Infection Prevention in Endoscopy: 2017 Update

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NESGNA Fall Conference, November 4, 2017
Disclosures

- None
Roadmap

• Back to Basics

• Reprocessing Endoscopes (SGNA, 2016)

• Essential Elements of a Reprocessing Program (CDC, 2017)
In the news

Superbug Found at Second L.A. Hospital

Elliana Deckerman
March 4, 2015

An additional 64 may have been exposed at Cedars-Sinai

Four patients have been infected with a deadly superbug at Cedars-Sinai Medical Center in Los Angeles, the hospital said Wednesday, and an additional 64 may have been exposed.

Health | Local News

Virginia Mason’s ‘superbug’ fix could get used elsewhere

Originally published February 24, 2015 at 8:00 pm | Updated February 25, 2015 at 7:18 am

After a “superbug” outbreak, Virginia Mason’s new protocol to stop the dangerous bacteria from spreading on medical scopes may be an option for other hospitals, a CDC official said.

UCLA superbug: Lawmaker asks Congress to investigate FDA response

Widow sues Virginia Mason; hospital begins notifying ‘superbug’ victims

Originally published March 4, 2015 at 7:26 pm | Updated March 5, 2015 at 4:18 pm

Theresa Bigler, of Woodway, is suing Virginia Mason Medical Center and a medical-device manufacturer after the death of her husband following a “superbug” infection. Hospital officials have reversed course to reach out to affected patients and families.
Olympus' redesigned scope is linked to infection outbreak

Doctors have tied a superbug outbreak at a foreign health facility to a medical scope that Olympus modified last year in an attempt to reduce its risk of spreading bacteria between patients.

Five patients treated with the modified device tested positive for the same potentially deadly bacteria, according to a report filed with the Food and Drug Administration.

By Melody Petersen  •  Contact Reporter

MARCH 22, 2017, 9:35 PM
But not a “new” story

- Transmission by endoscopes is thought to be rare, but incidence is not known; breaches in reprocessing have been associated with transmission
- Bacterial pathogens most common; also HBV, HCV
  - 2008-2009: 16 patients with ESBL *Klebsiella pneumoniae* linked to a duodenoscope, confirmed with molecular typing; practice audits found that manual cleaning and drying before storage were insufficient (Aumeran et al, 2010)
  - 2009: 13 patients with CRE *Klebsiella pneumoniae* linked to a single duodenoscope, linked by molecular typing (Carbonne et al, 2010)
  - 2012-2013: 12 patients with CRE *Klebsiella pneumoniae*, 6 of which linked to a single duodenoscope; ended after maintenance of scope (Kola et al, 2015)
Safety in the gastrointestinal endoscopy unit begins with clear and effective leadership that fosters a culture of safety including teamwork, openness in communication, and efforts to minimize adverse events.

ASGE Ensuring Safety in the Gastrointestinal Endoscopy Unit Task Force
Growth of resistant organisms

Superbug Scare At UCLA -- It's Not The Scopes That Should Scare You

There's a big brouhaha over a cluster of infections following endoscopy at UCLA, but this needs to be placed in some perspective. It's not the endoscopes...
Brief digression: resistant organisms

- The focus of recent reports has been on CRE: Carbapenem-resistant Enterobacteriaceae
  - *Klebsiella pneumoniae* carbapenemase (KPC) c. 1996
  - New Delhi Metallo-beta-lactamase (NDM) c. 2008
  - Up to 50% mortality

- They are easily recognizable, and while they were until recently fairly uncommon, their prevalence has been increasing

- Other organisms are more common
  - Extended spectrum beta-lactamases (ESBL) c. 1985
  - Vancomycin resistant enterococci (VRE) c. 1988
Patients with KPC-producing *Carbapenem-resistant Enterobacteriaceae* (CRE) reported to the Centers for Disease Control and Prevention (CDC) as of August 2017, by state

**KPC enzyme**

- None
- Reported

**Data Table**

CDC, updated 10/13/2017.
NDM, N=230

Patients with NDM-producing *Carbapenem-resistant Enterobacteriaceae* (CRE) reported to the Centers for Disease Control and Prevention (CDC) as of June 2017, by state

CDC, updated 10/13/2017.
New Delhi Metallo-β-Lactamase-Producing Carbapenem-Resistant *Escherichia coli* Associated With Exposure to Duodenoscopes

Lauren Epstein, MD, MSc; Jennifer C. Hunter, DrPH; M. Allison Arwady, MD; Victoria Tsai, MPH; Linda Stein, MPH; Marguerite Gribogianis, MPA; Mabel Frias, MPH; Alice Y. Guh, MD; Alison S. Laufer, PhD; Stephanie Black, MD; Massimo Pacilli, MS; Heather Moulton-Meissner, PhD; J. Kamile Rasheed, PhD; Johannetsy J. Avilan, BS; Brandon Kitchel, MS; Brandi M. Limbago, PhD; Duncan MacCannell, PhD; David Lonsney, PhD; Judith Noble-Wang, PhD; Judith Conway, RN; Craig Conover, MD; Michael Vernon, DrPH; Alexander J. Kallen, MD

**IMPORTANCE** Carbapenem-resistant Enterobacteriaceae (CRE) producing the New Delhi metallo-β-lactamase (NDM) are rare in the United States, but have the potential to add to the increasing CRE burden. Previous NDM-producing CRE clusters have been attributed to person-to-person transmission in health care facilities.

**OBJECTIVE** To identify a source for, and interrupt transmission of, NDM-producing CRE in a northeastern Illinois hospital.

CRE linked to ERCP

- Outbreak investigation at a tertiary care teaching hospital in Illinois; organism was a New Delhi metallo-β-lactamase (NDM) producing *E. coli*; increase in incidence over a several month period prompted an investigation

- Between 1/2013 and 12/2013, 39 case patients identified, 35 of whom had been exposed to a duodenoscope in a single hospital
  - After detection of initial case patients identified, hospital performed CRE screening on exposed patients

- No lapses in re-processing identified

- Scope in questioned was cultured, and environmental cultures from reprocessing areas and procedure rooms were obtained

Outbreak Investigation

Figure 1. Network Diagram of Case Patients

NDM indicates New Delhi metallo-β-lactamase. This diagram illustrates the suspected modes of transmission of NDM-producing Escherichia coli among case patients. Each box represents a case patient. Dashed lines connect case patients with a suspected source of NDM-producing E. coli (e.g., overlapped in the same hospital with a patient with NDM-producing E. coli, but did not share a room or ward with that patient). Patient identifiers beginning with C were identified through clinical culture and are numbered in order of date of positive culture; those beginning with an S were identified through screening culture and are ordered by date of endoscopic retrograde cholangiopancreatography procedure (if applicable). Thirteen case patients had exposure to more than 1 duodenoscope prior to their NDM-positive sample collection date. Two had exposure to 1 duodenoscope associated with the outbreak (C5 and S21). 11 had exposure to 1 outbreak-associated duodenoscope and to duodenoscopes not associated with the outbreak. Case patients with 1 duodenoscope exposure are included with the patient notification group in which they were first identified.
Findings

• Infection control practices and environmental assessment
  – No breaches identified
  – Used enzymatic cleaner and HLD product approved by FDA
  – Used compatible cleaning brushes
  – Scopes serviced according to service schedule

• Duodenoscope investigation
  – Three scopes implicated
  – By October 2013, hospital changed reprocessing from HLD to gas sterilization with ethylene oxide
  – Three rounds of post-processing cultures on all duodenoscopes were negative

• Laboratory Analysis
  – Isolates from all 39 case patients (9 initial, 2 later, 28 through screening) sent to CDC; all highly related by Pulse Field Gel Electrophoresis (PFGE)
Roadmap

• Back to Basics
• Reprocessing Endoscopes (SGNA, 2016)
• Essential Elements of a Reprocessing Program (CDC, 2017)
Roadmap

• Back to Basics
• Environment of Care
• Reprocessing Endoscopes
• ERCP-Associated Infections
Back to basics

- Transmission
- Hand Hygiene
- Transmission-Based Precautions
What are the green X’s?
Requirements for transmission

• A source (or reservoir) of infectious agents
  – Humans—patients, healthcare workers, visitors
  – Environment—contaminated instruments, surfaces

• A susceptible host with a portal of entry receptive to the agent
  – Age, underlying diseases, alteration of normal flora, lines/portals of entry

• Mode of transmission for the agent
Chain of infection

- Infectious Agent
- Reservoir
- Portal of Entry
- Susceptible Host
- Portal of Exit from Reservoir
- Means of Transmission
Breaking the chain

- Infectious Agent
  - Immunization
  - Screen HCWs
  - HH
  - Sterilization
  - Antimicrobials

- Susceptible Host
  - Gloves
  - Masks
  - Respirators
  - PPE
  - Needle and sharps disposal
  - HH

- Portal of Entry
  - HH

- Means of Transmission
  - HH

- Portal of Exit from Reservoir
  - Transmission based precautions
  - Sterilization, disposable supplies
  - Dressings covering wounds
  - Gloves when contact with body fluids
  - Covering mouth and nose when sneezing

- Reservoir
  - Immunization
  - Screen HCWs
# Modes of transmission

<table>
<thead>
<tr>
<th>Mode</th>
<th>Described</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Contact (Direct)</strong></td>
<td>Direct physical contact— touching an infected person or infectious material</td>
<td>Non-immune person touches varicella lesion</td>
</tr>
<tr>
<td><strong>Contact (Indirect)</strong></td>
<td>Transfer of infectious agent through contaminated intermediate</td>
<td>Stool contaminates hands of healthcare workers, patient care devices, <strong>medical instruments</strong></td>
</tr>
<tr>
<td><strong>Droplet</strong></td>
<td>Respiratory droplets carrying infectious pathogens transmit infection</td>
<td>Droplets from the respiratory tract of the source to the susceptible mucosal surfaces of the recipient; crossing distances of 3 to 6 feet</td>
</tr>
<tr>
<td><strong>Airborne</strong></td>
<td>Dissemination of either airborne droplet nuclei or small particles in respirable size range</td>
<td>Droplets or particles remain infective over time and distance</td>
</tr>
</tbody>
</table>
Interventions that work

• Resistant organisms such as CRE, ESBL, VRE, can colonize the GI tract

• With such a large potential reservoir, hand hygiene and barrier precautions, when indicated, are the mainstays of infection prevention to:
  – Reduce the risk of initial colonization, and
  – Prevent transmission to other patients
Hand hygiene

- Alcohol-Based Hand Rub (ABHR) is the recommended method
- Handwashing:
  - Hands visibly soiled
  - After bathroom use; before eating
  - For C diff, handwashing and then ABHR
- HH required before and after contact with the patient or the patient’s environment
  - Gloves are not a substitute
  - Neither are the sleeves of a precautions gown!
### Table: Key studies assessing the effect of hand hygiene interventions on MDROs’ transmission and/or infection

<table>
<thead>
<tr>
<th>Year</th>
<th>Country</th>
<th>Setting</th>
<th>Effect on hand hygiene compliance and/or consumption of alcohol-based handrubs (ABHR)</th>
<th>Impact on MDROs’</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>Switzerland</td>
<td>Hospital-wide</td>
<td>Significant increase in HH compliance from 48% to 60%. Increased consumption of ABHR from 3.5 to 15.4 L/1000 patient-days</td>
<td>Significant reduction in the annual overall prevalence of HAI (42%) and MRSA* cross-transmission rates (37%). Continuous increase in ABHR use. Stable HAI rates and cost savings in a follow-up study</td>
<td>Pittet D et al (9)</td>
</tr>
</tbody>
</table>
| 2008 | Australia  | 1: 6 pilot hospitals  
2: all public hospitals in Victoria (Australia) | 1) Increase of HH compliance 21% to 48%  
Increased consumption of ABHR from 5.3 to 27.6 L/1000 bed-days  
2) Increase of HH compliance from 20% to 53%. Mean ABHR supply increased from 6.0 to 20.9 L/1000 bed-days | 1) Significant reduction of MRSA bacteremia (from 0.05/1000 to 0.02/1000 pt-discharges per month) and of clinical MRSA isolates  
2) Significant reduction of MRSA bacteremia (from 0.03/1000 to 0.01/1000 pt-discharges per month) and of clinical MRSA isolates | Grayson ML et al (11) |
| 2009 | USA        | Hospital-wide                        | Significant increase of HH compliance from 49% to 98% with sustained rates greater than 90%                                                                 | Significant reduction of MRSA rates from 0.52 to 0.24 episodes/1000 patient days                        | Lederer JW et al (23) |
| 2010 | USA        | 2 acute hospitals                    | Significant increase of HH compliance from 65% to 82%                                                                                              | 51% decrease in hospital-acquired MRSA cases during the 12-month period                                | Carboneau C et al (20) |
| 2010 | Canada     | 3 tertiary care hospitals            | Significant difference of HH compliance between the intervention group (48.2%) and the control group (42.6%)                                       | No reduction in MRSA colonization. Intervention group: 48.2%, control group: 42.6%; intervention group: 0.73 cases per 1,000 patient-days. Mean in control group: 0.86 cases per 1,000 patient-days (statistically insignificant) | Mertz D et al (8) |
| 2011 | Taiwan     | Hospital-wide                        | Significant increase of HH compliance from 43.3% to 95.6%                                                                                            | 8.9% decrease in HAIs and a decline in the BSI caused by MRSA and extensively drug-resistant *Actinobacter baumannii*  
Every US$1 spent on HH could result in a US$23.7 benefit | Chen Y-C et al (18) |
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<tr>
<td>2011 Australia</td>
<td>Nationwide (521 hospitals)</td>
<td>In sites not previously exposed to the campaign, increase of HH compliance went from 43.6% to 67.8%</td>
<td>Significant reduction of overall MRSA BSI (from 0.49 to 0.3497 per 10,000 patients-days) but not of hospital-onset MRSA BSI</td>
<td>Grayson ML et al (10)</td>
</tr>
<tr>
<td>2012 Hong Kong (China)</td>
<td>18 LTCFs (4 months)</td>
<td>Significant increase of HH compliance in intervention arms (27% to 61% and 22% to 49%)</td>
<td>Significant decrease of respiratory outbreaks (IRR, 0.12; 95% CI, 0.01–0.93) and MRSA infections requiring hospital admission (IRR, 0.61; 95% CI, 0.38–0.97)</td>
<td>Ho M et al (12)</td>
</tr>
<tr>
<td>2013 Saudi Arabia</td>
<td>Hospital-wide</td>
<td>Significant increase of HH compliance from 38% in 2006 to 83% in 2011 Significant increase in ABHR consumption over time from 10.3 to 57.3 L/1,000 patient-days.</td>
<td>Significant reduction of MRSA infections (from 0.42 to 0.08), VAP (from 6.1 to 0.8), CLA-BSI (from 8.2 to 4.6), catheter-associated UTI (from 7.1 to 3.5)</td>
<td>Al-Tawfiq AA et al (24)</td>
</tr>
<tr>
<td>2013 Spain</td>
<td>Hospital-wide</td>
<td>Significant HH compliance increase from 57% to 85%</td>
<td>Significant reduction of MRSA infections/colonization/10,000 pt-days*</td>
<td>Mestre G et al (25)</td>
</tr>
<tr>
<td>2013 Serbia, France, (33 surgical wards of 10 hospitals)</td>
<td>Multicenter</td>
<td>HH compliance improved in all centres with overall compliance increase from 49.3% to 63.8%</td>
<td>Immediate non-significant increase in nosocomial MRSA isolation rate (aIRR, 1.44, 95% CI, 0.96 to 2.15) with no change in the trend in rates over time in the HH arm of the study Enhanced HH promotion alone was not associated with changes in MRSA infection rates.</td>
<td>Lee AS et al (26)</td>
</tr>
</tbody>
</table>

ABHR, alcohol-based handrub; BSI, bloodstream infection; CLA-BSI, central line-associated BSI; HAI, healthcare-associated infection; HH, hand hygiene; ICU, intensive care unit; LTCFs, long-term care facilities; MRSA, methicillin resistant Staphylococcus aureus; NA, not available; UTI, urinary tract infection; VAP, ventilator-associated pneumonia. *Statistics not reported.
Standard Precautions

• Hand hygiene
• No special room placement required
• Gloves
  – Blood, body fluids, secretions, excretions, mucous membranes, contaminated medical equipment
• Gowns
  – During any activities that may generate splashes or sprays of blood, body fluids, secretions, or excretions
• Mask, Eye Protection, Face Shield
  – A mask, in combination with eye protection or a faceshield, is worn to protect mucous membranes of the eyes, nose, and mouth during activities that may generate splashes or sprays of blood, body fluids, secretions, or excretions.
Transmission-based precautions

- Contact- gowns + gloves, patient placement
- Contact PLUS- gowns + gloves, patient placement, soap and water then AHBR
- Airborne- negative pressure, patient placement, HCW with N95 respiratory or PAPR
- Droplet- patient placement, HCW with surgical mask
- Combinations of these
Do it correctly!
Correct use of gown & gloves for Contact Precautions & Contact Precautions PLUS

Use hand hygiene first!

ALWAYS put on gloves before entering the room!

Wear a gown IF your body or clothes may contact the patient, items, or surfaces in the patient's room.

1. Don gown with opening at back.
2. Tie gown.
3. Pull gloves over cuffs of gown.

When finished, remove gloves first...

1. Pinch and pull off Glove #1
2. Hold Glove #1 in hand that is still gloved.
4. Pull Glove #2 so that it turns "inside out" over Glove #1.
5. Discard in trash.

...then remove gown.

1. Remove gown.
2. Fold "dirty side in."
3. Discard in hamper.

Use hand hygiene last!*

* When leaving a Contact Precautions PLUS room, always WASH HANDS and then use Cal Stat.

Do not save gown for reuse!
Human factors: role models

- Be a role model
- Speak up
- Be gracious

Hand hygiene adherence is influenced by the behavior of role models

James Schneider, MD; David Moromisato, MD; Beth Zemetra, RN; Lisa Rizzi-Wagner, RN; Niurka Rivero, MD; Wilbert Mason, MD; Flerida Imperial-Perez, RN; Lawrence Ross, MD

**Objective:** Proper hand hygiene (HH) reduces nosocomial infections. Therefore, factors that influence HH behavior of healthcare workers are of great interest. We hypothesized that strict HH adherence by supervisor role models would improve the HH behavior of junior staff.

**Design:** Prospective observational study.

**Setting:** Pediatric and cardiac intensive care units of a tertiary care children's hospital.

**Subjects:** Two critical care fellows and four nurse orientees.

**Interventions:** First, we observed and recorded HH adherence of the fellows and nurse orientees and their respective supervising attending physician or nurse preceptor during daily patient care. Subsequently, we paired the same fellows and nurse orientees with a different supervisor who maintained strict HH adherence, and again noted HH adherence. We used measures of HH opportunities and HH adherence consistent with guidelines set by the Centers for Disease Control and Prevention and Association for Professionals in Infection Control and Epidemiology.

**Measurements and Main Results:** HH adherence by fellows and nurse orientees at baseline was 22% of 200 HH opportunities, and improved to 56% of 234 opportunities as a result of role modeling—an average increase of 34% points (95% confidence interval, 18.7–51; p < 0.01 by linear regression), representing a HH adherence rate greater than 1.5 times that of the baseline. The control senior practitioners' HH adherence rate was 20% of 180 opportunities compared with the study senior practitioners' HH adherence of 94% of 187 opportunities—an average difference of 72% points higher compared with the control senior practitioners (95% confidence interval, 56–88.3; p < 0.01 by linear regression).

**Conclusions:** HH adherence of junior practitioners improved under the supervision of adherent role models. These results suggest that HH behavior of senior practitioners plays a crucial influence on other staff. Senior healthcare practitioners should consider the important role they may play in reinforcing or weakening a culture of patient safety and proper HH. (Pediatr Crit Care Med 2006; 10:360–363)

**Keywords:** role; handwashing; infection control; nosocomial infections; behavior; health personnel
Environment of care

• Physical space
  – Easily cleaned
  – No tape on surfaces
  – Supplies stored correctly

• Cleaning the space
  – Regular cleaning schedule, including floors

• Behavior in the space
  – Adherence to appropriate precautions
  – Hand hygiene when going from dirty to clean (i.e., getting clean supplies during a case)
  – Don’t eat/drink where you treat
Roadmap

• Back to Basics
• Reprocessing Endoscopes (SGNA, 2016)
• Essential Elements of a Reprocessing Program (CDC, 2017)
Endoscope-specific factors influencing effectiveness of reprocessing endoscopes (1)

- Scope-related
  - Complex design that may impede effective reprocessing, including elevator mechanism
  - Different models with different procedures
  - Occult damage

SGNA, 2016; U.S. FDA, March 2015.
Endoscope-specific factors influencing effectiveness of reprocessing endoscopes (2)

• Personnel factors
  – Lack of knowledge or unfamiliarity
  – Inadequate number of staff
  – Frequent disruptions during reprocessing
  – Inadequate training
  – Limited accountability
  – Production pressure
Endoscope-specific factors influencing effectiveness of reprocessing endoscopes (3)

- Reprocessing itself
  - Many steps
  - Prone to human error
  - Lag time or delay in reprocessing
  - Inadequate enzymatic concentration/temp/time
  - Inappropriate use of HLD
  - Dilution of enzymatic cleaner
  - Inadequate manual cleaning prior to HLD
  - Inadequate drying before storage
  - Lack of quality control measure to detect problems or lapses

SGNA, 2016; U.S. FDA, March 2015.
Endoscope-specific factors influencing effectiveness of reprocessing endoscopes

- Reprocessing equipment
  - Equipment malfunction
  - Incorrect connectors for flushing aids or AERs
  - Unrecognized problems with water supply
## Spaulding classification system

<table>
<thead>
<tr>
<th>Type of Equipment</th>
<th>Defined</th>
<th>Example</th>
<th>Reprocessing Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Critical</td>
<td>Enters sterile space</td>
<td>Reusable biopsy forceps</td>
<td>Sterilization</td>
</tr>
<tr>
<td>Semi-Critical</td>
<td>In contact with mucous membranes or non-intact skin</td>
<td>Endoscopes</td>
<td>Sterilization or High Level Disinfection</td>
</tr>
<tr>
<td>Non-Critical</td>
<td>In contact with intact skin</td>
<td>Blood pressure cuff</td>
<td>Soap and water or with germicide</td>
</tr>
</tbody>
</table>
Sterilization vs High Level Disinfection

- **Sterilization:**
  - Complete elimination or destruction of all microbial life
  - Meticulous cleaning first
  - Single use or sterilize with steam if possible
    - Heat-sensitive objects can be treated with EtO, hydrogen peroxide gas plasma, or if other methods are unsuitable, by liquid chemical sterilants
    - Liquid sterilants will only work if cleaning precedes treatment and if used according to instructions (concentration, contact time, temperature and pH)

- **HLD:**
  - Complete elimination of all microorganisms; small amount of bacterial spores allowed
  - Meticulous cleaning first
  - HLD, can be done in Automated Endoscope Reprocessor (AER)
Every patient must be considered a potential source of infection, and all endoscopes must be decontaminated with the same degree of rigor following every endoscopic procedure.
Reprocessing is complex

- Pre-Cleaning
- Manual Cleaning
  - High Level Disinfection
  - Rinsing
  - Drying
  - Storage
# Pre-cleaning and cleaning

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pre-Cleaning</strong></td>
<td>Immediately after removal of insertion tube from patient and prior to disconnecting from power source; <strong>occurs at the point of use</strong></td>
<td>Removal of bioburden before it has a chance to dry</td>
</tr>
<tr>
<td>Leak Testing</td>
<td>Performed in designated reprocessing area; can be performed manually (dry or wet), or by mechanical AER</td>
<td>Detects damage to interior or exterior— if damaged, reprocessing procedures will not be effective</td>
</tr>
<tr>
<td>Manual Cleaning and Rinsing</td>
<td>Use of (fresh) enzymatic cleaning solutions; a manual process; includes immersion in enzymatic solution, <strong>meticulous brushing</strong>, flushing</td>
<td>Composition of soil in endoscopes includes proteins, fats, carbohydrates and various chemical salts</td>
</tr>
<tr>
<td>Visual inspection</td>
<td>Visually inspect for conditions that could affect the disinfection process (e.g., cracks, corrosion) and use magnification and adequate lighting to help assist in visual inspection.</td>
<td>Ensure that endoscope is visibly clean; because it is impossible to visualize internal channels, this is where a <strong>rapid cleaning monitor</strong> or rapid audit tool for residual organic soil can be used prior to HLD.</td>
</tr>
</tbody>
</table>
Reprocessing is complex

- Pre-Cleaning
- Manual Cleaning
- **High Level Disinfection**
- Rinsing
- Drying
- Storage
High Level Disinfection

• Endoscopes are heat labile; only HLD with chemical agents or low-temperature sterilization technologies are possible

• **NO** low-temperature sterilization techniques are FDA-cleared for duodenoscopes

• HLD can be done manually or using Automated Endoscope Reprocessors (AERs)
  – The FDA has approved some AERs as washer-disinfectors, which do not require manual precleaning and channel brushing, however, existing guidelines state that manual cleaning and brushing are still needed when using these AERs

• Effectiveness of HLD depends on
  – Effective pre-cleaning, manual cleaning, and rinsing to decrease organic load and microbial content of scope
  – Drying after rinsing to avoid diluting the HLD
  – Proper preparation and use in accordance with manufacturer’s IFUs

Reprocessing is complex

- Pre-Cleaning
- Manual Cleaning
- High Level Disinfection
- Rinsing
- Drying
- Storage
# Rinsing, drying, and storage

<table>
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<tr>
<th>Step</th>
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<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Rinsing</strong></td>
<td>All surfaces and removable parts must be rinsed, and all channels flushed using fresh clean water</td>
<td>Prevents exposure and potential injury of skin and mucous membranes</td>
</tr>
<tr>
<td><strong>Drying</strong></td>
<td>Channels flushed with alcohol, purged with air until dry</td>
<td>Avoid moist environment for bacterial growth and biofilm formation</td>
</tr>
<tr>
<td><strong>Storage</strong></td>
<td>Stored vertically in a clean, well-ventilated and dust-free area; no kinking of the scopes!</td>
<td>Protect from contamination</td>
</tr>
</tbody>
</table>

Standards of Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes, SGNA, 2016.
Re-processing challenges

- Manual, prone to human error
- Production pressure, financial pressure, space contraints
- Some areas of the scope, including elevator mechanism, are difficult to access and microscopic crevices may not be reached for manual removal of bioburden
- Between 1/2013 and 12/2014, the Food and Drug Administration (FDA) received 75 Medical Device Reports related to ~135 patients concerning possible microbial transmission
Completed all steps during manual cleaning with HLD (N = 69)

<table>
<thead>
<tr>
<th>% Complete</th>
<th>Task Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>77%</td>
<td>Leak test in clear water</td>
</tr>
<tr>
<td>100%</td>
<td>Disassemble endoscope completely</td>
</tr>
<tr>
<td>43%</td>
<td>Brush all endoscope channels and compartments</td>
</tr>
<tr>
<td>99%</td>
<td>Immerse endoscope completely in detergent</td>
</tr>
<tr>
<td>99%</td>
<td>Immerse components completely in detergent</td>
</tr>
<tr>
<td>99%</td>
<td>Flush endoscope with detergent</td>
</tr>
<tr>
<td>96%</td>
<td>Rinse endoscope with water</td>
</tr>
<tr>
<td>84%</td>
<td>Purge endoscope with air</td>
</tr>
<tr>
<td>100%</td>
<td>Load and complete automated cycle for high-level disinfection</td>
</tr>
<tr>
<td>86%</td>
<td>Flush endoscope with alcohol</td>
</tr>
<tr>
<td>45%</td>
<td>Use forced air to dry endoscope</td>
</tr>
<tr>
<td>90%</td>
<td>Wipe down external surfaces before hanging to dry</td>
</tr>
</tbody>
</table>

Completed all steps during manual cleaning with HLD (N = 69)

All steps performed in 1.4% of scopes

Personnel skipped 2 or more steps for 45% of scopes

Approaches to improving reprocessing

• Ensure reprocessing is completed according to established protocol
  – Establish institutional program for reprocessing
  – Ensure best practices at each stage of reprocessing
  – Training, retraining, demonstrated competencies

• Monitoring the adequacy of endoscope reprocessing
  – Lack of widely accepted bioburden/microbial benchmarks
  – Lack of widely validated methods of assessment
Microbiological Monitoring of Reprocessing

• Bioburden
• ATP
• Culture
Monitoring reprocessing: bioburden assays

- Surveillance for bioburden and organic matter: protein, carbohydrate, hemoglobin

- Rapid evaluation within minutes

- Allows assessment of adequacy of manual cleaning prior to HLD; if results are positive, allows for re-cleaning prior to HLD

- Proposed benchmarks: 6.4µg/cm² protein; 1.2µg/cm² carbohydrate; 2.2µg/cm² hemoglobin

Bioburden assays

• Three available technologies:
  • Scope-Check
    • Protein residue on surface of endoscope
  • EndoCheck
    • Protein and blood residues within biopsy channel
  • ChannelCheck
    • Protein, blood, and carbohydrate residues within biopsy channel

ChannelCheck

- Place distal end of the lumen item inside a clean collection container
- Inject 10ml of sterile water through the proximal part of the lumen/channel, followed by 10ml of air to aid in complete flushing
- Collect all the fluid that drains from the distal end into the sample collection container
- Mix the sample well (swish)
- Put test strip in, fully submerged, stir for 10 seconds with the test strip
- Remove, dab on an absorbent surface, wait 90 seconds.
ATP bioluminescence

- Light producing reaction between ATP, luciferin and luciferase to estimate levels of ATP in a sample; photons converted to Relative Light Units (RLU)

- ATP is found in all living cells and can indicate the presence of viable organisms and cells that have recently died

- Indirect marker of bioburden

- Benchmark for manual cleaning: < 200 RLUs

Potential targeting of specific sites

<table>
<thead>
<tr>
<th>Component</th>
<th>n</th>
<th>Before manual cleaning</th>
<th>After manual cleaning</th>
<th>n &gt; 200 RLU s</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Before</td>
<td>After</td>
<td>RLU s, mean (range)</td>
<td>RLU s, mean (range)</td>
</tr>
<tr>
<td>Control handle</td>
<td>6</td>
<td>11</td>
<td>45,499 (158–169,846)</td>
<td>41 (7–217)</td>
</tr>
<tr>
<td>Distal end</td>
<td>11</td>
<td>13</td>
<td>46,227 (1,495–234,336)</td>
<td>86 (14–254)</td>
</tr>
<tr>
<td>Biopsy port</td>
<td>9</td>
<td>14</td>
<td>168,247 (563–507,549)</td>
<td>1,314 (42–6,736)</td>
</tr>
<tr>
<td>Channel</td>
<td>15</td>
<td>22</td>
<td>17,238 (403–65,842)</td>
<td>383 (32–1,552)</td>
</tr>
</tbody>
</table>

**NOTE.** All comparisons between mean relative light units (RLUs) before and after manual cleaning by component were statistically significant ($P \leq .001$).
Ready for prime-time?

- Does the detection of ATP > 200 RLU correlate with presence of organisms and risk of transmission of infection?
- What is the relationship between intermediate test results (i.e., ATP, heme, protein) and terminal culture outcomes?
- What about the role of biofilm formation – may impede standard reprocessing.
Culture

• In the US, surveillance culturing of reprocessed scopes is not formally recommended by FDA, CDC

• Challenges:
  – Technique
  – Turn around time; sequestration
  – Benchmark/threshold: 20cfu/mL\textsuperscript{1} vs 100cfu/mL\textsuperscript{2}

• Thus, culturing may be used periodically, but is NOT feasible as a real-time quality control measure

• Bacteria are sensitive to HLD, the key for quality monitoring is really in assuring removal of bioburden using a non-culture method

\textsuperscript{1}\textsuperscript{Beilenhoff et al, Endoscopy, 2007; \textsuperscript{2}Alfa et al, Am J Infect Control, 2012; Komanduri et al, Gastrointestinal Endoscopy, 2014.}
CDC Interim Protocol for Hospitals

• Optional approach to detect bacterial contamination of duodenoscopes
  – Routine culturing of endoscopes is not part of current guidelines

• Facilities can choose to perform post-reprocessing cultures periodically (e.g., monthly or after every 60 procedures per scope, weekly, or after each use)

• Cultures should be obtained after the scope has been reprocessed and dried
CDC Protocol (cont’d)

• Reprocessing
  – Facilities should review all steps in reprocessing several times a year and ensure strict adherence to manufacturer’s instructions, and pay particular attention to inspection and manual cleaning, as well as drying

• Use of culturing
  – Surveillance: routine culturing not part of US guidelines
  – Optimal frequency has not been established
  – Provides a sampling method for culturing

• Non-culture methods
  – Facilities may choose to use, however, interpretation of results is not standardized
  – Results may provide insight regarding quality of reprocessing

CDC Protocol (cont’d)

• During Outbreaks
  – Facilities should consider performing a series of duodenoscope surveillance cultures after reprocessing
  – Until the limits of detection are defined, negative surveillance cultures alone should not be used to rule out duodenoscopes as a source of cross-transmission

• Remedial Actions
  – Any duodenoscope found to be contaminated with any high-concern organisms or unacceptable CFU of low-concern organisms should be reprocessed again with repeat post-reprocessing cultures obtained
  – The duodenoscope should not be used again until it has been demonstrated to be free of high-concern organisms and has an acceptable level of low-concern organisms
  – Positive cultures should prompt a procedure review to ensure adherence to the manufacturer’s reprocessing instructions and to ensure cultures are being performed correctly
  – Patient information and notification
Perspective: Rutala and Weber

- Enforcement of best practices is essential

- Understand the frequency and level of microbial contamination after cleaning and HLD

- Surveillance cultures cannot be used as a real-time monitoring process; but periodic surveillance may be appropriate

- Need to define cutoffs, sampling scheme, trigger for further action, what are those actions

- Investment in R&D of better technology to make scopes easier to clean

Roadmap

• Back to Basics
• Reprocessing Endoscopes (SGNA, 2016)
• Essential Elements of a Reprocessing Program (CDC, 2017)
Essential elements of reprocessing program (CDC, 2017)

- Administrative
  - Leadership, policies, management oversight
- Documentation
  - Tracking, start/end times, effectiveness of products, PM, etc
- Inventory
- Physical Setting
  - Separate reprocessing from patient care
- Education, Training and Competencies
  - Certification in reprocessing does not mitigate need for orientation, ongoing training and education, competency assessments
- Risk Assessment and Quality Assurance
  - Audits, gap analyses
- Disinfection/Sterilization Breach or Failure
- Unresolved Issues
  - Supplemental methods (repeat HLD, culture+quarantine, liquid chemical sterilants, ETO)
  - Endoscope storage interval
  - Endoscope storage space
  - Replacement of endoscopes
Take-home messages

• Infection prevention basics

• Getting reprocessing right is challenging, but there are many resources to help

• Stay tuned…this is a rapidly evolving field
Essential Resources


- **Standards of Infection Prevention in Reprocessing of Flexible Gastrointestinal Endoscopes, SGNA, 2016.**

- **Interim Duodenoscope Sampling Method, CDC, 2015.**

- **Interim Duodenoscope Culture Method, CDC, 2015.**