Objectives

• Discuss why infection prevention is so important in GI suites
• Identify Standard Precautions and their application in the GI suite
• Review updates in endoscopy reprocessing, guidelines and standards
• List the decontamination and disinfection steps of a flexible endoscope from bedside to storage
• Name at least 2 ways to demonstrate quality assurance in endoscopy reprocessing
Understanding CRE, the 'nightmare' superbug that contributed to 2 deaths in L.A.

By Ben Brumfield, CNN
Updated 3:18 PM ET, Thu February 19, 2015

Watch Out for Endoscopes Linked to Superbug Outbreak, FDA Says

Deadly bacteria on medical scopes trigger infections

Huntington Hospital bacterial outbreak infected 3 patients

Hepatitis scare
Transmission of Pathogens –
What do we **KNOW** we’re transmitting

• Most commonly reported exogenous organisms - P. aeruginosa and salmonella
  o Inadequate drying of channels with 70% alcohol and forced air
  o Lack of manual cleaning
  o Colonization of AER or water supply to endoscope
  o Failure to disinfect elevator channel of duodenoscope resulting in biofilm (1)

• Other bacterial pathogens
  o Salmonella spp., Heliobacterpylori, Carbapenem-resistant Enterobacteriaceae (CRE), Enterobactercloacae, Klebsiella spp., Clostridium difficile, Derratiamarcescens, Mycobacterium fortuitum and Flavobacterium spp.

Transmission of Pathogens –
What do we **KNOW** we’re transmitting

- Hepatitis B and C Virus
  - Asymptomatic, long incubation period
  - Outbreak in Nevada ASC from unsafe injection practices (2)
  - Transmissions in New York, Oklahoma and Nebraska r/t preparation and administration of parenteral medication (3)
  - Endoscopic transmission not well documented; few cases implement inadequate endoscope reprocessing


Transmission of Pathogens in Endoscopy

- 2002-2006 – 7,034 patient notifications
- February 2008-Hepatitis C outbreak in Las Vegas
  - 50,000 patients, physicians and staff tested
  - Re-use of syringes and multi-dose vials of sedation drugs
  - Investigation found reprocessing lapses as well and re-use of single use items
- 2010-Palomar Pomerado Health System
  - 3,400 patients who received care between Dec. 1, 2008 and March 22, 2010 notified that they could receive free testing for diseases after having endoscopies with potentially dirty equipment
  - "Although we were disinfecting all equipment, some of the steps as recommended by the manufacture were not always completed"
- October 2011-Endoscopic Clinic in Ottawa, Ontario
  - 6,800 patients notified
  - Scheduled inspection the College of Physicians and Surgeons of Ontario
  - Improper reprocessing upper and lower GI endoscopes for almost a decade
    - Expired Chemicals
    - Cross contamination
Transmission of Pathogens in Endoscopy

- **September 2013** – Advocate Lutheran General Hospital, Chicago, IL
  - 38 patients exposed to CRE from Jan – Sept 2013 by ERCP scopes
  - 28 colonized, 10 infected – 2 died
  - Investigation revealed elevator channel contaminated with CRE
  - CDC – no breaches found/CMS -“failed to reprocess ERCP endoscopes as recommended by the endoscope manufacturer” – brush and detergent

- **January 2014** - Virginia Mason, Seattle, Washington
  - 39 patients infected with CRE – November 2012 – January 2014 ERCP scopes
  - Drastically changed reprocessing procedure – disinfected, cultured, held for 48 hours, re-cultured

- **January 2015** – UCLA Medical Center, Los Angeles, CA
  - 180 patients exposed, 2 deaths – CRE
  - No breaches in reprocessing found by CDC

- **February 2015** – Cedar Sinai Medical Center, Los Angeles, CA
  - 67 patients exposed, 4 infected with CRE – free home testing kit offered
  - L.A. County health officials said they found no breaches in the cleaning protocol at Cedars

- Jan 2013-Dec 2014 – FDA received 75 medical device reports (MDR) encompassing approx. 135 patients in the US relating to possible microbial transmission from duodenoscopes (not all cases are reported) (FDA Safety Communication Feb 29, 2015)
NEW UNDERSTANDINGS of how biofilms develop and propagate suggest ideas for preventing and eliminating them. Standard antibiotics often fail because they do not penetrate biofilms fully or do not harm bacteria of all species and metabolic states in the films.

1. Free-swimming bacterial cells alight on a surface, arrange themselves in clusters and attach.

2. The collected cells begin producing a gooey matrix.

3. The cells signal one another to multiply and form a microcolony.

4. Chemical gradients arise and promote the coexistence of diverse species and metabolic states.

Pseudomonas - thrives in moist environments
Carbapenem-resistant Enterobacteriaceae (CRE) - gene transfer
What does good Infection Prevention look like in the GI Suite?

- Infection Prevention Program/Plan – accessible to staff
- Documented training and adherence to **Standard Precautions**
- All the time, every day, every patient...this is the minimum infection prevention practices that apply to ALL patient care, in any setting where healthcare is delivered
  - Hand hygiene
  - Personal Protective Equipment (PPE)
  - Safe injection practices
  - Meticulous scope reprocessing
Guiding Professional Organizations

- Association for the Advancement of Medical Instrumentation
  http://www.aami.org/index.aspx
- American Society for Gastrointestinal Endoscopy
  http://www.asge.org/healthcare
- Occupational Safety & Health Administration
  https://www.osha.gov/index.html
- Centers for Disease Control and Prevention
  http://www.cdc.gov
- United States Department of Labor
  http://www.dol.gov
- The Joint Commission
  http://www.jointcommission.org/
- U.S. Food and Drug Administration
  http://www.fda.gov
- World Health Organization
  http://www.who.int/en
- Accreditation Association for Ambulatory Health Care, Inc.
  http://www.aaahc.org/
- International Guidelines for Health Care Providers

“supplement and not replace or modify manufacturer recommended reprocessing procedures”
Basic Infection Prevention

- Hand hygiene
  - Consistent

- Personal Protective Equipment (PPE)
  - Easily obtainable
  - Don’t forget mask during decontamination process

- Safe Injection Practices
  - Since 2001, at least 50 outbreaks involving unsafe injection practices reported to CDC
  - 90% occurred in outpatient settings

The Joint Commissions National Patient Safety Goal NPSG.07.01.01 and CMS– GI suites must monitor hand hygiene, feed data back to staff, set goals for improvement. Think about: Patient as observer.

http://www.researchgate.net/publication/38064122_Engaging_the_patient_as Observer_to_promote_hand_hygiene_compliance_in_ambulatory_care
Endoscopy Clinic Nevada 2007

Fig. 1. Illustration of how indirect syringe reuse can lead to HCV contamination of a shared medication vial. (Data from Centers for Disease Control and Prevention (CDC). Acute hepatitis C virus infections attributed to unsafe injection practices at an endoscopy clinic—Nevada, 2007. MMWR Morbid Mortal Weekly Rep 2008;57:513–7.)
Endoscope Reprocessing
Why High Level Disinfection (HLD)?

- Critical, semicritical, and noncritical according to the degree of risk for infection involved in use of the items
- **Semicritical items** contact mucous membranes or nonintact skin
- These medical devices should be free from all microorganisms; however, small numbers of bacterial spores are permissible
- Semicritical items **minimally** require high-level disinfection using chemical disinfectants
- Endoscopes are considered **semicritical devices**

Challenges

- Complex design of equipment, particularly ERCP and EU
- Reprocessing detailed, multi-step process
- Processing space may be limited
- Microorganisms more and more resistant to antibiotics
- Time constraints – scope turnaround time
- Regulatory guidelines conflicting and ever-changing
- Flexible endoscopes acquire high levels of bioburden because of the cavities they enter
  - CDC reports that the bioburden found on flexible gastrointestinal endoscopes after use can be as high as 10,000,000,000 (that’s billion folks), with the highest levels found in the suction channels
- Even with full adherence to reprocessing protocols, endoscopes may remain contaminated with pathogenic microorganisms

Flexible Endoscope Reprocessing Steps (bedside to storage)

- Pre-treatment/pre-cleaning
- Leak Testing
- Manual cleaning
- Rinse after manual cleaning
- High level disinfection (auto vs manual)
- Rinse after disinfection
- Drying
- Storage
Manufacturer’s “Instructions for Use” (IFU)

- “Closely follow…adherence” – FDA
- “Meticulously follow” – AAMI
- “Meticulous adherence to” – SGNA
- “Strict adherence to” – CDC
- “Follow” – TJC
- “Clean according to” - APIC
What to do with IFUs

• Develop employee competencies that incorporate them
  o Partner with your Infection Preventionist

• Make sure IFUs are...
  o Current/Updated
    • Check websites of manufacturers and guiding bodies
  o Readily available
  o User-friendly
  o Available for each type of scope
Staff Competencies

- Competencies for staff working with specific HLD processes should be initiated and reviewed:
  - Upon new hire
  - AT LEAST annually
    - *** Duodenscopes: CDC 2015 recommends “several times a year”
  - When new equipment is acquired
  - When guiding/regulatory bodies provide updates
- Personnel responsible for reprocessing endoscopes are encouraged to seek certification in flexible endoscope reprocessing
Pre-cleaning

• Perform pre-cleaning immediately with enzymatic detergent to remove debris before bioburden can form (manual and automated)
  o Check IFUs if pre-cleaning cannot be done “immediately”, some IFUs state within one hour – may require longer enzymatic soak before sending for manual clean

• Clean external surface/components of the endoscope using soft cloth, sponge or brushes – see IFU
  o Sponge or cloth must be disposed of, sterilized or HLD between cases

• Transport the soiled endoscope to reprocessing area in a manner that prevents exposure of staff, patients or the environment to the potentially infectious organisms
  o Reprocessing should occur in a room separate from procedure room
Leak Testing

- Failure - Follow IFU - usually disinfection, remove from service and send for repair
- If scope cannot be properly disinfected, it should be considered a contaminated medical device and flagged by attaching a biohazard label or placing in red biohazard bin/bag
- Make sure employees know what to do if scope fails leak test
Manual Cleaning – Enzymatic Cleaner

- Follow detergent’s IFU – be able to measure accordingly
- Disconnect and disassemble endoscope components as far as possible and completely immerse endoscope and components in enzymatic detergent
- Detergent - Medical-grade, low-foaming, neutral pH
- Drain/discard enzymatic detergents between use – not microbiocidal
- After enzymatic discard, disinfect sink or basic before next cleaning
Manual Cleaning

• Necessary prior to automated or manual disinfection
• Flush and brush ALL accessible channels to remove all organic and other residue. Continue brushing until no visible debris
• Use brushes appropriate for the size of the endoscope’s channel, parts, connectors and orifices and brushes should be disposable or thoroughly cleaned and disinfected between uses – see IFU
• Reusable endoscopic accessories (e.g., biopsy forceps or other cutting instruments) that break the mucosal barrier should be mechanically cleaned and then sterilized between each patient use – HLD is NOT appropriate for these items
Manual Cleaning - Duodenoscopes

• Duodenoscopes
  o Manually clean elevator mechanism and surrounding recesses, even when using AER. Raise and lower elevator throughout manual cleaning to allow brushing of both sides. (FDA, Feb 2015)
  o Thoroughly clean elevator mechanism until free of all visible debris – open/raised and closed/lowered positions and consideration be given to use of a magnifying glass (e.g. 10x) to improve detection of residual debris around elevator mechanism. (CDC, March 2015)
    • Look at the brush 360
  o Make sure cleaning area is set up with a bright light and magnification so all sections of the scope being cleaned can be well visualized (APIC Feb 2015)
High Level Disinfecting (HLD)

• Standard for reprocessing of GI endoscopes
• Manual and automated
• AER - Must be compatible with endoscope
• Endoscope must be able to be disinfected by AER – Elevator wire channel is not effectively disinfected by some AEDs – may require 2-5 ml syringe
• Attachments – IFU
• Prepare HLD according to IFU
  o Typically reused
  o Test to assure remain above Minimum Effective Concentration (MEC) – usually test strips – usually before each load – if below, must discard
    • Test strips
      o Product specific
      o Quality control for test strips (log)
• Discard at end of reuse life, regardless of MEC
  o Do not recommend “topping off” to extend MEC – if issue, lot number would be hard to determine - reuse life is determined by first use/activation of original solution
Rinsing after disinfection

- Needed to remove chemical residue from disinfection that might injure skin and mucous membranes of next patient
Drying

• Drying is as important to the preventing to disease transmission and nosocomial infection as cleaning and HLD
• The final drying steps greatly reduce the possibility of recontamination of the endoscope by waterborne microorganisms such as Pseudomonas aeruginosa
• Flush channels with 70-90% ethyl or isopropyl alcohol and dry using forced air
  o Alcohol acts with remaining water on channel surfaces and acts to encourage evaporation of residual water as air flows through the channel
• Thoroughly dry all removable parts
• **Duodenoscopes:**
  o CDC 2015 – Ensure channels of duodenoscope and elevator mechanism are thoroughly dried prior to storage. If not completely dry, bacterial growth can occur, forming biofilm that is difficult to remove and could result in persistent contamination
Storage

• In manner to protect from contamination
• Hang vertically to facilitate drying
• Caps, valves and other detachable components removed – lowers risk of trapping liquid inside instrument – facilitates continued drying
• Storage area should be clean, well ventilated and dust free – discouraging microbial contamination
Storage (not so great)
Interval of Storage b/f re-reprocessing

- AAMI ST91 2015 – Conduct risk assessment to determine maximum storage time for an endoscope before it needs to be reprocessed to use on next patient
- AORN – 5 days (under review for 2016)
- APIC – 7 days
- CDC – not addressed
- FDA – not addressed
- Multisociety guidelines - unresolved issue but reuse within 10-14 days of HLD appears safe
- SGNA 2012 – warrants further investigation

Suggestions:
  - Risk assessment – work with Infection Preventionist
  - Attainable policy
Other

- Water bottles used for cleaning lens and irrigation during procedure
  - Follow IFU
  - HLD or sterilize water bottle and connecting tube AT LEAST daily
  - Use sterile water to fill
Latest Guidelines

- **March 11, 2015 – CDC –**
  - Duodenoscope Reprocessing
    - Inspection and manual cleaning
    - Drying
  - “Surveillance: Although routine culturing of endoscopes is not part of current U.S. guidelines, recent outbreaks associated with duodenoscopes have led some facilities to consider regular monitoring to assess the adequacy of duodenoscope reprocessing.”
  - “Facilities should ensure that each endoscopic procedure is appropriately documented with regard to specific endoscope used in order to allow identification of exposed patients should microbial growth be detected.”

(Interim Protocol for Healthcare Facilities Regarding Surveillance for Bacterial Contamination of Duodenoscopes after Reprocessing, CDC, March 11, 2015)
Latest Guidelines

- **August 4, 2015 – FDA** - “Hospitals and healthcare facilities...may take one or more of the following steps to further reduce the risk of infection and increase the safety of these devices (elevator scopes). Those steps to be considered are:
  - Microbiological culturing
  - Ethylene Oxide Sterilization
  - Use of a Liquid Chemical Sterilant Processing System
  - Repeat HLD

- FDA recommends healthcare facilities performing ERCP evaluate whether they have the expertise, training and resources to implement one or more of these options.”
  - (FDA Safety Communication: Supplemental Measures to Enhance Duodenoscope Reprocessing – August 4, 2015)
HLD vs Sterilization of Elevator Scopes

- AAMI ST91 – 2015 – Sterilization preferred method for all scopes when allowed by IFU
- ASGE (interim dated 3/17/15) – Consider
- CDC – addressed in 2008 or 2015 guidelines
- FDA (supplemental measures 8/4/15) –
  - Perform risk assessment
  - Consider Ethylene oxide sterilization
  - Use of a liquid chemical sterilent processing system
  - Repeat HLD
- Multisociety guidelines – unresolved issue
- SGNA 2013 – not addressed
Quality Controls

• “The use of methods that are able to quantitatively or chemically detect organic residues that are not detectable using visual inspection should be considered and included in facility policies and procedures on device cleaning.” AAMI ST91:2015
  - **Microbial surveillance** (culturing) of elevator mechanism – post HLD
  - **ATP** – Adenosine triphosphate
  - **Residue Assay** – process to quantitatively measure presence or amount of target
  - **Scope lumen visualization** - to view interior endoscope channels after cleaning
Culturing

- Considerations:
  - Interpretation of culture results
  - High rate of false positives
  - Resource intensive – costs and staff time
  - Can be “outsourced” – environmental or contract labs
  - Duodenoscopes quarantined until culture results known – can take 48 hours or longer

ATP Testing

- Sensitive indicator of hygienic status and potential risk
- Relatively easy to perform
- Can use for environmental surfaces as well
- How it works:
  - Special sponge which is passed down the instrument’s channels
  - Swab is then immersed into a luciferase/luciferin reagent
  - Within 15 seconds, light is emitted in direct proportion to the amount of ATP present.
  - The test swab device uses a bioluminescent chemistry technology to convert the invisible concentration of ATP present in the sample into a visible light output.
  - The quantitative result is displayed on-screen in terms of relative light units (RLUs), with 1 RLU roughly equivalent to 1 fmol of ATP
Residue Assay

- Detect the presence of low levels of common scope residues - protein, carbohydrates and hemoglobin
- Cleaning procedure verification
- Easy to perform testing/low cost
- How it works:
  - Test strip dipped into sterile water that has been flushed through the endoscope channel after manual cleaning but before HLD
  - 90 seconds – compare test strip to color guide on bottle
Monitoring Limitations

ATP
• Does not replace cultural testing when warranted (outbreak)
• ATP not produced in certain microbes such as viruses
• Unable to detect gram-negative bacteria as efficiently due to incomplete cell lysis
• Cannot differentiate ATP from different sources
• Detection does not always translate to viable microbes
• No universal ATP RLU standard

Residual Assay
• Does not replace cultural testing when warranted (outbreak)
• Residual check only and not specifically for bacteria
• Only test scope channels
• Check only for cleaning efficacy, not disinfection
Scope lumen visualization

- Advantages
  - You can see inside the scope
  - Quick

- Disadvantages
  - Expensive
  - Microbial contamination is not visible
Summary

How to avoid breaches in Infection Prevention?

• Standard Precautions practiced diligently – without exception – to protect patient and you

• Adherence to EVERY step of the scope reprocessing process

• Competency reviews and infection prevention updates at hire and at least annually thereafter (SGNA, 2012)
  o Include Standard Precautions, equipment reprocessing, PPE use, bloodborne pathogens, disease transmission, safe handling of chemicals and procedures for waste management (SGNA, 2012)

• Consider implementing a quality assurance tool to effectively monitor scope cleaning efficacy
References

• Association for the Advancement of Medical Instrumentation (AAMI), “Flexible and semi-rigid endoscope processing in health care facilities,” ANSI/AAMI ST91.
• Association for Professionals in Infection Control (APIC) Text, Chapter 55 – Endoscopy, 2015.
Have a nice day!

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