3M Infection Prevention Solutions

Cleaning Endoscopes: Up Periscope! Is there danger ahead? Re-thinking the Risk for Endoscopy-Associated Infections

San Francisco Bay Area APIC
February 11, 2015
Eden Medical Center
Castro Valley, CA

3M

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Learning Objectives

- Summarize recent articles related to the increased risk for endoscopy-associated infections.
- Learn why assumptions on the effectiveness of endoscopy reprocessing is currently being re-evaluated
- Discuss some strategies for strengthening quality improvement programs.

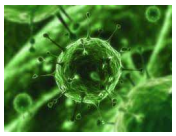
- *All images are from Google images unless otherwise indicated*

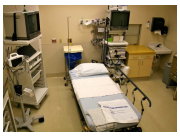
More than 20 million GI endoscopic procedures are performed every year in the USA.

GI endoscopy is considered a very safe procedure.

What is the incidence of pathogen transmission?

Experts assume it is a rare event….





Are the assumptions valid

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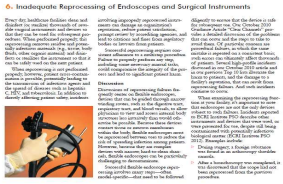
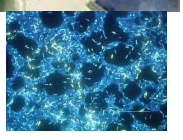
#4 ECRI Top Ten Healthcare Hazards for 2015, Up from #6 in 2014 and still top 10 from 2011, #3

"Although the incidence is likely very low, the consequences of reprocessing failures can be severe. Of the 13 immediate threat to life (ITL) discoveries from the Joint Commission surveys conducted in 2013, seven were directly related to the improper sterilization or high-level disinfection of equipment (Joint Commission 2014). This topic, which has appeared on our Top 10 Health Technology Hazards list in the past, retains a spot near the top because we continue to see media reports, receive problem reports, and investigate cases involving the use of potentially contaminated instruments on patients."



6. Inadequate Reprocessing of Endoscopes and Surgical Instruments

What are the assumptions?



- Reprocessing guidelines are effective and produce scopes that are clean and ready to use
- Endoscopy-associated infections are rare
- Reprocessing guidelines are being followed and lapses are rare

Assumptions and Risk Assessment Drives Behavior

- When are patients notified? What do we tell them?
- Do we report the lapse? Do we even know when one has occurred?
- What actions do we take when a lapse occurs?

"Flexible endoscope reprocessing has been shown to have a narrow margin of safety. Any slight deviation from the recommended reprocessing protocol can lead to the survival of microorganisms and an increased risk of infection."

Alfa, M.J., *et al.* (2006). *American Journal of Infection Control, 34(9), 561-570.*

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Assumption #1:
Reprocessing guidelines are being followed and lapses are rare.

- ***"My people are following guidelines and are doing a good job, they aren't making mistakes."***
- ***"These are good people who work hard and do their job well"***
- ***"We are following SGNA guidelines to the letter."***

Assumption 1: Reprocessing guidelines are being followed and lapses are rare.

Unresolved Issues and Controversy

No longer debated are the successes of infection prevention used regarding equipment care. Due to strict adherence to high-level disinfection protocols and reprocessing guidelines, infection rates associated with endoscopy procedures are now 1 in 1.8 million procedures.

Endoscopy Suite Equipment: Cleaning, Care and Controversies, Kay Miller Temple, EndoNurse, April 2014

"Although reprocessing lapses resulting in patient exposure to contaminated endoscopes are common, they are rarely reported in medical journals"
Reporting Lapses: What are we Missing? Cori L. Ofstead, PhD. et al 2013

"Recommended reprocessing may not eliminate clinically-relevant biofilm."
Transmission of multidrug-resistant organsims and other pathogens via contaminated endoscopes: Can buildup of biofilm be eliminated by routine cleaning and high-level disinfection? Michelle J. Alfa, PhD, et.al. 2013

Lead the Way

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Assumption #1:
Reprocessing guidelines are being followed and lapses are rare.

- **Reprocessing lapses are rarely reported in medical journals leading to the false conclusion that reprocessing lapses are rare.**
- **A recently published study looked for reprocessing lapses in peer-reviewed literature, gov't reports, state health depts, CDC, FDA, Dept of Veteran affairs and media reports The study was limited to Jan. 2005 – June 2102.**
  - **They found that improper endoscope reprocessing is an ongoing and pervasive problem**
  - **In Table 1, if you add up the number of estimated exposed patients you come up with over 30,500 people exposed and this is just the tip of the iceberg. > 99% of these cases were not found in peer-reviewed medical journals**

Reported gastrointestinal endoscope reprocessing lapses: The tip of the iceberg.

Alexandra M. Dirlam-Langlay, Cori L. Ofstead, Natalie J. Mueller, Pritish K. Tosh, Todd H. Baron, Harry P. Wetzler; American Journal of Infection Control, 41 (2013) 1188-94

Table 1
Lapses published in media reports and related sources; North America, January 2005 June 2012

Type of health care facility	Location	Pub. Year	Type of endoscope	Errors	Estimated duration of lapse	Estimated patients: Exposed	Notified	Tested	Tested positive	Microorganisms found
Private hospital[9,10]	North Carolina	2012	GI endoscope NOS	No cleaning or sterilization for 1 channel	5 months	10	Yes	Yes (viral)	ND	ND
Outpatient endoscopy clinic[20,21,72]	Ontario	2011; 2012	GI endoscope NOS	Multiple reprocessing and chemical issues	9 years	6,900	Yes	Yes (viral)	408	Hepatitis B; hepatitis C
Academic medical center[34,35]	Louisiana	2011	GI endoscope NOS	No HLD	8 months	222	Yes	Yes (viral)	ND	ND
Private medical center[18,19,36]	Oregon	2011	Colonoscope	No HLD	ND	18	Yes	Yes (viral)	ND	ND
Academic medical center[37,38]	Louisiana	2011	GI endoscope NOS	Inadequate HLD temperature	8 weeks	360	Yes	Yes (viral)	ND	ND
Public hospital[39,73,74,86]	British Columbia	2010; 2011	Duodenoscope	Improper reprocessing; Endoscopes not cleaned before reprocessing	20 months	516	Yes	Yes (viral)	31	Pseudomonas; hepatitis C; HIV*
Public hospital and academic medical center[25,83]	Minnesota	2010	GI endoscope NOS	Improper HLD of 1 channel	3 years	2,000	Yes	No	ND	ND
Private medical center, hospital, and outpatient surgery center[14,82,83]	California	2010	Colonoscope	Improper HLD; Expired disinfectant	16 months	3,600	Yes	Yes (viral)	ND	ND
Private hospital[75,76,84]	Pennsylvania	2010	GI endoscope NOS	Improper HLD of 1 channel	5 years	75	Yes	Yes	ND	ND
Public hospital[77,78,84]	British Columbia	2010	Colonoscope; Gastroscope	No HLD for 1 channel	20 months	9,000	Yes	No	ND	ND
Two county hospitals and a regional cancer treatment center[79,80]	Florida	2009; 2010	Duodenoscope	Improper cleaning of elevator channel	≥8 months	191	Yes	Yes	13	Klebsiella pneumoniae (carbapenemase-producing); Escherichia coli (carbapenemase-producing); Pseudomonas aeruginosa; Proteus mirabilis; Serratia
Outpatient surgery center[81,85,86]	Georgia	2009; 2010	Colonoscope	Inadequate HLD time	17 months	1,200	Yes	Yes	ND	ND
Public hospital[44,48]	Newfoundland and Labrador	2009	GI endoscope NOS	Inadequate disinfectant amount; AER malfunction	17 months	2,900	ND	ND	ND	ND
Outpatient surgery center[45,87]	Nevada	2008; 2009	GI endoscope NOS	Inadequate HLD time	2 years	ND	Yes	Yes	ND	ND
GI facility NOS[88]	U.S. NOS	2008	Colonoscope	Improperly cleaned, contaminated, damaged endoscope	Single incident	1	ND	ND	ND	ND
Public hospital[49,50,51,88,89]	Alberta	2007; 2008	Endoscope NOS	Improper cleaning and HLD; No diastemicity	4 years	2,872 (500 due to endoscopes)	Yes	Yes (viral)	ND	Staphylococcus aureus (methicillin-resistant)
Two private hospitals[52,90,91]	California	2006	Gastroscope	Improper reprocessing	>1 year	305	Yes	Yes	ND	ND
Private hospital[92]	West Virginia	2006	Endoscope NOS	Improper HLD	10 months	"1000s"	Yes	ND	ND	ND
Private hospital[93,94]	Pennsylvania	2005	Colonoscope	No HLD of auxiliary channels	4 months	200	Yes	Yes (viral)	ND	ND
Private hospital[95,96]	Virginia	2005	GI endoscope NOS	Inadequate HLD time	10 days	344	Yes	Yes (viral)	ND	ND
Private hospital[98,99]	California	2005	GI endoscope NOS	Multiple equipment and operator issues	ND	2,116	Yes	Yes (viral)	ND	ND

AER, automated endoscope reprocessor; GI, gastrointestinal; HLD, high-level disinfection; ND, not disclosed; NOS, not otherwise specified.
*Indicates previously identified cases that tested positive.

AJIC Dirlam-Langlay et al / American Journal of Infection Control xxx (2013) 1-7

30,577 Pts exposed through endoscopes, MRSA, K pneumonia (CRE), Hep B, HepC

Why are flexible endoscopes difficult to reprocess?

- Complex design
- Multiple, long, narrow, channels that are difficult to clean
- Lack of consistent effective training
- Lack of time and resources for adequate reprocessing
- Visual inspection not adequate to monitor efficacy of reprocessing.
- > 120 step involved in reprocessing!!

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Basic steps for Reprocessing Flexible Endoscopes

- **Pre-cleaning – Bedside**
- **Transport to Reprocessing - <1 hour**
- **Manual Cleaning**
- **Rinsing**
- **High-level disinfection – Manual, Automated (AER)**
- **Drying (Alcohol flush, Air flush)**
- **Storage**

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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

Guidelines were followed only 1.4% of the time (manual cleaning followed by automated high-level disinfection) vs 75.4% using ECR (automated cleaning and disinfection)

Multiple steps skipped 45% of the time.

Ofstead, Cori L., Wetzler, Harry, P., Alycea Snyder, Rebecca A. Horton Endoscope Reprocessing Methods: A Prospective Study on the Impact of Human Factors and Automation. 2010 Gasteroenterology Nursing. Vol 33, No. 4, pp. 304-311

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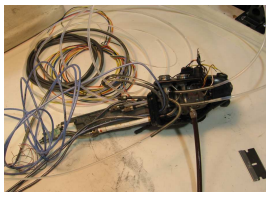

"***The biggest problem is that we can't see inside these scopes. To put it bluntly, we're just taking a shot in the dark with reprocessing."***

- ***Nancy Chobin, RN, St. Barnabas Health Care System. Livingston, New Jersey***
- "Probing the Challenges of Endoscopes"
- Biomedical Instrumentation & Technology May/June 2011

Assumption 2: When guidelines are followed the result is an endoscope that is clean and safe

IS THIS SCOPE CLEAN?

WHAT DOES YOUR GUT TELL YOU?

Looks can be deceiving. This scope only received pre-cleaning in the patient room after the procedure. The Relative Light Unit (RLU) reading for the exterior of the distal tip was 633 RLU's

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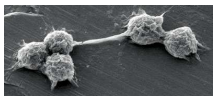
Assumption 2

When guidelines are followed the result is an endoscope that is clean and safe

"We are following the reprocessing guidelines so our scopes are clean and safe to use on our patients. Are you saying our scopes are not clean?"

Even after proper reprocessing your scopes could still be dirty



Water Pressure and Connectors Do They Matter?

Of course they do

- Low pressure purging outlets are used to irrigate the scope channels
- High pressure purging is designed to irrigate the smaller/hard to reprocess channels (e.g. Aux. water channel, Duodenoscope (ERCP) elevator wire channel)

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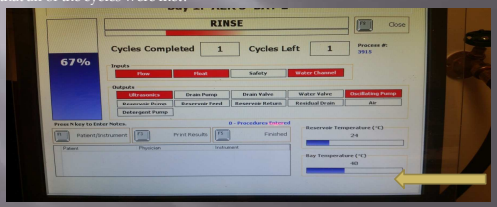
Time & Water Temperature

- Custom Ultrasonics AER recommends a H20 setting of 110 degrees F/43 degrees C
- Temperature should not exceed 115 F/46 C and should NOT drop below 105 F/40 C
- Immersion time requirements are based on the detergent, enzymatic and high level disinfection manufactures Instructions for Use (IFU)
- Questions to ask ourselves: Did the temperature meet its requirements? Has the scope been immersed long enough to meet the manufactures IFU? Have I ensured that all of the cycles were met?



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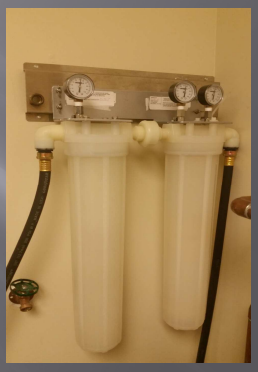
Water Quality & Filters

- In the U.S. as we know water quality varies and thus could affect the outcome of a process.
- Potable water although containing a low number of water borne microorganisms can still pose a risk when reprocessing flexible endoscopes.
- Some questions to ask: Are water softeners needed? Do we need a filtration system? If so what type?
- Custom Ultrasonics uses two different filter in their Automated Endoscope Reprocessors (AER's) that require routine changes.
  a. .5 micron filter for removing gross sediment from water
  b. 0.1 micron bacterial



.5 micron filter 0.1 micron bacterial filter

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All Scopes are NOT created equal

DUODENOSCOPE WITH ELEVATOR WIRE CHANNEL

DUODENOSCOPE WITHOUT ELEVATOR WIRE CHANNEL

KAISER PERMANENTE

Assumption 2

When guidelines are followed the result is an endoscope that is clean and safe

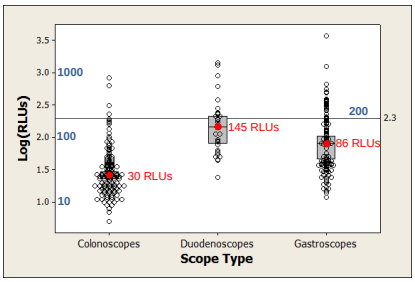
- Michelle Alfa *et al. 2012.* **Establishing a clinically relevant bioburden benchmark: A quality indicator for adequate reprocessing and storage of flexible gastrointestinal endoscopes.** American Journal of Infection Control 40 p. 233-236.
- **Issues addressed:** Assess the bioburden level in routinely reprocessed flexible GI endoscopes that were stored over a week-end and to define a realistic benchmark for residual microbial levels.
- **Findings**: **14.1% of scopes tested had detectable growth after reprocessing.**
- **Conclusions and Recommendations:** A benchmark of < 100 cfu/mL is achievable.

Bommarito, Marco, Grace Thornhill, Dan Morse. *A Multi-site Field Study Evaluating the Effectiveness of Manual Cleaning of Flexible Endoscopes using an ATP Detection System.* Oral Poster presentation. Session 2109, Publication 40. APIC2013 Ft. Lauderdale, FL. June 9,2013

- **This abstract won the William A. Rutala Abstract Award—recognizes the best abstract on the subject of disinfection, sterilization, or antisepsis.**

- **Summary**
  - 3 out of 20 scopes used to examine GI tracts and colons were improperly cleaned

Comparison by Type of Scope



- One-way ANOVA p-value<0.0005. All pair wise p-values are less than 0.05
- Manual cleaning of colonoscopes resulted in significantly lower RLU levels than gastroscopes and duodenoscopes.
- We observed failure rates in the manual cleaning step to be highest for duodenoscopes (30% failure rate, 10/30) and gastroscopes (24%, 28/116) and lowest for colonoscopes (3%, 4/129).

#APIC2013 Annual Educational Conference & International Meeting APIC 2013 FT. LAUDERDALE, FL JUNE 8–10

Reprocessing might not be enough to remove biofilm

American Society for Microbiology, Denver, CO, May 18-21, 2013

Transmission of multidrug-resistant organisms and other pathogens via contaminated endoscopes: Can buildup of biofilm be eliminated by routine cleaning and high-level disinfection?

Alexandra Dirlam Langlay, Ph.D[1]., Pritish Tosh, MD[2], Michelle Alfa, Ph.D., PhD[3,4], Harry P. Wetzler, MD, MSPH[1],Cori L. Ofstead, MSPH[1] [1] Ofstead and Associates, Inc., St. Paul, MN, [2]Mayo Clinic, Rochester, MN, [3] Diagnostic Services of Manitoba, Winnipeg, MB, Canada; [4] University of Manitoba, Department of Medical Microbiology, Winnipeg, MB, Canada.

Issues addressed:

To assess the effectiveness of current reprocessing methods at preventing biofilm formation or removing it from endoscope channels.

Findings/Conclusions

- Biofilm (containing pathogens) can persist in fully-reprocessed endoscope channels
- Reprocessing deficiencies due to complex endoscope design
- Recommended reprocessing may not eliminate clinically relevant biofilm.

Even if the scope is contaminated, the microbes are usually harmless and besides, the scope is being used in non-sterile sites of the body….

Examples of microbes found on endoscopes or in scope-related outbreaks

Acinetobacter baumanii
Aspergillus spp
Burkholderia
Candida glabrata
Clostridium difficile
Enterobacteriaceae
Enterococcus spp
E. coli
Mycobacterium chelonae
Mycobacterium fortuitum
Ochrobacterum anthropi
Proteus mirabilus
Psuedomonas aeruginosa
Salmonella spp
Serratia spp
Staphylococcus aureus (MRSA)
Viruses: Hepatitis B &C, HIV, Condyloma
Klebsiella pneumoniae (CRE)

Assumption 3: Endoscopy-associated infections (EAI) are rare and often inconsequential

Assumption 3:
Endoscopy-associated infections (EAI) are rare and often inconsequential

"The risk of EAI is extremely rare, 1 in 1.8 million procedures. Even if our patients were exposed we have not seen any problems."

There is now compelling evidence that the current risk estimate is wrong and that pathogens are being transmitted at a much higher rate than originally thought.

The current risk estimates are wrong :
Cori Ofstead, MSPH and Associates/Mayo

- Ofstead, Cori, L., Alexandra M. Dirlam Langlay, Natalie J. Mueller MPH, Pritish K. Tosh, Harry P. Wetzler. 2013. **Re-evaluating endoscopy-accosiated risk estimates and their implications**. *American Journal of Infection Control*. 41 p734-6.
- **Issues addressed:** Evaluate the origins and accuracy of the risk estimates after a single outbreak involved more cases of EAI that would be expected in 1 year nationwide.
- **Findings:**
  - Math was wrong: they got the wrong answer because they did the division wrong
  - Math was wrong: counting errors led to wrong numerator (28 instead of 145)
  - Flawed methods include
    - Population size unsubstantiated (unsupported denominator)
    - Incidence of infection not assessed among at risk population
    - Counted only cases of infection that were published in peer-reviewed literature
    - Counted only cases of infection that were reviewed in a single 1993 article
- **Conclusion – No credible estimate of infection risk**

Spach et al. 1993 Transmission of infection by gastrointestinal endoscopy and bronchoscopy. Ann Int Med. 118:117-128

- This paper is the only citation used by ASGE to come up with the current risk assessment (1 in 1.8 million).
- *What the Spach paper also said:*
  - " These recognized and reported cases, however, probably represent a minority of all infections transmitted by endoscopy…."
  - " Finally, from the practitioners perspective, the incentive for recognizing and reporting these infections is minimal."
  - "Given the above limitations and lack of prospective endoscopy, the true incidence of infections transmitted by endoscopy is impossible to determine.'

Assumption 3:
Endoscopy-associated infections (EAI) are rare and often inconsequential

- **We are not finding pathogen transmission because we are not looking in the right places.**
  - Currently exposed patients are only screened for 3 viruses HIV and Hepatitis B & C. Should also be looking for bacteria that live in the GI tract (enterics).
  - There is now documentation that transmission rates of pathogens from improperly reprocessed duodenoscopes were as high as 42%.
  - CRE (Carbapenem Resistant Enterobacteriaceae), a family of bacteria is that is now on CDC's list of most dangerous bacteria. CRE has shown to be transmitted by contaminated scopes. There is no treatment for CRE; mortality rate is around 47%.

Monitoring and Improving the Effectiveness of Cleaning Medical and Surgical Devices. M. Alfa. 2013. AJIC 41 S56-S59.

- Transmission rate is 41%
- KPAC is an MDRO which means any further antibiotic therapy will select for growth of this bug.
- Rate of transmission from contaminated scopes previously unknown and thought to be unimportant and insignificant
- Does bowel prep change the microbial flora predisposing the patient to colonization?
- What are the effects of colonization with no apparent symptoms?

Table 1
Summary of transmission of *K pneumoniae* by the same ERCP duodenoscope

Date of duodenoscopy	Specimen	Infection/ colonization	Outcome
August 1	Rectal swab	Colonization	Source case
August 18	Rectal swab	Colonization	Alive
August 29	Blood	Infection	Death (unrelated to *K pneumoniae*)
September 1	Rectal swab	Colonization	Alive
September 3	Rectal swab	Colonization	Death (unrelated to *K pneumoniae*)
September 14	Blood	Infection	Death (unrelated to *K pneumoniae*)
September 15	Rectal swab	Colonization	Alive
September 28	Rectal swab	Colonization	Alive

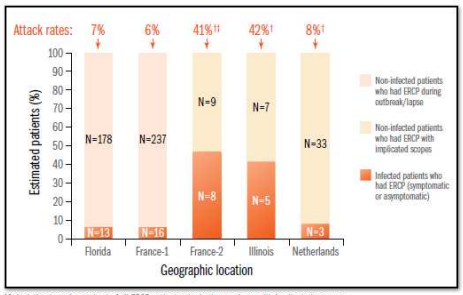
ERCP, endoscopic retrograde cholangiopancreatography.
NOTE. Table adapted from data in Carbonne et al 2010.[12]

Multidrug resistant organisms are being transmitted Ofstead and Associates/ Mayo

American Society for Gastrointestinal Endoscopy/Digestive Disease Week.
Orlando, FLA. May 18-21, 2013

- **Transmission of multidrug-resistant organisms via contaminated duodenoscopes.**
  Cori L. Ofstead, MSPH[1], Alexandra Dirlam Langlay, Ph.D[1]., Harry P. Wetzler, MD, MSPH[1], Pritish Tosh, MD[2], Todd Baron, MD[3] [1] Ofstead and Associates, Inc., St. Paul, MN, [2] Division of Infectious Diseases and [3]Division of Gastroenterology and Hepatology, Mayo Clinic, Rochester, MN
- Link to poster: http://www.ofsteadinsights.com/?p=1855
- **Issues addressed**
  - Guidelines say that there is little to no risk of exogenous infection with endoscopy.
  - The association between post-ERCP infections and endoscope reprocessing lapses was examined.
- **Findings**
  - Reprocessing lapses resulting in duodenoscope contamination with pathogens, including MDROs and have led to serious ERCP-associated infections. Confirmed by genetic testing.
  - Infection rates among patients exposed to contaminated duodenoscopes ranged from 6-42%.
- **Recommendations**
  - Routine monitoring is recommended to detect reprocessing errors and endoscope contamination prior to patient exposure.
  - Guidelines should be revised to reflect high attack rates and the need for patient follow up when reprocessing lapses occur

Figure 2: Infection rates among patients exposed to contaminated duodenoscopes



†Calculation based on subset of all ERCP patients who had procedures with implicated scopes;
‡Reported attack rate did not include index case

A carbapenem-resistant Klebsiella pneumoniae outbreak following bronchoscopy

Letters to the Editor / American Journal of Infection Control 42 (2014) 935-40 937

Table 1
Patients with carbapenem-resistant *Klebsiella pneumoniae* (CRKP) identified during the course of the outbreak

Patient	Date of admission	Isolation of CRKP	Type of infection/colonization	Route of transmission
A	May 14	May 22 (tracheal secretion)	Pneumonia, sepsis	Contact with index patient
B	May 19	May 23 (tracheal secretion)	Pneumonia	Contact with index patient
C	May 07	May 22 (tracheal secretion)	Pneumonia, sepsis	Contact with patient A
D	May 20	May 26 (tracheal secretion)	Pneumonia	Bronchoscopy (instrument A)
E	April 18	June 9 (tracheal secretion)	Pneumonia	Bronchoscopy (instrument A)
F	May 25	June 11 (urine)	Colonization	Contact with patient E
G	May 30	June 11 (rectal swab)	Colonization	Bronchoscopy (instrument A)
H	May 19	June 28 (urine/rectal swab)	Colonization	Contact with patients E and F

The outbreak ended after both endoscopes were submitted to the manufacturer who observed defects of the internal channel surfaces in both instruments. After repair, the bronchoscopes were used again, but surveillance sampling of the endoscopes was performed in short time intervals after reprocessing of the instruments. Flushing solutions of bronchoscope A still showed bacterial contamination > 200 CFU/mL, but no CRKP was detected. Nevertheless, bronchoscope A was taken out of use. In addition, microbiologic testing of endoscopes, which was performed twice a year before the outbreak took place, is now conducted more frequently.

Janine Zweigner, MD et.al. Institute of Hygiene and Environmental Medicine-University Medicine, Berlin, Germany

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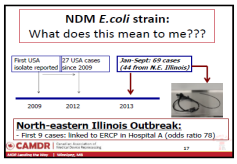
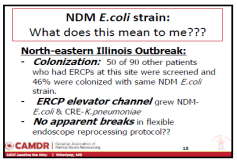
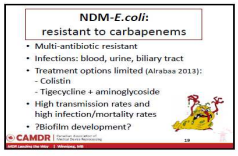
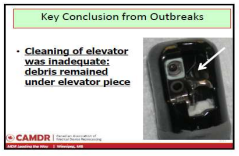
Medical Device Reprocessing: Can We "Ban the Biofilm"?
Michelle J. Alfa, PhD, FCCM (presentation October, 2014)



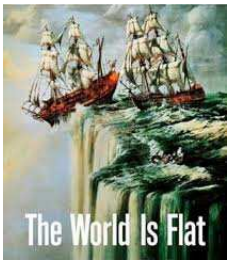






3M

Research is always producing new data and sometimes, in light of that new data, we have to re-evaluate what we think is true.



What are the new assumptions based on current clinical data?

1. Endoscope reprocessing is often not performed according to standards and guidelines. Reprocessing lapses are common and often go undetected for prolonged periods of time. This has resulted in an increased risk of cross-contamination and infection.
2. Patients are being exposed to improperly cleaned and disinfected scopes resulting in serious infections with multi-drug resistant organisms.
3. The current risk estimate is inaccurate, outdated and based on flawed methodology. The current risk of EAI is unknown and likely much higher that originally thought.

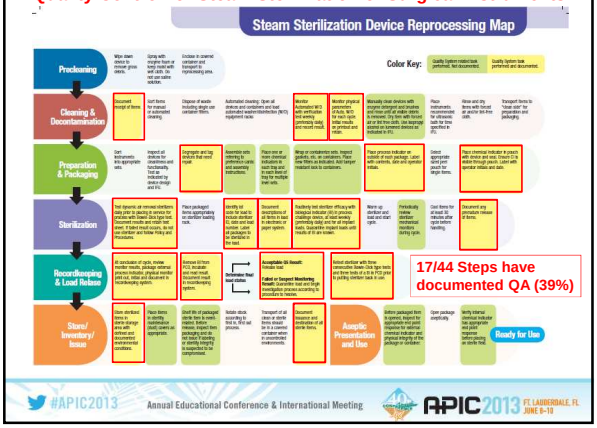
What are some steps that we can take now?

How well do you know this area?

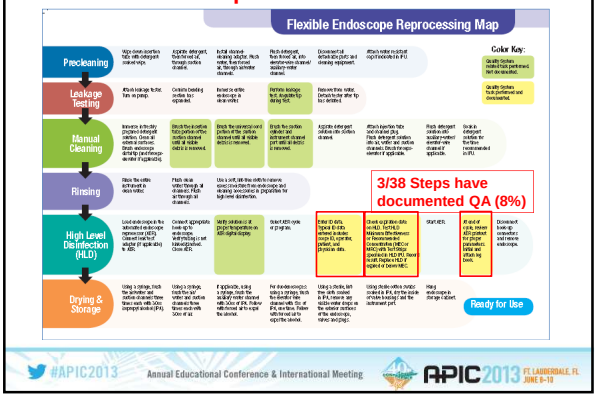
Implement better Quality Improvement Programs

Compare what is in place for Steam Sterilization processes to the high-level disinfection of flexible endoscopes.

Quality Control for Steam Sterilization of Surgical Instruments



Reprocessing a Flexible Endoscope is a Complicated Process



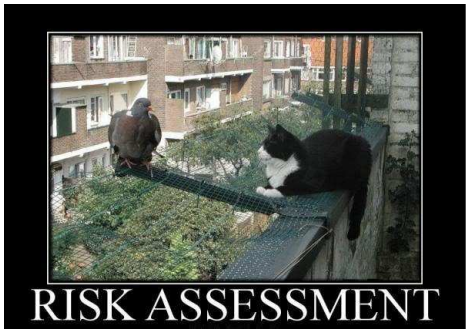
What can we do now?

Implement a monitoring program to assess:

- ✓ Contamination levels
- ✓ Compliance to protocols
- ✓ Document Training and Competency
- ✓ Provide feedback to improve performance
- ✓ Assess if current protocols are effective

Do you know what is going on?

- ✓ Infection Control practices (PPE, Hand Hygiene, Surface Decontamination)
- ✓ Bedside flush
- ✓ Storage and Transportation (Drying, clean storage cabinets)
- ✓ How do you investigate lapses in reprocessing?



How clean is clean?

Scope ID	Pre-Hand Wash Data Carbohydrate	Protein	Blood	ATP-RLU	Post-Hand Wash Data Carbohydrate	Protein	Blood	ATP-RLU
GIF #1	neg	neg	pos	9447	neg	neg	neg	124
PCF #21	neg	neg	neg	16	neg	neg	neg	3
CF #19	neg	neg	neg	27	neg	neg	neg	6
CH #28	neg	neg	neg	22	neg	neg	neg	9
CFH #11	neg	neg	neg	53	neg	neg	neg	13
PCF-H100 #32	neg	neg	neg	59	neg	neg	neg	50
GIF #21	neg	pos	neg	204	neg	neg	neg	121
PCF-Q100 #45	neg	neg	neg	167	neg	neg	neg	104
GIF #9	neg	neg	neg	37	neg	neg	neg	74
CFH-100 #53	neg	neg	neg	62	neg	neg	neg	74
PCF-H190AL #63	neg	neg	neg	60	neg	neg	neg	30
GIF-Q160 #7	neg	neg	neg	12,032	neg	neg	pos	436
SIG #46	neg	neg	neg	5	neg	neg	neg	15
PCFH180 #49	neg	neg	neg	79	neg	neg	neg	112
CFH-180 #28	neg	neg	neg	33	neg	neg	neg	26
CFH-180 #68	neg	neg	neg	223	neg	neg	neg	22
CFH -180 #29	neg	neg	neg	16	neg	neg	neg	115
CFH -180 #29	neg	neg	neg	78	neg	neg	neg	78
GIF-Q160 #32	neg	neg	pos	1183	neg	neg	neg	276
CFH-180 #19	neg	neg	neg	67	neg	neg	neg	31
HealthMark Contro	POS	POS	POS					
CFH #58	neg	neg	neg	51	neg	neg	neg	7
CFH #48	neg	neg	neg	82	neg	neg	neg	9
CFH-180 #34	neg	neg	neg	17	neg	neg	neg	7
PCF-H #49	neg	neg	pos	422	neg	neg	neg	7
CFH 180 #56	neg	neg	pos	245	neg	neg	neg	4
CFH 180 #6	neg	neg	pos	79	neg	neg	neg	8
GIF 180 #54	neg	neg	neg	222	neg	neg	neg	8

ATP (ADENOSINE TRIPHOSPHATE) FLEXIBLE ENDOSCOPE STORAGE DURABILITY

DATE	DEPT.	SCOPE TYPE	SCOPE SERIAL #	# OF DAYS IN CABINET	RLU READING OF SCOPE EXTERIOR	RLU READING OF SCOPE CHANNEL	RLU READING AT TOUCH POINT	TESTER	CABINET TYPE
1/8/2013	G.I/SPEC PROC	ERCP	2102049	11	27	15	N/A	GRISBY	INNERSPACE CABINET
1/8/2013	G.I/SPEC PROC	GIF XP180N	2100785	13	31	18	N/A	GRISBY	INNERSPACE CABINET
1/8/2013	G.I/SPEC PROC	GIF2TH180	2100274	27	18	16	N/A	GRISBY	INNERSPACE CABINET
1/8/2013	G.I/SPEC PROC	CF H180AL	2106369	27	22	12	N/A	GRISBY	INNERSPACE CABINET
1/8/2013	OR/HNS	LF TP	1102022	28	47	13	N/A	GRISBY	MED MEDICAL CABINET
1/8/2013	ANES. OAK	LF P	1600622	27	47	NON CHANNEL	N/A	GRISBY	MED MEDICAL CABINET
1/14/2013	ANES. OAK	STORZ 113018ND1	2051206	6 1/2 MONTHS	39	20	N/A N/A	GRISBY	THESE SCOPES HAVE/ARE NOT UGED IN ANESTHESIA
1/14/2013	ANES. OAK	STORZ 113028UD2	2051241	6 1/2 MONTHS	48	11	N/A	GRISBY	THESE SCOPES HAVE/ARE NOT UGED IN ANESTHESIA
2/11/2013	PPU	BF 160	2513640	34	39	NON TESTED	N/A	GRISBY	INNERSPACE CABINET
3/20/2013	PPU	BF XP-160	2600274	46	NON TESTED	1ST TEST 33 2ND TEST 2	N/A	GRISBY	INNERSPACE CABINT

KAISER PERMANENTE

ALL ENDOSCOPES WERE TESTED AFTER BEING HIGH LEVEL DISINFECTED

ATP (ADENOSINE TRIPHOSPHATE) FLEXIBLE ENDOSCOPE STORAGE DURABILITY

3/26/2013	PPU	BF 3C40	1010344	42	NON TESTED	1ST TEST 126 (I touched the swab by mistake on the counter) 2ND TEST 3	N/A	GRISBY	INNERSPACE CABINET
3/26/2013	PPU	BF 3C30	2600830	42	NON TESTED	2	N/A	GRISBY	INNERSPACE CABINET
3/26/2013	PPU	BF XP60	1600097	42	NON TESTED	2	N/A	GRISBY	INNERSPACE CABINET
3/26/2013	PPU	BF 3C160	1100066	20	NON TESTED	9	N/A	GRISBY	INNERSPACE CABINET
3/26/2013	PPU	BF 160	2513640	40	NON TESTED	6	N/A	GRISBY	INNERSPACE CABINET
4/19/2013	PULM	BF Q180	2043333	28	21	7	N/A	GRISBY	INNERSPACE CABINET
4/19/2013	PULM	BF P180	2142561	28	29	3	N/A	GRISBY	INNERSPACE CABINET
4/19/2013	PULM	BF Q160	2043341	28	10	6	N/A	GRISBY	INNERSPACE CABINET
5/3/2013	G.I/SPEC PROC	BF XT160	1200131	23	NON TESTED	12	N/A	GRISBY	INNERSPACE CABINET
5/3/2013	G.I/SPEC PROC	BF 1T20	1810303	23	NON TESTED	4	N/A	GRISBY	INNERSPACE CABINET
5/10/2013	G.I/SPEC PROC	GIF 2TH180	2100274	29	22 87	4	N/A	GRISBY	INNERSPACE CABINET
5/10/2013	G.I/SPEC PROC	CF H180AI	2106369	29	TOUCHED SCOPE TO SEE IF DIFFERENT READING	3	N/A	GRISBY	INNERSPACE CABINET
6/4/2013	G.I/SPEC PROC	BF 1T20	1810303	32	REVIEW TOUCH POINT	NON TESTED	12 insertion tube completely touch wall of cabinet	GRISBY	INNERSPACE CABINET

KAISER PERMANENTE

ALL ENDOSCOPES WERE TESTED AFTER BEING HIGH LEVEL DISINFECTED

ATP (ADENOSINE TRIPHOSPHATE) FLEXIBLE ENDOSCOPE STORAGE DURABILITY

6/7/2013	G.I/SPEC PROC	GIF H180J	2104749	7	REVIEW TOUCH POINT	NON TESTED	9 @ 20 depth touching hook	GRISBY	INNERSPACE CABINET
6/7/2013	G.I/SPEC PROC	GIF H180J	2104749	7	REVIEW TOUCH POINT	NON TESTED	8 @ distal tip touching another scope	GRISBY	INNERSPACE CABINET
6/7/2013	G.I/SPEC PROC	GIF H180J	2104735	10	REVIEW TOUCH POINT	NON TESTED	6 @ 20 depth touching hook	GRISBY	INNERSPACE CABINET
6/7/2013	G.I/SPEC PROC	GIF H180J	2104735	10	REVIEW TOUCH POINT	NON TESTED	7 @ distal tip touching another scope	GRISBY	INNERSPACE CABINET

KAISER PERMANENTE

ALL ENDOSCOPES WERE TESTED AFTER BEING HIGH LEVEL DISINFECTED

ATP results after manual cleaning

DATE	DEPT	SCOPE TYPE	SCOPE SERIAL #	# OF DAYS IN CABINET	RLU READING OF SCOPE EXTERIOR	RLU READING OF SCOPE CHANNEL	RLU READING AT TOUCH POINT	TESTER	CABINET TYPE
11/12/2014	GI	GIF-H180J	testing after manual cleaning, 24 hrs after preclearing	N/A	15	7	N/A	G. Grichy	N/A
11/12/2014	GI	PCF-H190L	testing after manual cleaning, 24 hrs after preclearing	N/A	17	11	N/A	G. Grisby	N/A
11/12/2014	GI	TJF-160F	testing after manual cleaning, 24 hrs after preclearing	N/A	20	6	N/A	G. Grisby	N/A
1/21/2015	OR/HNS	LF-TP	1102022	60	74 was touched	4	N/A	G. Grisby	MPD Medical
1/21/2015	ICU/Resp	LF GP	2716990	61	25 was touched	6	N/A	G. Grisby	Innerspace
1/21/2015	OR/HNS	LF-DP	1101335	65	11	5	N/A	G. Grisby	Innerspace

KAISER PERMANENTE

Regulatory Bodies, Associations, Mfr

- **AAMI/FDA – How Clean is Clean Summit (Sept. 2013)**
- **ASGE and SGNA – Meeting Fall of 2013 to address new clinical data**
  - **Revise standards to address the unknown risk estimates?**
  - **Centralized reporting for reprocessing lapses?**
- **Manufacturers need to revise IFU for cleaning and reprocessing that reflect current scientific evidence.**

Lead the Way

3M Infection Prevention Solutions

3M

The future of Endoscopy procedures? A safer, non-invasive approach.....