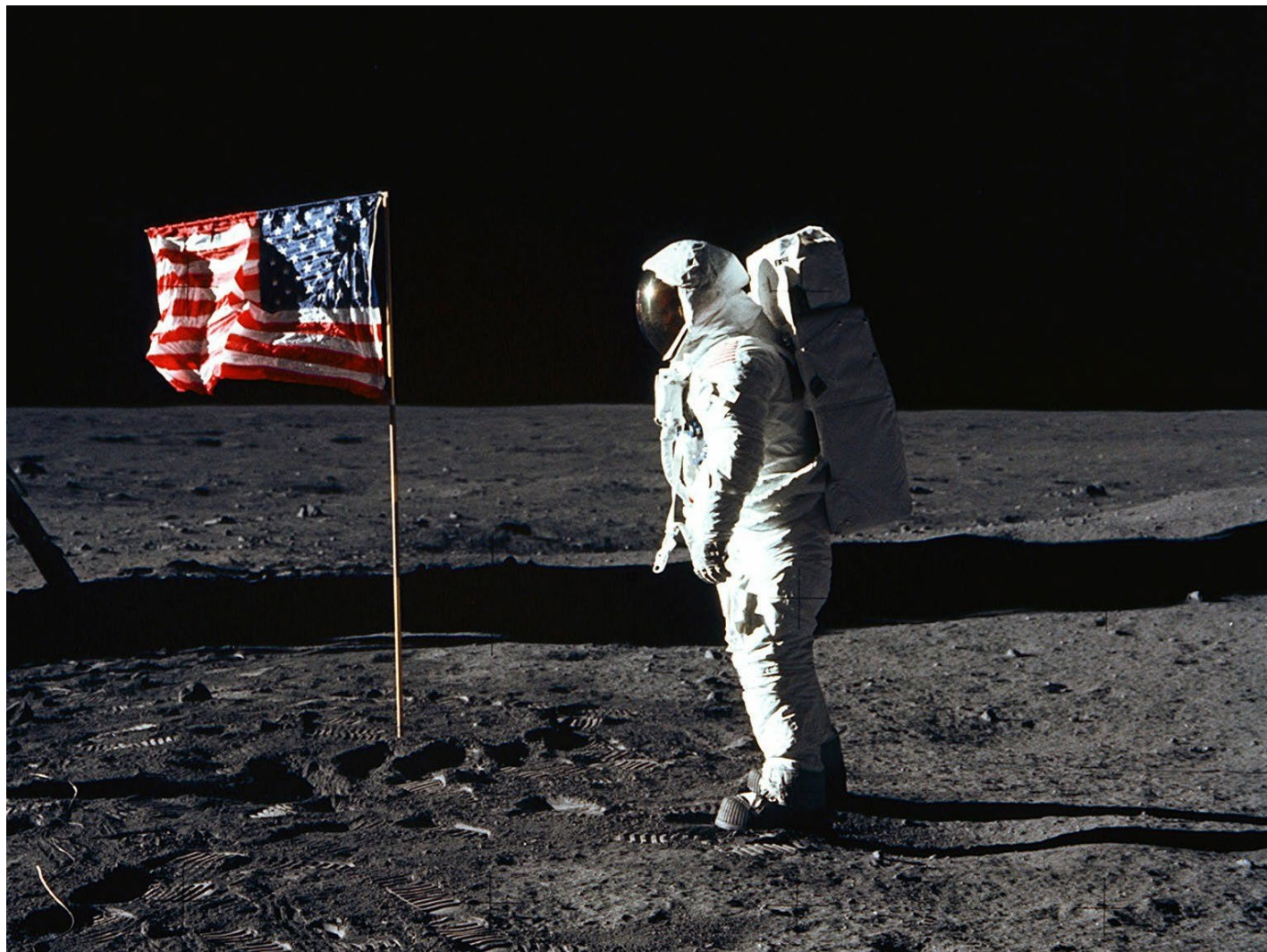
IF "Plan A"
Didn't Work.
The alphabet has
25 more letters!
Stay Cool.

Once we, Infection Prevention, are fully engaged, the myriad elements and complexities of HLD within our facilities will lead us where they need us to go.

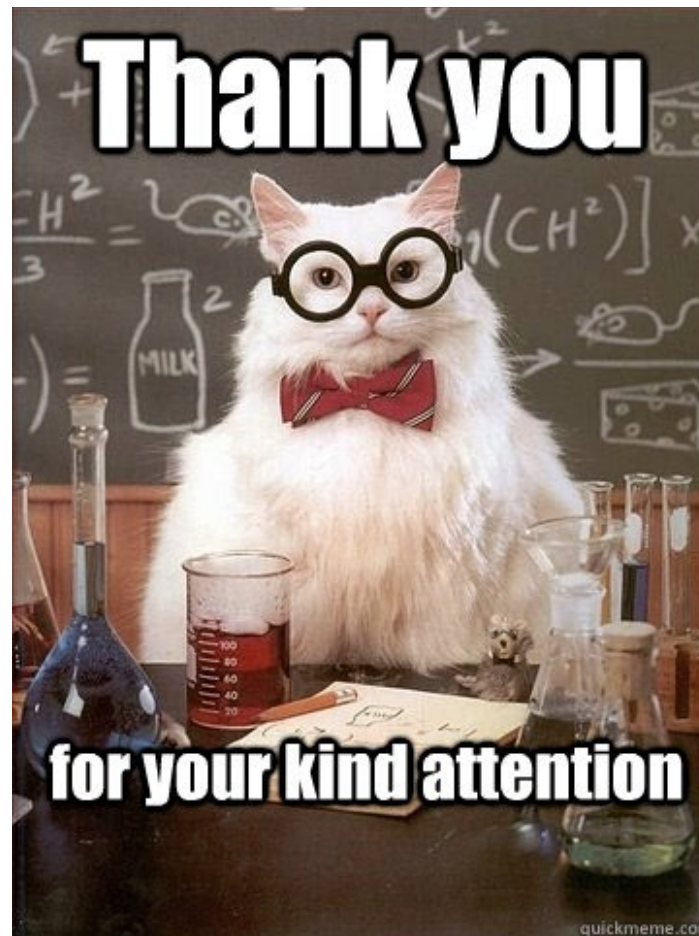


Now, turn to someone sitting close to you and tell each other what your plan for improvement is for next week at your facility.

Jot your plan down.



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Thank you to Drs. Rutala, Weber, and Sickbert-Bennett and all my colleagues at UNC Health Care. Without every one of my colleagues in Chapel Hill, this presentation would not be possible. They have given me all the opportunities I asked for (and some I didn't).



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QUESTIONS?



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Infection Control and Epidemiology