DIRTY SCOPES: What You Need to Know About the New Reprocessing Guidelines and Infection Risk

A collaborative industry presentation on September 14, 2016 sponsored by the American Bar Association’s Health Law Section and the American Association of Legal Nurse Consultants with cooperation from the Association of periOperative Registered Nurses and The American Association of Nurse Attorneys.
Today’s Presentation

• Jonathan D. Stewart, JD, MS, CPHRM
  o Attorney and risk manager from Washington will discuss human and design factors that contribute to inadequate scope re-processing, and the resultant clinical and organizational risks.

• Sharon A. Van Wicklin, MSN, RN, CNOR, CRNFA(E), CPSN-R, PLNC
  o Senior perioperative practice specialist from Colorado who was the lead author of the AORN Guideline for Processing Flexible Endoscopes will address the new guidelines.

• M. Joanne Walker, RN, BSEd
  o Legal nurse consultant from California will provide tips on examining the medical chart for breaches in the standard of care.

• Sharon K. McQuown, MSN, RN, LNCC
  o Litigation nurse from Texas will moderate this presentation.
Basics

• This presentation will address flexible endoscopes: colonoscopes and duodenoscopes

• These endoscopes have multiple lumens (channels) which, if not disinfected, can transmit disease between patients

• Flexible endoscopes are classified as semi-critical reusable medical equipment and as such must be high-level disinfected or sterilized
250,000 – 400,000 deaths/year due to medical injuries

99,000 deaths/year due to health care-associated infections

? ? ? due to improperly reprocessed endoscopes
Preventable Tragedies: Superbugs and How Ineffective Monitoring of Medical Device Safety Fails Patients

United States Senate
HEALTH, EDUCATION, LABOR, AND PENSIONS COMMITTEE
Patty Murray, Ranking Member

Minority Staff Report
January 13, 2016

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Estimated # of Patients Infected</th>
<th>Approximate time infections</th>
<th>Duodenoscope Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Erasmus Medical Center, Rotterdam, Netherlands</td>
<td>30</td>
<td>January 2012</td>
<td>Olympus</td>
</tr>
<tr>
<td>Clinique De Bercy, Charleroi-Le-Pont, France</td>
<td>3</td>
<td>October 2012</td>
<td>Olympus</td>
</tr>
<tr>
<td>University of Pittsburgh Medical Center Presbyterian Hospital,</td>
<td>13*</td>
<td>November 2012</td>
<td>Olympus</td>
</tr>
<tr>
<td>Pittsburgh, PA</td>
<td></td>
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<tr>
<td>New York Presbyterian/Weill Cornell Medical Center, New York</td>
<td>15</td>
<td>December 2012</td>
<td>Olympus</td>
</tr>
<tr>
<td>City, NY</td>
<td></td>
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<tr>
<td>UMass Memorial Medical Center, Worcester, MA</td>
<td>20</td>
<td>December 2012</td>
<td>Olympus</td>
</tr>
<tr>
<td>Carolinas Medical Center, Charlotte, NC</td>
<td>1</td>
<td>2013</td>
<td>Olympus</td>
</tr>
<tr>
<td>Thomas Jefferson University Hospital, Philadelphia, PA</td>
<td>8</td>
<td>January 2013</td>
<td>Olympus</td>
</tr>
<tr>
<td>Charite-Universitatsmedizin, Berlin, Germany</td>
<td>5</td>
<td>February 2013</td>
<td>Olympus</td>
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<tr>
<td>Advocate Lutheran General Hospital, Park Ridge, IL</td>
<td>32</td>
<td>March 2013</td>
<td>Pentax</td>
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<tr>
<td>Froedtert Hospital, Milwaukee, WI</td>
<td>5</td>
<td>May 2013</td>
<td>Olympus</td>
</tr>
<tr>
<td>Virginia Mason Hospital and Medical Center, Seattle, WA</td>
<td>32</td>
<td>Spring/Summer 2013</td>
<td>Olympus</td>
</tr>
<tr>
<td>Clinique De Bercy, Charleroi-Le-Pont, France</td>
<td>2</td>
<td>November 2013</td>
<td>Olympus</td>
</tr>
<tr>
<td>Hartford Hospital, Hartford, CT</td>
<td>12</td>
<td>January 2014</td>
<td>Olympus</td>
</tr>
<tr>
<td>Massachusetts General Hospital, Boston, MA</td>
<td>7</td>
<td>Before Spring 2014</td>
<td>Pentax</td>
</tr>
<tr>
<td>Advocate Good Samaritan Hospital, Downers Grove, IL</td>
<td>3</td>
<td>May 2014</td>
<td>Fujifilm</td>
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<tr>
<td>Evangelisches Waldkrankenhaus, Spandau, Berlin, Germany</td>
<td>4</td>
<td>May 2014</td>
<td>Olympus</td>
</tr>
<tr>
<td>Boca Raton Regional Hospital, Boca Raton, FL</td>
<td>9*</td>
<td>August 2014</td>
<td>Olympus</td>
</tr>
<tr>
<td>Cedars-Sinai Medical Center, Torrance, CA</td>
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<td>August 2014</td>
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<tr>
<td>UCLA Medical Center, Los Angeles, CA</td>
<td>4</td>
<td>October 2014</td>
<td>Olympus</td>
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<tr>
<td>Carolinas Medical Center, Charlotte, NC</td>
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<tr>
<td>MGH Gastroenterology Associates, Boston, MA</td>
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<td>Pentax</td>
</tr>
<tr>
<td>Massachusetts General Hospital, Boston, MA</td>
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<td>Pentax</td>
</tr>
<tr>
<td>Universitair Medisch Centrum, Utrecht, Netherlands</td>
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<td>January 2015</td>
<td>Olympus</td>
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<tr>
<td>Allegheny General Hospital, Pittsburgh, PA</td>
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<td>February 2015</td>
<td>Olympus</td>
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<tr>
<td>Fox Chase Cancer Center, Philadelphia, PA</td>
<td>3</td>
<td>April 2015</td>
<td>Fujifilm</td>
</tr>
</tbody>
</table>
Clinical risk

Inadequate Cleaning of Flexible Endoscopes before Disinfection Can Spread Deadly Pathogens

The failure to adequately规程 contaminated instruments—that is, to clean and disinfect or sterilize them—before using them on subsequent patients can lead to the spread of deadly pathogens.

A key aspect of effective reprocessing is cleaning biological debris and other foreign material from instruments before the disinfection or sterilization step. If this procedure is not carried out effectively, the disinfection or sterilization step may not be effective.

Flexible endoscopes, in general, and duodenoscopes in particular, are of specific concern because their complex design and long, narrow channels can make effective cleaning difficult. A report of their reprocessing without Endocytoscopy (CRE) infections that occurred a few years ago is a reminder that the problem is not new.

Endoscopes need to be replenished to clean biologically dirty endoscopes that have not been successfully disinfected between cases.

Failure to comply with these recommendations may lead to complications that affect the reprocessing protocol that can lead to deadly infections.
Reputational risk

The Seattle Times

Undisclosed superbug sickens dozens at Virginia Mason

‘Superbug’ infected spouse at Virginia widow told over a year later

Superbug linked to 2 deaths at UCLA hospital; 179 potentially exposed
Regulatory & accreditation risk

- Federal government
- State government
- Voluntary accreditation bodies

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Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C-15-32 Hospitals/CAHs/ASCs

DATE: April 3, 2015
TO: State Survey Agency Directors
FROM: Director
Survey and Certification Group

SUBJECT: Alert Related to Outbreaks of Carbapenem-Resistant Enterobacteriaceae (CRE) during gastrointestinal endoscopy, particularly Endoscopic Retrograde Cholangiopancreatography (ERCP)

Memorandum Summary:

- **Situation**: Recent newspaper articles, medical publications, and adverse event reports associate multidrug-resistant bacterial infections caused by CRE with patients who have undergone ERCP. Duodenoscopes used to perform ERCP are difficult to clean and disinfect, even when manufacturer reprocessing instructions are followed correctly, and have been implicated in these outbreaks. The U.S. Food and Drug Administration (FDA) has issued a Safety Communication warning, with related updates, that the design of duodenoscopes may impede effective cleaning.

- **Expectations for Reprocessing Duodenoscopes**: Hospitals, critical access hospitals (CAHs), and ambulatory surgical centers (ASCs) are expected to meticulously follow the manufacturer’s instructions for reprocessing duodenoscopes, as well as adhere to the nationally recognized Multisociety consensus guidelines developed by multiple expert organizations and issued in 2011.
And that’s just duodenoscopes

Endoscopes have been the vector for patient-to-patient transmission of:

- Salmonella
- Hepatitis B
- Hepatitis C
- Pseudomonas
- H. pylori
Some good news

Regulators, manufacturers, researchers, and clinicians are continually working to improve the reliability of endoscope reprocessing.
Processing Flexible Endoscopes

Sharon A. Van Wicklin, MSN, RN, CNOR, CRNFA(E), CPSN-R, PLNC
What’s the evidence?
Literature Search

Systematic search: January 1994 – October 2015
  • Ovid
  • EBSCO
  • MEDLINE®
  • CINAHL®
  • Scopus®
  • Ovid Cochrane Database of Systematic Reviews

Relevant guidelines and guidance
  • Government agencies
  • Professional organizations
  • Standards setting bodies

Supplementary searches
Evidence Review

Records identified by librarian through database searching:
- CINAHL: 1082
- Cochrane: 0
- Ovid MEDLINE: 1620
- Scopus: 1952

Additional records identified: 377

Records including duplicates: 5030

Records after duplicates removed: 3397

Records excluded by librarian: 1520

Records screened by author: 1877

Records excluded by author: 620

Full-text sources excluded: 839
- Duplicates: 8
- Multiple publications: 14
- No guidance: 103
- Out of scope: 350
- Higher quality evidence available: 364

Full-text sources requested by author: 1257

Full-text sources cited in guidance: 418

Evidence Review
Complex Design
Cycle of Processing

**Acquisition**
1. Purchase
2. Loan
3. Repair

**Transport IV**

**Precleaning III**

**Use**

**Storage IX**

**High-Level Disinfection or Liquid Chemical Sterilization VIII**

**Cleaning VI**

**Inspection VII**

**Packaging and Sterilization VIII**

**Disposition**
1. Decontaminate and repair
2. Discard
Cycle of Processing

Acquisition
1. Purchase
2. Loan
3. Repair

Leak Testing V

Cleaning VI

FAIL

Transport IV

Precleaning III

Use

Storage IX

High-Level Disinfection or Liquid Chemical Sterilization VIII

Inspection VII

Packaging and Sterilization VIII

Disposition
1. Decontaminate and repair
2. Discard

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Cycle of Processing

**Acquisition**
1. Purchase
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**Use**

**Storage IX**

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**Cleaning VI**

**High-Level Disinfection or Liquid Chemical Sterilization VIII**

**Inspection VII**

**Packaging and Sterilization VIII**

**Disposition**
1. Decontaminate and repair
2. Discard
• Preclean as soon as possible after use
Transporting

• Transport in a closed container or transport cart that is
  • leak proof
  • puncture resistant
  • large enough to contain all contents
  • labeled with a biohazard legend

• Begin processing as soon as possible
  • Follow manufacturer’s IFU for delayed processing
Leak Testing

• Perform leak testing before
  • manual cleaning
  • placing the endoscope into cleaning solutions
Manual Cleaning

• Begin manual cleaning as soon as possible after leak testing

Cleaning is the most important step in processing flexible endoscopes!
Inspecting

- Use lighted magnification to inspect for cleanliness and damage
  - Use a borescope* to inspect internal channels
  - Remove defective endoscopes from service and repair or replace

*Borescope: A device used to inspect the inside of an instrument through a small opening or lumen of the instrument
Inspecting

Inspect and evaluate for:
- cleanliness
- missing parts
- clarity of lenses
- integrity of seals and gaskets
- moisture
- physical or chemical damage
- function
Cleaning Verification

• Verify manual cleaning of flexible endoscopes using cleaning verification tests at established intervals and when new endoscopes are purchased
• Cleaning verification tests include
  • Adenosine triphosphate (ATP)
  • Protein
  • Carbohydrate
• Cleaning verification tests may help reduce errors in manual cleaning and improve cleaning effectiveness
## Disinfection/Sterilization

<table>
<thead>
<tr>
<th>Classification</th>
<th>Disinfection Level</th>
<th>Effectiveness</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Critical:</strong> Items that come in contact with sterile tissue or the vascular system</td>
<td>Sterilization</td>
<td>Kills all microbial life</td>
<td>Surgical instruments</td>
</tr>
<tr>
<td><strong>Semicritical:</strong> Items that come in contact with mucous membranes or non-intact skin</td>
<td>Sterilization&lt;br&gt;<strong>High-level disinfection</strong></td>
<td>Kills all microorganisms, but not necessarily all bacterial spores</td>
<td><strong>Flexible endoscopes</strong></td>
</tr>
<tr>
<td><strong>Noncritical:</strong> Items that come in contact with intact skin</td>
<td>Intermediate-level disinfection&lt;br&gt;Low-level disinfection</td>
<td>Kills viruses, mycobacteria, fungi, vegetative bacteria&lt;br&gt;Kills vegetative bacteria, some fungi, lipid viruses</td>
<td>Blood pressure cuffs&lt;br&gt;Stethoscopes</td>
</tr>
</tbody>
</table>
Mechanical Processing

- Mechanically clean and process or mechanically clean and sterilize flexible endoscopes
- Mechanically rinse and flush the endoscope and endoscope channels with critical or sterile water

*Critical water: Water that is extensively treated to remove microorganisms and other materials
• Conduct a risk assessment to determine whether endoscope lumens should be flushed with 70% to 90% ethyl or isopropyl alcohol
Dry exterior surfaces of the endoscope with a soft, lint-free cloth or sponge.

Dry endoscope channels by purging with instrument air or with a mechanical processor drying system.

*Instrument air: A medical gas that is not respired, is filtered to 0.01 micron, free of liquids and hydrocarbon vapors, and dry to a dew point of -40º F (-40º C)
• Store flexible endoscopes in a drying cabinet*

*Drying cabinet: A medical device designed for storage of flexible endoscopes that circulates continuous HEPA-filtered air through each endoscope channel and within the cabinet
If a drying cabinet is not available, store flexible endoscopes in a closed cabinet with HEPA-filtered air that provides positive pressure and allows air circulation.
Storage

• Use a distinct visual cue that clearly identifies flexible endoscopes as processed and ready for use

• Wear clean gloves when handling processed endoscopes
## Storage

<table>
<thead>
<tr>
<th>Professional Organization Recommendations</th>
<th>Studies</th>
<th>Facility Variables</th>
</tr>
</thead>
<tbody>
<tr>
<td>• 3 hours to 1 month</td>
<td>• 48 hours to 56 days</td>
<td>• Type of endoscopes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Processing effectiveness</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Compliance with IFU</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Storage conditions</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Frequency of use</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Patient population</td>
</tr>
</tbody>
</table>
• Establish a policy to determine the maximum safe storage time for processed flexible endoscopes
Competent Personnel

• Processing should be performed by personnel who have received education and completed competency verification activities
Processing Controls

- Perform processing in the same manner in all locations
- Provide sufficient time and numbers of personnel
- Schedule procedures to allow sufficient time for processing
- Maintain sufficient inventory to meet the demand
- Process all endoscopes in the same manner
Water Quality

What’s in YOUR WATER?

• Monitor and audit facility water quality

• Assess at established intervals and after major maintenance to the water supply system
Preventive Maintenance

- Collaborate with manufacturer service personnel to determine schedules for preventive maintenance
  - Align frequency of maintenance with
    - manufacturer’s IFU
    - unique variables
  - Use qualified individuals
Thank you!

Photograph courtesy of North Kansas City Hospital, North Kansas City, MO.
Endoscopy Record Review

WHAT LEGAL NURSE CONSULTANTS (LNCs) SHOULD LOOK FOR
Presenter

Joanne Walker RN
Perioperative Specialist
OR & GI
Regulatory Compliance and Professional Organizations

- Each state’s Department of Health
- Corporate/local facility policies
- Centers for Medicare and Medicaid Services (CMS)
- The American Society for Gastrointestinal Endoscopy (ASGE)
- The Association of periOperative Registered Nurses (AORN)
Accrediting Organizations

- The Joint Commission (TJC)
- The Accreditation Association for Ambulatory Health Care, Inc (AAAHC)
- The American Society for Gastrointestinal Endoscopy (ASGE)
- The American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF)
CMS Ambulatory Surgical Center Conditions for Coverage

- Distinction between sterile surgical room and non-sterile procedure room
- Non-sterile procedure environments, including endoscopy units, now held to same standard as sterile operating rooms
- This includes safe staffing and documentation requirements
Documentation should clearly and accurately describe situations or events occurring to patients undergoing endoscopy.

Information should be divided into 3 major components: Pre-Procedure, Intra-Procedure, and Post-Procedure.

This applies to every facility: endoscopy center, surgery center, hospital.

Each institution must comply with applicable regulations and guidelines.
Pre-Procedure Documentation

- All elements of pre-procedure documentation must be present: History & Physical (H&P), baseline Vital Signs (VS), allergies, anesthesia evaluation with American Society of Anesthesiologists (ASA) classification (if not conscious sedation by RN), signed anesthesia and procedure consents
- Any special requirements re: patient positioning (e.g. neck issues so need extra pillow under head for lying on side, history of left hip replacement)
- Handoff to include all details to ensure patient safety
Intra-Procedure Documentation

- Peri-procedure nursing record detailing names of MD/Nurse Endoscopist, anesthesia provider or RN administering conscious sedation, all other personnel in procedure room including company reps and Radiology Technicians
- Same requirement no matter where procedure room is located, e.g. Radiology Dept for ERCP/stent placement
- Must begin with time-out and commencement of anesthesia administration until completion of diagnostic or therapeutic procedure
- Same requirements as OR documentation
Post-Procedure Documentation

- Post-procedure note to include diagnosis; details of procedure, including all findings; any complications or adverse outcomes; patient’s condition and prognosis after procedure.
- Post-procedure nursing record of VS monitoring, medications ordered/administered, and all interventions/outcomes during recovery phase, plus discharge instructions and names of family/others present who are responsible for patient in 24 hour period post-discharge.
Documentation of Scope Cleaning

- No requirement by accrediting organizations to have details of cleaning procedure in patient record at the present time
- Facility policy on scope identification (e.g. unique scope number facility uses for tracking)
- Cleaning log (kept by GI techs performing cleaning): either on paper in log book, or in automated endoscopy reprocessor (AER) as electronic log that can be printed
- LNC may recommend attorney obtain log book page/printout as part of Discovery
Future of Endoscopy Documentation may include:

- Requirement by accrediting organizations that facilities develop protocols for tracking scope disinfection, i.e. a form which becomes a permanent part of patient records (e.g. OR sterilization cycles on instrument tray lists);
- manufacturers of AERs add internet capability to log reporting, to enable interface with EMR systems;
- scope manufacturers engrave unique identification numbers on every scope and keep a record of the facility that purchases them (e.g. for traceability of third party sellers of refurbished equipment that may require modification).
References

*Guidelines for Nursing Documentation in Gastrointestinal Endoscopy*
The Society of Gastroenterology Nurses and Associates, Inc; 2013

*Standards of Infection Prevention in Reprocessing Flexible Gastrointestinal Endoscopes*
The Society of Gastroenterology Nurses and Associates, Inc; 2016

[www.sgna.org](http://www.sgna.org)
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Contact info:
Joanne Walker RN
443-616-4954
jwalklnc@yahoo.com
How and Why Endoscope Reprocessing Fails: Lessons from Human Factors/Ergonomics

Jonathan D. Stewart, J.D., M.S., RN, CPHRM
Contributors to disease transmission through endoscopes:

- Use of improper disinfecting agents
- Contamination of water source or colonization of Automated Endoscope Reprocessor (AER)
- Flaws in endoscope design that prevent disinfection
- Failure to follow disinfection procedures
### Nielsen-Shneiderman Heuristics

Zhang et al, 2003

<table>
<thead>
<tr>
<th>Heuristic</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consistency</td>
<td>Users should not have to wonder whether different words of situations or actions mean the same thing.</td>
</tr>
<tr>
<td>Visibility</td>
<td>Inform users about what is going on with the system through appropriate display of information.</td>
</tr>
<tr>
<td>Match</td>
<td>The image of the system perceived by users should match the model the users have.</td>
</tr>
<tr>
<td>Minimalist</td>
<td>Any extraneous information is a distraction and a slowdown.</td>
</tr>
<tr>
<td>Memory</td>
<td>Don’t require users to memorize a lot of information. Memory load reduces user’s capacity to carry out the tasks.</td>
</tr>
<tr>
<td>Feedback</td>
<td>Give users prompt and informative feedback about their actions.</td>
</tr>
<tr>
<td>Flexibility</td>
<td>Users always learn and are always different. Give users flexibility of customization and shortcuts to up performance.</td>
</tr>
<tr>
<td>Message</td>
<td>Messages should be informative enough so that users understand the nature of errors, learn from errors, and recover from errors.</td>
</tr>
<tr>
<td>Error</td>
<td>It’s better to design interfaces that prevent errors from happening in the first place.</td>
</tr>
<tr>
<td>Closure</td>
<td>Every task has a beginning and an end. Clearly notify users about the completion of a task.</td>
</tr>
<tr>
<td>Undo</td>
<td>Allow users to recover from errors. Reversible actions also encourage exploratory learning.</td>
</tr>
<tr>
<td>Language</td>
<td>Language should be always presented in a form understandable by the intended users.</td>
</tr>
<tr>
<td>Control</td>
<td>Don’t give users the impression that they are controlled by the systems.</td>
</tr>
<tr>
<td>Document</td>
<td>Always provide help when needed.</td>
</tr>
</tbody>
</table>
Trained evaluators observed reprocessing of the commonly used Olympus GIF 180 endoscopes. They identified 324 unique usability problems arising from 662 heuristic violations. Three heuristics accounted for 81% of the violations.
Minimize memory load

- Don’t require users to memorize a lot of information. Memory load reduces users’ capacity to carry out the tasks.

Informative feedback

- Give users prompt and informative feedback about their actions.

Visibility of system state

- Inform users about what is going on with the system through appropriate display of information.
Recommendations for improving reliability of endoscope reprocessing

- Create and use instructional aids that apply human factors principles
- Optimize reprocessing workspaces
- Use color coding, labeling, and feedback mechanisms to reduce reliance on memory
- Improve endoscope design to facilitate reprocessing
QUESTIONS?