



# Quality Improvement and Human Factors Related to Sterile Processing

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## About ECRI Institute

- ▶ International, independent, not-for-profit applied research institute focused on patient safety, healthcare quality, and risk management
- ▶ 50-year history; 450-person staff
  - ▶ Evidence-Based Practice Center under the Agency for Healthcare Research and Quality (AHRQ)
  - ▶ Federally designated Patient Safety Organization

# ECRI Institute: (Just) A Few Things That We Do . . .

- ▶ Perform head-to-head evaluations of medical technologies for more than 45 years
- ▶ Operate the Medical Device Problem Reporting Program, investigating problem reports involving healthcare equipment (>30,000 reports reviewed)
- ▶ Conduct accident investigations (~3,000 investigations)
- ▶ Publish annual Top 10 Health Technology Hazards list

# Learning Objectives

- ▶ Describe examples of reprocessing failures and their impact on patient care
- ▶ Recognize the prevalence of retained bioburden on dental and surgical instruments
- ▶ Describe how the design of dental and surgical instruments may impact reprocessing effectiveness
- ▶ Recognize the importance of proper instrument cleaning on the success of reprocessing
- ▶ Identify opportunities for improvement of human factors issues within your reprocessing system

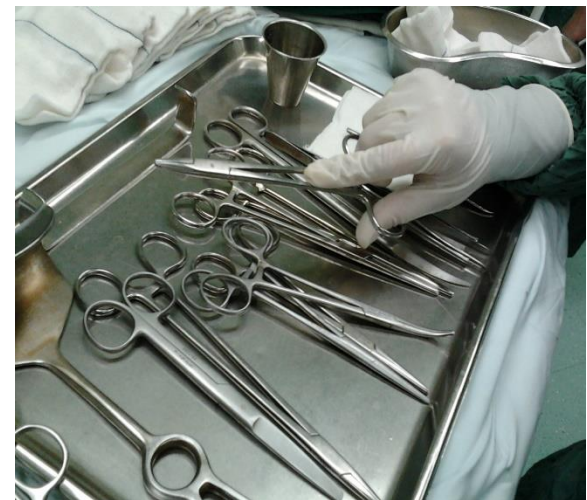
# Human Factors

- ▶ 1 : an applied science concerned with designing and arranging things people use so that the people and things interact most efficiently and safely — called also biotechnology, human engineering, human factors
- ▶ 2 : the design characteristics of an object resulting especially from the application of the science of ergonomics

<https://www.merriam-webster.com/dictionary/ergonomics>

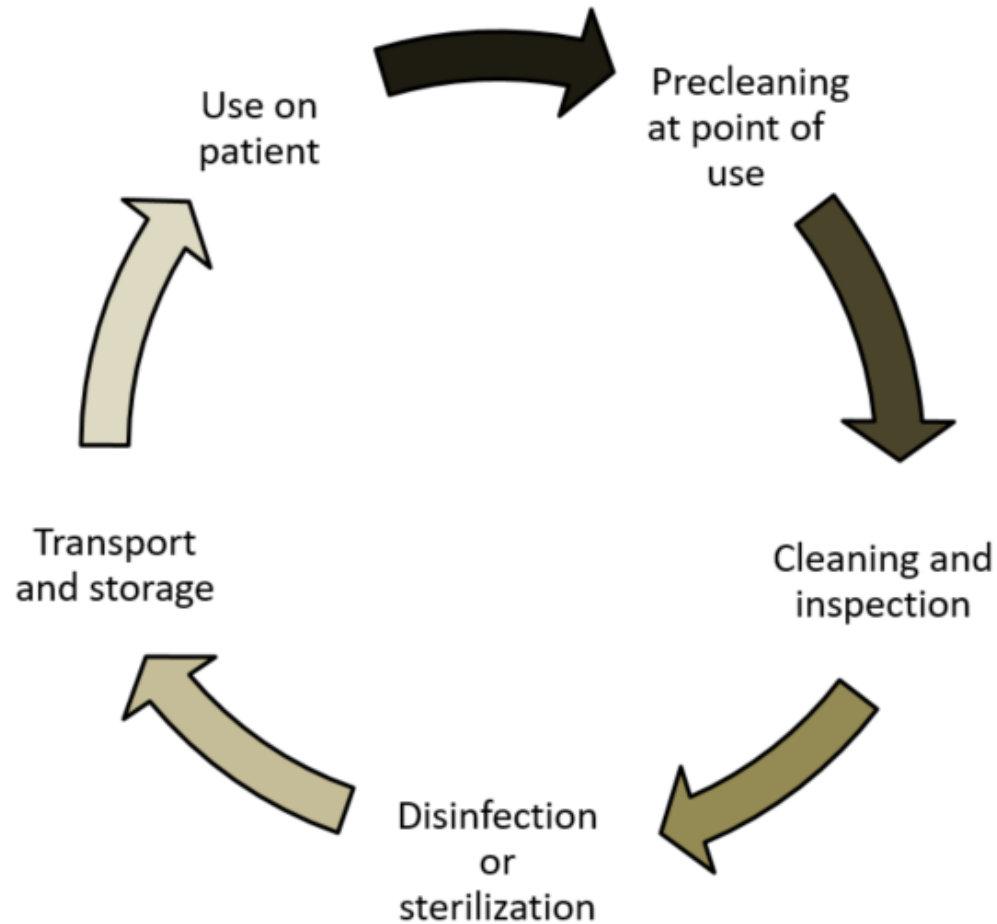
# What Is Reprocessing?

- ▶ Goals
- ▶ Why it's needed
- ▶ What can happen if it's not effective
- ▶ Impact of surgical site infections (SSIs)
- ▶ What a reprocessing tech does (or doesn't) do can affect lives



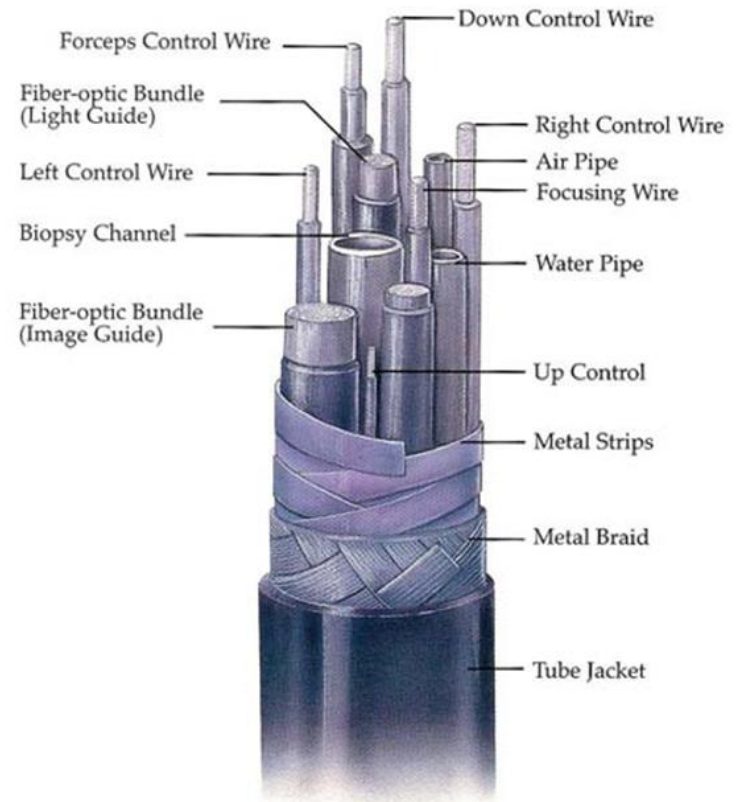
By) رمين (own work) [CC0], via Wikimedia Commons.

# A Day in the Life of a Reusable Instrument



# Flexible Endoscopes: The Poster Child for Challenging Reprocessing

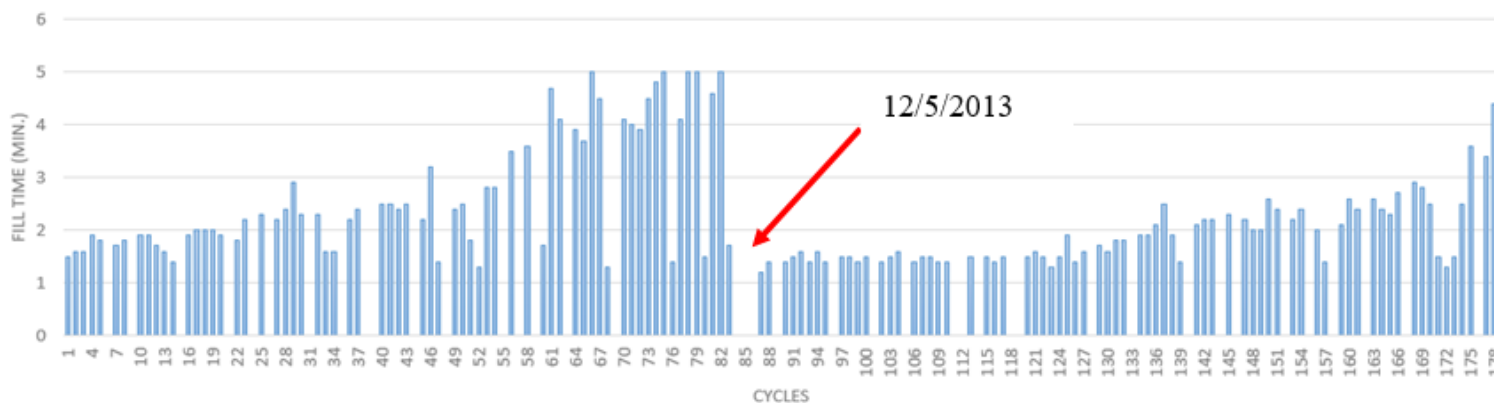
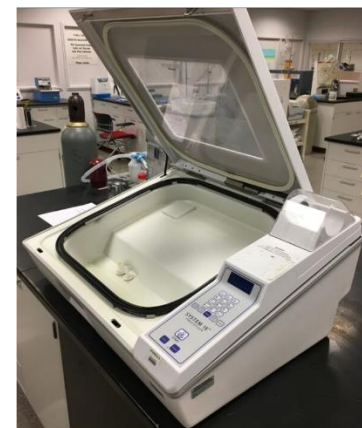
- ▶ Some of the most complex reusable instruments
- ▶ Delicate design
- ▶ Bioburden  $>10^6$  higher than surgical instruments
- ▶ Long narrow internal channels





# Case 1: Bronchoscopy Patients Presenting with *Mycobacterium* Infections

- ▶ What are mycobacteria? (*Mycobacterium avium* complex)
- ▶ Patient safety concern
- ▶ Source: bronchoscope or procedure suspected
- ▶ Clue—automated endoscope reprocessor (AER) operation records



# Case 1: Bronchoscopy Patients Presenting with *Mycobacterium* Infections (cont'd)

- ▶ Cause—erratic water filter replacement intervals
- ▶ Lessons learned:
  - Be aware of vendor service recommendations
  - Filters have limited life
  - Bacteria can penetrate a 0.1- $\mu$ m filter when overgrown

# Case 2: Fungal Colonization of Endoscopes

- ▶ Random culturing of endoscopes
- ▶ Source: unknown
- ▶ Patient safety implications
- ▶ Findings:
  - Cramped workspace with scopes being dried in open cabinet
  - Poor condition of work area noted
  - Suction shared in contaminated and “clean” areas



# Case 2: Fungal Colonization of Endoscopes (cont'd)

## ▶ Lessons learned

- Work area should be maintained, and clutter addressed
- Contaminated and clean areas should be segregated
- Contaminated and clean equipment should not be shared
- Cabinets and work area need to be impervious and in good condition



# Case 3: Patients Exposed to Ineffectively Reprocessed Scopes

- ▶ Busy endoscopy department changed AER liquid chemical germicide (LCG) from Cidex\* to Rapicide†
- ▶ Reservoir temperature not changed
- ▶ Vendor could not guarantee high-level disinfection at temperature used
- ▶ Notified hundreds of patients that scopes may have been contaminated

\*Advanced Sterilization Products, Johnson & Johnson

†Medivators, a Cantel Medical Company

Dear Mr. Adams,

ABC Hospital is notifying patients who have had open-heart surgery, about a potential infection risk related to this surgery. We are contacting you today, as you or a member of your family have been identified in clinical records as a patient who might be affected.

The Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) are investigating reports that a device used to heat and cool the blood during surgery has been linked to a rare bacterial infection caused by *Mycobacterium chimaera*, a type of bacteria known as nontuberculous mycobacterium (NTM). For patients who have had one of these surgeries, the chances of getting this infection are very low. CDC estimates the risk to be less than 1 percent. Of the [number of patients] at [HOSPITAL], who have had open heart surgery, we are aware of [number] of patient(s) who have developed this infection.

This infection is very slow growing and difficult to diagnose. It is possible to develop symptoms years after surgery, so it is important to know the symptoms to look for. Discuss any symptoms or questions you may have with your primary care doctor. This infection cannot be spread person-to-person.

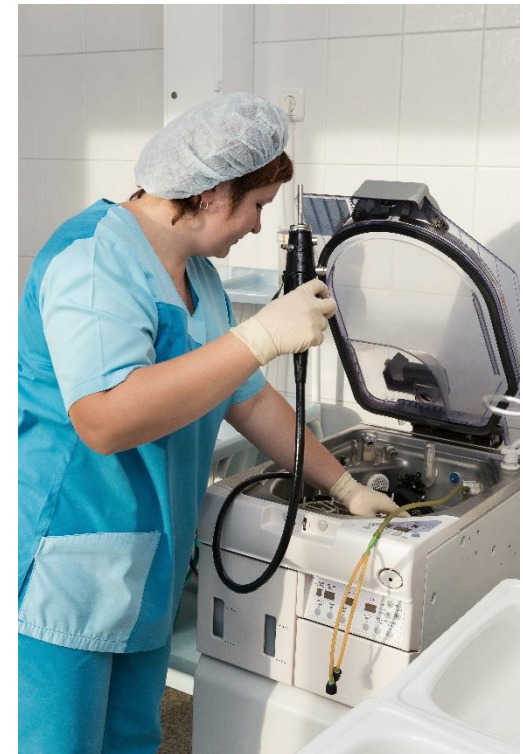
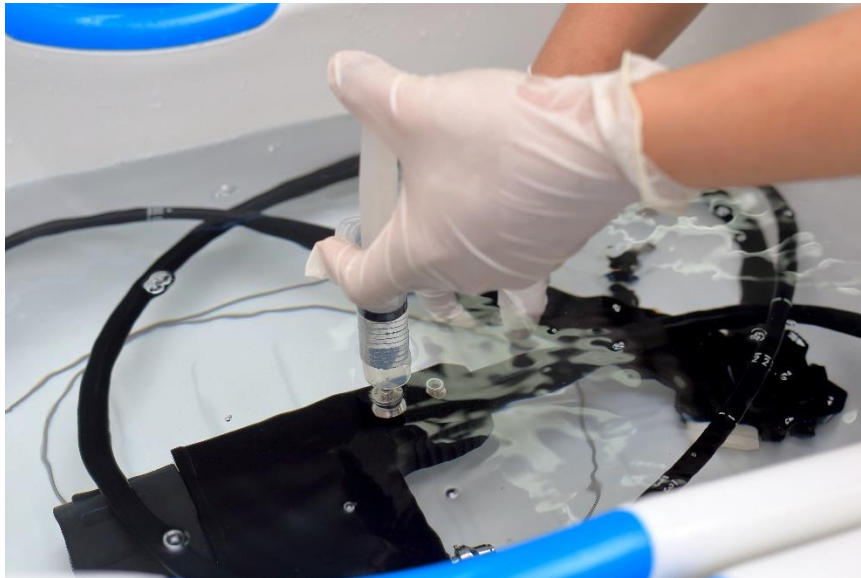
# Case 3: Patients Exposed to Ineffectively Reprocessed Scopes (*cont'd*)

## ▶ Lessons learned:

- When equipment or solutions change, review instructions for use (IFUs)
- Disinfecting and sterilizing agents have very specific time and temperature requirements
- Periodically review procedures to ensure they are current
- Maintaining good documentation is critical

# Case 4: Delayed Reprocessing

- ▶ Situation: Reprocessing staff in busy endoscopy center found they sometimes couldn't get all scopes reprocessed by the end of their day, especially for overnight and weekend emergency procedures
- ▶ Sporadic reports of patient infections associated with scope procedures
- ▶ Scopes were precleaned, then manually cleaned



# Case 4: Delayed Reprocessing (cont'd)

## ▶ Lessons learned:

- Reprocessing must be done in timely manner
- Consider whether endoscope inventory is sufficient
- Cleaning by itself isn't an end point
- Delays can result in microbial proliferation and biofilms
- Dried material impossible to remove—premature instrument failure





# Conclusions

- ▶ Notified hundreds of patients that scopes might have been contaminated
- ▶ Reprocessing is a critical part of the instrument life cycle and patient safety
- ▶ Reprocessing procedures are designed to eliminate contamination risk, but:
  - Each step is critical to the next and none can be omitted or shortchanged without impacting the end result; never leave your wingman
  - Steps must be performed in a timely manner or effectiveness may suffer
  - Safety margin is slim; processes can be intolerant of even small errors or oversights
  - Seemingly minor tasks (e.g., equipment servicing, checking potency of LCG) can be very important to effectiveness

# Conclusions (*cont'd*)

- ▶ Adequate workspace is important; separation of contaminated and clean work locations is crucial
- ▶ When changing equipment or solutions, review procedures and IFUs to confirm they still apply
  - Disinfecting and sterilizing agents have very specific contact time and temperature requirements
  - Regularly reviewing procedures is a prudent practice

# Conclusions (cont'd)

Reprocessing is a critical link in the chain of steps involved in successfully treating patients . . .

## Outcomes matter



# **Best Practices to Reduce Bioburden on Medical Equipment after Reprocessing**

# Bioburden

- ▶ Bioburden is “the degree of microbial contamination or microbial load; the number of microorganisms contaminating an object.”

“Bioburden.” Farlex Partner Medical Dictionary. 2012 [cited 2018 Mar 27]. <http://medical-dictionary.thefreedictionary.com/bioburden>



# Biofilm

- ▶ Biofilm is “a slime-enclosed community of bacterial colonies that is very difficult to eradicate even with the most powerful antibiotics or sterilizing systems.”
- ▶ “Biofilms can occur on any body surface, on teeth (as dental plaque), medical equipment, medical tubing, contact lenses and elsewhere.”

“Biofilm.” American Heritage Medical Dictionary. 2007 [cited 2018 Mar 27]. <http://medical-dictionary.thefreedictionary.com/biofilm>

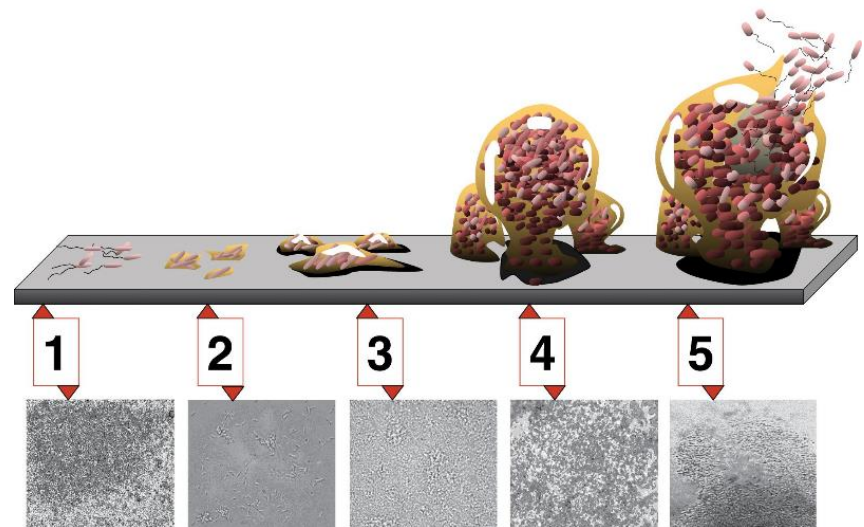


Photo source: Davis D. Wikimedia Commons.  
<https://commons.wikimedia.org/wiki/File%3ABiofilm.jpg>

# Biofilm (*cont'd*)

- ▶ Biofilms can be visible to the naked eye in an aquatic or industrial environment (e.g., when pipes are fouled).
- ▶ Biofilms can also be microscopic and can develop on the surfaces of medical devices and equipment very rapidly (within minutes).

Koseki H, Yonekura A, Shida T, Yoda I, Horiuchi H, Morinaga Y, Yanagihara K, Sakoda H, Osaki M, Tomita M. Early staphylococcal biofilm formation on solid orthopaedic implant materials: in vitro study. PLoS ONE 2014 Oct 9;9(10):e107588.

<http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0107588> PubMed:

<https://www.ncbi.nlm.nih.gov/pubmed/25299658> doi: 10.1371/journal.pone.0107588





# Dental Biofilm



Lagdive SS, Lagdive SB, Mani A, Anarthe R, Pendyala G, Pawar B, Marawar PP. Correlation of mast cells in periodontal diseases. J Indian Soc Periodontol 2013 Jan;17(1):63-7.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3636948/> PubMed:

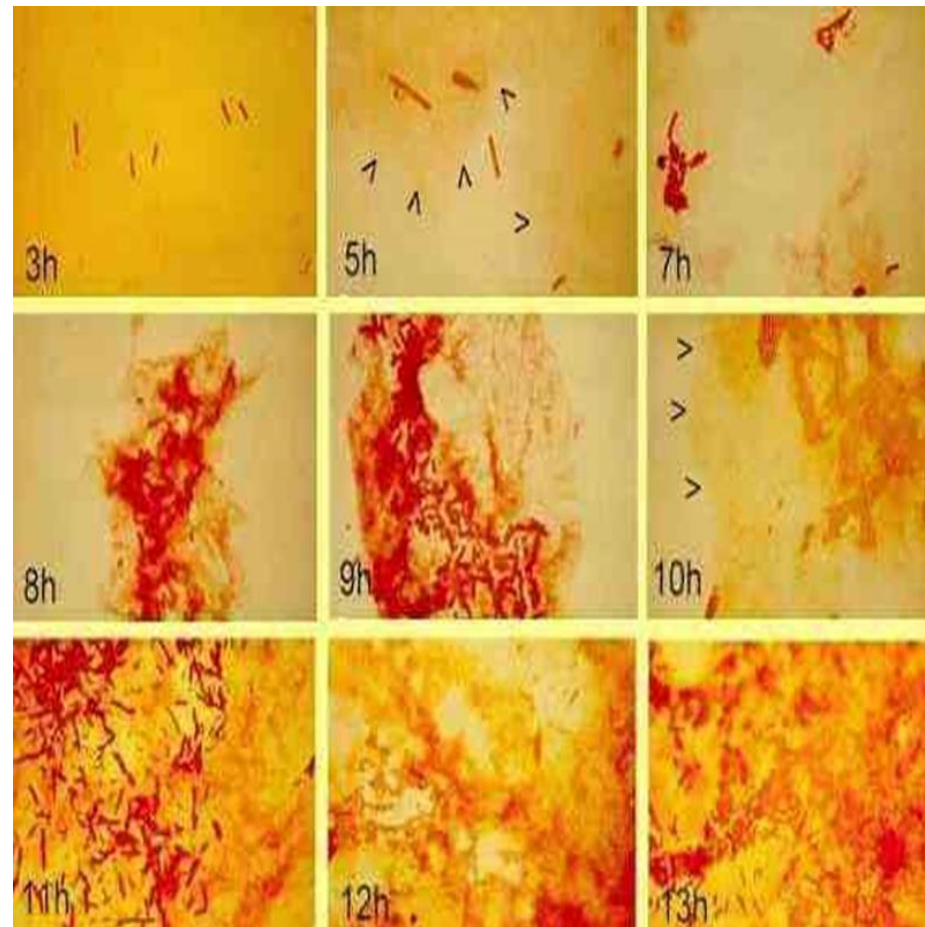
<https://www.ncbi.nlm.nih.gov/pubmed/23633775> oi:

10.4103/0972-124X.107500. License:

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# Dental Biofilm



Reprinted from Journal of Microbiological Methods, Vol 2, Allison DG, Sutherland IW, A staining technique for attached bacteria and its correlation to extracellular carbohydrate production, 93-9, Copyright 1984, with permission from Elsevier and DG Allison and IW Sutherland.

# Healthcare-Associated Infection

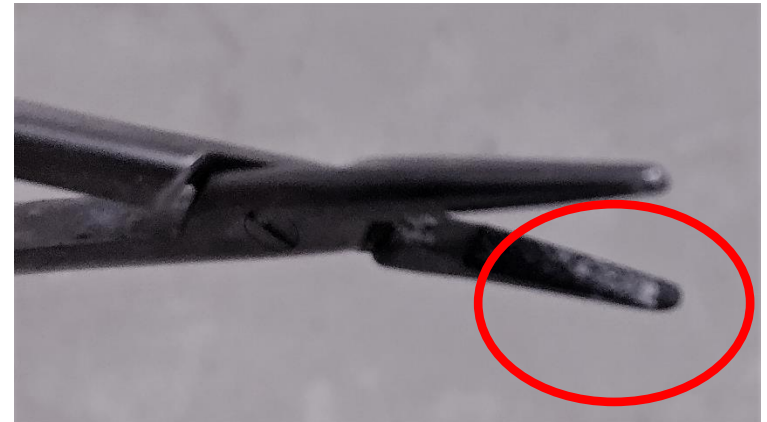
- ▶ Healthcare-associated infections are sometimes linked to instruments and equipment that have been processed appropriately (CDC; Dancer et al.)
  - Because of their design, these instruments have proved to be difficult to clean and disinfect or sterilize appropriately (CDC).



Centers for Disease Control and Prevention (CDC). Notes from the field: New Delhi metallo- $\beta$ -lactamase-producing *Escherichia coli* associated with endoscopic retrograde cholangiopancreatography - Illinois, 2013. MMWR Morb Mortal Wkly Rep 2014 Jan 3;62(51-52):1051. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4663693/> PubMed: <https://www.ncbi.nlm.nih.gov/pubmed/24381080>

Dancer SJ, Stewart M, Coulombe C, Gregori A, Viridi M. Surgical site infections linked to contaminated surgical instruments. J Hosp Infect 2012 Aug;81(4):231-8. <http://dx.doi.org/10.1016/j.jhin.2012.04.023> PubMed: <https://www.ncbi.nlm.nih.gov/pubmed/22704634> doi: 10.1016/j.jhin.2012.04.023

# Design



*Enhanced from image on left*

# Endotoxin

- ▶ Endotoxin presence on surgical instruments, which may contribute to orthopedic prostheses loosening, has been noted by researchers (Goveia et al.; Landgraeber et al.).
- ▶ Many adverse outcomes related to the use of poorly reprocessed instruments are likely to go unrecognized until problems arise.
  - Infection
  - Loosening of prostheses

Goveia VR, Mendoza IY, Guimarães GL, Ercole FF, Couto BR, Leite EM, Stoianoff MA, Ferreira J. Endotoxins in surgical instruments of hip arthroplasty. Rev Esc Enferm USP 2016 May-Jun;50(3):405-10. <http://dx.doi.org/10.1590/S0080-623420160000400005> PubMed: <https://www.ncbi.nlm.nih.gov/pubmed/27556710> doi: 10.1590/S0080-623420160000400005

Landgraeber S, von Knoch M, Löer F, Brankamp J, Tsokos M, Grabellus F, Schmid KW, Totsch M. Association between apoptosis and CD4(+)/CD8(+) T-lymphocyte ratio in aseptic loosening after total hip replacement. Int J Biol Sci 2009;5(2):182-91. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2640493/> PubMed: <https://www.ncbi.nlm.nih.gov/pubmed/19214244>

# Quantitative Results: Reprocessing Failures

- ▶ Pennsylvania state data:
  - 0.122 per 1,000 inpatient claim records in 2005
  - 0.448 per 1,000 inpatient claim records in 2014

Davis J. Retained bioburden on surgical instruments after reprocessing: are we just scraping the surface? Pa Patient Saf Advis 2017 Jun [cited 2018 Mar 27].

[http://patientsafety.pa.gov/ADVISORIES/Pages/201706\\_71.aspx](http://patientsafety.pa.gov/ADVISORIES/Pages/201706_71.aspx)



# Qualitative Examples from Event Report Narratives

“Loaner instruments ran through washer decontaminator then wrapped and run through sterilizer. While setting up, staff noticed dried blood on the set.”

“While pushing bone graft into the instrument, a large piece of dried tissue from a previous case came out onto the field, contaminating the patient’s bone graft and set-up.”

“Debris from a prior procedure dislodged from the endoscope and floated into the ventricle, unable to retrieve. Ventricle flushed and patient placed on antibiotics.”

Davis J. Retained bioburden on surgical instruments after reprocessing: are we just scraping the surface? Pa Patient Saf Advis 2017 Jun [cited 2018 Mar 27]. [http://patientsafety.pa.gov/ADVISORIES/Pages/201706\\_71.aspx](http://patientsafety.pa.gov/ADVISORIES/Pages/201706_71.aspx)

# Qualitative Examples from Event Report Narratives (*cont'd*)

“Laminectomy with local bone graft. Staff noted that a sterilized instrument pan containing spinal instruments was found to be contaminated with old bone and tissue from a previous case. The case was delayed.”

“Fragments of bone cement were observed in the patient’s knee, and the surgeon had not used cement. The scrub nurse noticed the instrument impactor in the set had cement from a previous case on it. Wound class was changed from 1 to 2.”

Davis J. Retained bioburden on surgical instruments after reprocessing: are we just scraping the surface? Pa Patient Saf Advis 2017 Jun [cited 2018 Mar 27]. [http://patientsafety.pa.gov/ADVISORIES/Pages/201706\\_71.aspx](http://patientsafety.pa.gov/ADVISORIES/Pages/201706_71.aspx)



# Lessons Learned through Consultation

- ▶ Staffing patterns misaligned with case loads
- ▶ Demands for quicker turnaround of instruments
- ▶ Subpar levels of instruments
- ▶ Unfamiliarity with manufacturers' IFUs and care of instruments
- ▶ Staff not wiping, precleaning, or soaking instruments prior to sending for reprocessing

# Lessons Learned through Consultation (*cont'd*)

- ▶ Used trays sitting for prolonged periods before being sent for reprocessing
- ▶ Used trays sitting for prolonged periods before handling in the reprocessing department
- ▶ The procedure area and reprocessing departments treated as separate
- ▶ Lack of standardized training and education
- ▶ Poor workflow design in the reprocessing department
- ▶ Inconsistent auditing of process measures and quality indicators

# Leadership Support

- ▶ Ask senior executives to periodically include reprocessing departments in leadership rounding
- ▶ Voice support for reprocessing staff's contribution to patient care
- ▶ Ask staff about opportunities for improvement
  - What aspects of your work environment may contribute to reprocessing problems?
  - When adverse events or near misses occur, do you always report them? If not, why not?
  - What could leadership do to support you in performing your job?
  - What changes could be made in your unit to promote patient safety more consistently?

# Foster Respect

- ▶ Promote respect within and between department staff
- ▶ Prohibit disruptive behavior
- ▶ Prohibit distracted behavior (e.g., texting)



Photo source: Alpha Stock Images. <http://alphastockimages.com/>

# Key Points: Staff Training

- ▶ Training
- ▶ Competence
- ▶ Turnover

# Key Points: Staffing

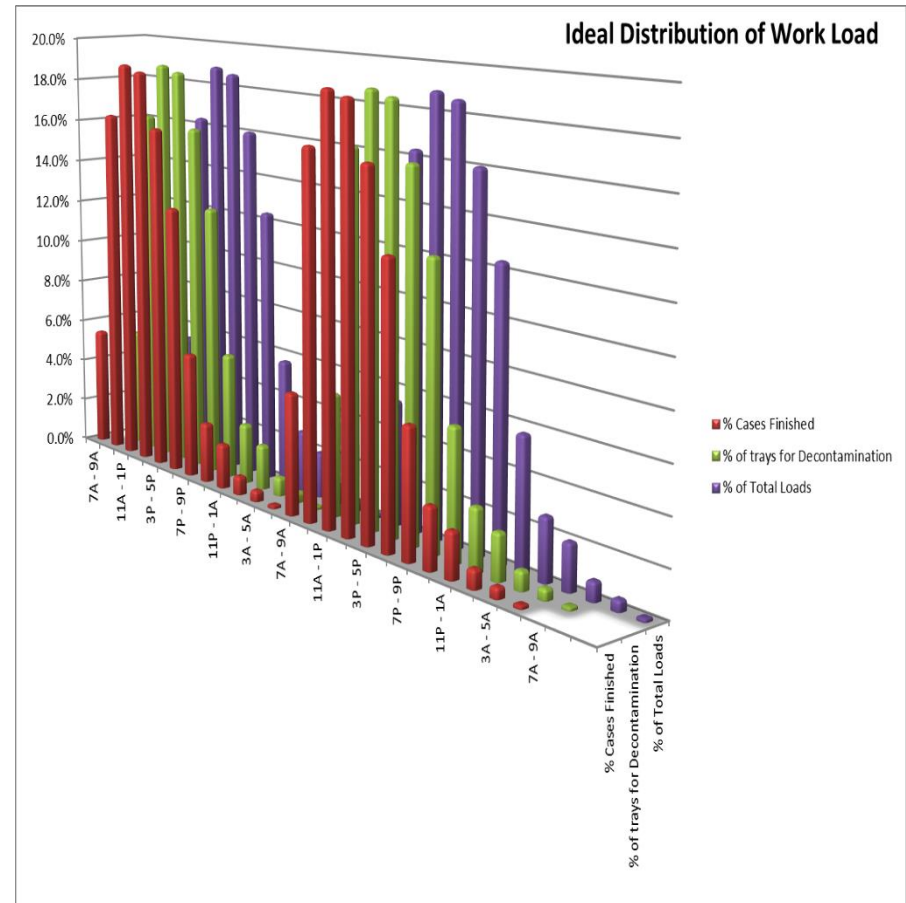
- ▶ Capacity Line Balancing
- ▶ Analyze all work of the department
  - Case carts
  - Pack and prep
    - ▷ # Trays
    - ▷ # Peel packs
  - Decontamination
  - Sterilization
  - Patient care items (e.g. commodes, pumps etc.)
  - Daily sterilizer testing and maintenance
  - Non productive hours (vacation, sick, education, breaks)

# Key Points: Staffing (*cont'd*)

- ▶ Leverage your data to determine staffing needs
  - Instrument tracking system
  - Time studies
  - OR logs
  - Sterilization logs
- ▶ Plan for the unexpected
  - Unexpected increase in volume
  - Staff turnover
- ▶ Avoid Efficiency Thoroughness Tradeoff due to productivity pressures

# Key Points: Staffing (cont'd)

Average volume for processing	Benchmark productivity	Total time (hrs) based on benchmarks	FTEs required (based on 7 hours productive time)	Current FTE staffing (13 FTE daily) assuming same ratio for assembly and decontamination	Current operating capacity (%)
Tray Assembly: 327 trays	20 min/tray	$\left(\frac{327 * 20}{60}\right)$ = 109 hour	$\left(\frac{109}{7}\right)$ = 15.5 FTE	8.7	$\left(\frac{15.6}{8.7}\right)$ = 180%
Tray Decontamination: 327 trays	10 min/tray	$\left(\frac{327 * 10}{60}\right)$ = 54.5 hour	$\left(\frac{54.5}{7}\right)$ = 7.8 FTE	4.3	$\left(\frac{7.8}{4.3}\right)$ = 181%
Totals	30	163.5 hours	23.3 FTE	13	$\left(\frac{23.3}{13}\right)$ = 180%





# Key Points: Teamwork

- ▶ High-quality reprocessing of reusable medical equipment is a mission-critical task.
  - Leadership is part of the team.
  - Procedure units cannot exist without an adequate flow of quality medical equipment (i.e., good patient care depends on availability of quality equipment).
  - Efforts are needed to unify departments and processes around the care and maintenance of mission-critical items.
  - Never leave your wingman.



# Key Points: Teamwork (*cont'd*)

- ▶ Reprocessing and procedure area staff need to have access to each instrument's IFU, which includes particular methods for cleaning, care, disinfection, sterilization, and maintenance.
  - Once debris dries inside or on an instrument surface, the instrument becomes increasingly difficult to clean.
  - When *cleaning starts at the point of use* (in the procedure area), removing debris at the point of reprocessing becomes more effective (AST).

Standards of practice for the decontamination of surgical instruments. Littleton (CO): Association of Surgical Technologists (AST); 2009.

[http://www.ast.org/uploadedFiles/Main\\_Site/Content/About\\_Us/Standard\\_Decontamination\\_%20Surgical\\_Instruments\\_.pdf](http://www.ast.org/uploadedFiles/Main_Site/Content/About_Us/Standard_Decontamination_%20Surgical_Instruments_.pdf)



## Key Points: Teamwork (*cont'd*)

- ▶ Include reprocessing staff in the staff meetings of the procedure team.
- ▶ Walk in each other's shoes.
- ▶ Create a reprocessing/procedure area liaison work group for reprocessing and procedure area to interact, plan, and problem solve.
- ▶ Develop a standardized process to ensure notification of reprocessing staff of changes in schedules and prioritization of instruments for turn around.
- ▶ Include representation from reprocessing on the OR/procedure area committee and include in block allocation decisions.

# Key Points: Purchase Wisely

- ▶ Design plays a vital role in determining how easily an effective, high-quality reprocessing method can be accomplished.
- ▶ When purchasing equipment and instruments, consider the design and ease of reprocessing.
- ▶ Involve all staff and leaders in the purchasing decision.

# Key Points: Audit, Audit, Audit!

- ▶ Pull trays off the carts and inspect
- ▶ Look at how instruments are returned from the procedure area for reprocessing
- ▶ Document the results
- ▶ Share audit results with staff
  - Conduct safety huddles—mindfulness
  - Do not blame—find the gaps
  - Consult with staff—they usually have answers



# Key Point: Workarounds

- ▶ Returned unused
- ▶ Surgeons wanted trays “just in case” due to quality issues
- ▶ Stringer size
- ▶ Instruments sprayed with solution cleaner
- ▶ Never opened



# Conclusion

- ▶ Reprocessing is a complex process that affects:
  - Patient outcomes
  - Patient satisfaction
  - Staff satisfaction
  - Workflow
  - Facility's bottom line
  - Many other variables
  
- ▶ This presentation is intended to give facilities a starting point for self-assessment of the reprocessing continuum.

# Questions?

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# Thank You

Special thanks to Chris Lavanchy, BSME Engineering Director, Health Devices Group, ECRI Institute, who developed slides within this presentation.