Infection Control Principles and Practice in Endoscopy

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Disclosures:

• I have no conflict of interests.
• I have no financial relationships to disclose.
• There is no commercial support for this presentation.
• I do not endorse any of the products discussed or displayed in conjunction with this activity.
OBJECTIVES

- Discuss current reprocessing and infection control practices and principles in the GI unit

- Disseminate information and promote understanding, which leads to the prevention of infection in the Endoscopy Unit

- Discuss managing infection control initiatives in an Endoscopy unit from reprocessing endoscopes to transmission of infection including patients, staff and endoscopes

*Disclaimer*: Topics and recommendations highlighted in this presentation do not replace specific endoscope care and reprocessing instructions and information provided by the original equipment manufacturer (OEM)
INTRODUCTION

- Reports of infection in GI Endoscopy gain national media coverage
- 2008 hepatitis C outbreak at a Las Vegas colonoscopy clinic and associated properties was “preventable” and “costly”. The combined cost of the outbreak was estimated at $16.3 to $21.9 million.
- Veterans’ Hospitals 2008 (TN, Florida, Georgia)
- June 9, 2010: 68 ASCs in three states (ASGE)
  - 28.4% failed to adhere to recommended practices regarding reprocessing equipment
  - Two-thirds of the 68 centers had a lapse in infection control practices in at least one of five infection control categories
- May 2010 to September 2011 Minnesota Department of Health
  - 7 Endoscope reprocessing breeches
  - 5 Healthcare facilities
- July 2012 Jury finds a hospital “negligent” for improperly cleaning and disinfecting GI endoscopes
- More healthcare-associated outbreaks linked to endoscopes than to any other medical device-CDC
- April 2012- Top 10 technology hazards list-ECRI Institute
- 2013 - Atlanta Surgery Center
- 2014 – Illinois, New Delhi (NDM) producing Escherichia coli-elevator channel
- 2016 – Top 10 Technology Hazards List – ECRI Institute
Top 10 Health Technology Hazards for 2016
EXECUTIVE BRIEF

ECRI Institute is providing this abridged version of its 2016 Top 10 list of health technology hazards as a free public service to inform healthcare facilities about important safety issues involving the use of medical devices and systems. The full report is available to members of certain ECRI Institute programs through their membership web pages and to others through the Solutions Kit described in the inset on the next page.

THE LIST FOR 2016

1. Inadequate Cleaning of Flexible Endoscopes before Disinfection Can Spread Deadly Pathogens
2. Missed Alarms Can Have Fatal Consequences
3. Failure to Effectively Monitor Postoperative Patients for Opioid-Induced Respiratory Depression Can Lead to Brain Injury or Death
4. Inadequate Surveillance of Monitored Patients in a Telemetry Setting May Put Patients at Risk
5. Insufficient Training of Clinicians on Operating Room Technologies Puts Patients at Increased Risk of Harm
6. Errors Arise When HIT Configurations and Facility Workflow Do Not Support Each Other
7. Unsafe Injection Practices Expose Patients to Infectious Agents
8. Gamma Camera Mechanical Failures Can Lead to Serious Injury or Death
9. Failure to Appropriately Operate Intensive Care Ventilators Can Result in Preventable Ventilator-Induced Lung Injuries
10. Misuse of USB Ports Can Cause Medical Devices to Malfunction

THE PURPOSE OF THE LIST

The safe use of health technology—from syringes to bedside patient monitors to health information systems—requires identifying possible sources of danger or difficulty with those technologies and taking steps to minimize the likelihood that adverse events will occur. This list will help healthcare facilities do that.

Produced each year by ECRI Institute’s Health Devices Group, the Top 10 Health Technology Hazards list identifies the potential sources of danger that we believe warrant the greatest attention for the coming year. The list does not enumerate the most frequently reported problems or the ones associated with the most severe consequences—although we do consider such information in our analysis. Rather, the list reflects our judgment about which risks should receive priority now.

All the items on our list represent problems that can be avoided or risks that can be minimized through the careful management of technologies. Additional content provided with the full article, which is available separately, provides guidance to help manage the risks. In this way, the list serves as a tool that healthcare facilities can use to prioritize their patient safety efforts.
RISK OF INFECTION

- Endoscopes reprocessed appropriately pose virtually no risk of patient-borne or environmental microorganisms
  - Early Incidence of cross-infection 1:1.8 million (*Kimmey, 1993*)
  - Recent estimate of risk of infection 1:10 million (*Nelson, 2007*)
- 1966-1992: 281 reported cases
- 1988-1992: 28 reported cases
- All published occurrences of pathogen transmission related to GI Endoscopy have been associated with failure to follow established guideline's and equipment (AER) or product (HLD) failure until recently
- Reprocessing must be in accordance with reprocessing and infection control guidelines and manufacture’s instructions
Endoscopy Related Infections

- HEP B: 5 cases, disinfection and cleaning processes, HLD exposure time

- HEP C: 8 cases, needles, multi-dose vials, syringes,
- HIV: No case

- Bacteria: Pseudomonas 216 cases, Salmonella 48 cases, reprocessing failures, channels, water supply, AER failure

- H. Pylori: 12 cases, inappropriate LCG, inadequate exposure time, PPE
- Prions: no reported cases

- Carbapenem-resistant Enterobacteriaceae (CRE): multi-drug resistant bacteria, “superbugs” 75 patients
That scope goes where?
BREACHES IN PROTOCOL

- Efficacy of manual cleaning and high-level disinfection is personnel dependent – arise as a result of human error, AER failure, HLD failure
- Complex design
- Failure to follow established cleaning/disinfection/sterilization guidelines and infection control practices (Olfstead et al 43-47% of time)
  - Inadequate cleaning (clean all channels)
  - Use of defective equipment (AER mal-function)
  - Flaws in design of endoscopes or AERs
  - Inappropriate/ineffective disinfection (time exposure, perfuse channels, test concentration, ineffective disinfectant, inappropriate disinfectant)
  - Altering equipment
  - Staff rushed due to high volume
  - Rapid turnaround (Alfa, AJIC 25 minutes for ERCP scope/6.5 minutes)
  - Out of date training
- Chemicals may not be used correctly
- Filters bacterial breakthrough if not changed
INFECTION CONTROL IN ENDOSCOPY

- **Endogenous**: Patients own flora/bacteria entering the blood stream or sterile tissue causing infection

- **Exogenous**: Patient to Patient transmission of pathogens

- Healthcare worker ↔ patient
ENDOGENOUS INFECTIONS

- Endogenous Infections may occur during Endoscopy
  - Bacteremia – 4.1% (Diagnostic)
  - Bacteremia - Therapeutic
    - EGD – 8.9%
    - Colon – 4.4%
    - ERCP – 6.4%-18%
    - EUS – 0-5.8%
    - Sclero therapy – 14.6%
    - Dilation – 22.8%
    - PEG-29%
      - Antibiotics (7%) Jain, Larson, Ann. Inter. Med. 1987
  - Unclear if brief bacteremia is clinically significant

- Antibiotic prophylaxis
- ASGE Guidelines
EXOGENOUS INFECTIONS

• Exogenous Infections
  • Inadequately cleaned or disinfected scopes, accessories, equipment (AER)
  • Improper use of aseptic technique
    • Medication vials
    • IV tubing
    • Syringes
    • Needles

• Bacterial Infections
  • C. Difficile
  • H. Pylori
  • Salmonella
  • Pseudomonas

• Parasites

• Fungi

• Prions

• Viral Infections
  • HIV
  • Hep C
  • Hep B

• Miscellaneous Microbial

• Aseptic Techniques

• Follow Instructions

New York Society for Gastrointestinal Endoscopy
39th Annual New York Course
Staff - Patient

- Healthcare worker exposure
  - Estimated 13.2% risk of exposure to a patient’s body fluids during a GI Endoscopy
    - 4.1% splash rate to eyes
  - Needle Sticks
  - Inhalation of aerosolized microorganisms
  - Higher H. Pylori infection in endoscopy personnel with an increase prevalence with year of practice

- Standard Precautions
- Contact precautions
- Aseptic Technique
- PPE
  - <10% of endoscopy staff routinely wear gowns, masks, eyewear
PROFESSIONAL SOCIETY GUIDELINES

- Multi-society guideline on reprocessing flexible GI endoscopes (2011)

- SGNA “Standards of Infection Control In Reprocessing of Flexible Gastrointestinal Endoscopes” (2012)

- OEM instructions for use and reprocessing
Changes in Multisociety Guidelines 2011

• Review of expanded details to critical reprocessing steps
  Review of reprocessing issues for various endoscope attachments such as flushing catheters
• Distinction between risks related to endoscope reprocessing and those related to pre procedural practices
• Discussion of related issues for which data are absent or insufficient to guide practice
  – Endoscopy shelf life or “hang time”
  – Microbiological surveillance testing after reprocessing
  – Questions regarding scope durability and longevity from the standpoint of infection prevention.
• Professional associations and regulatory agencies recognize high-level disinfection as the standard of care in reprocessing flexible endoscopes
• The use of non-immersible endoscopes is no longer acceptable because they cannot be completely immersed in liquid
• FDA approved new labeling for some AER’s (automatic endoscope reprocessors)
**BIOBURDEN/BIOFILM**

- **Bio burden:** population of viable microorganisms on a product and or package  *(AAMI ST:79)*

- **Biofilm:** matrix of different types of bacteria and exopolysaccharides secreted from the bacteria and adherent to the interior surfaces of endoscopes
# CDC Spaulding Classification of Medical Devices

<table>
<thead>
<tr>
<th>Level of Risk</th>
<th>Application</th>
<th>Process</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Critical</td>
<td>Entry or penetration into sterile tissue, cavity or bloodstream</td>
<td>Sterility required (Steam, gas)</td>
<td>Biopsy forceps</td>
</tr>
<tr>
<td>Semi-Critical</td>
<td>Contact with intact non-sterile mucosa or non-intact skin</td>
<td>Sterilization preferred where possible, if sterilization not possible, high level chemical disinfection required</td>
<td>Flexible endoscope</td>
</tr>
<tr>
<td>Non-Critical</td>
<td>Contact with intact skin</td>
<td>Clean as necessary with detergent and water</td>
<td>Blood pressure cuff</td>
</tr>
</tbody>
</table>
COMPONENTS OF INFECTION CONTROL PROGRAM

- Standard Precautions
- Personal Protective Equipment (PPE)
- OSHA
- Reprocessing procedures and Multi-society guidelines
- Disease transmission
- Maintenance of a Safe work environment
- Handling of HLD/sterilants-procedures for waste management
- Additional training and competency
  - New Model of Scope
  - AER
- Annual updates and competency
PERSONNEL

- Ability to read, understand and implement instructions
- Temporary personnel should not be allowed
- All staff should have education, training, and competency regardless of the setting (Orientation and Continuous)
PERSONAL PROTECTIVE EQUIPMENT (PPE)

- SGNA recommends gowns, gloves, and protective eye wear or mask combination when handling HLD.

- It’s the law – OSHA

- Violators:
  - Minimum $100.00
  - Maximum $7,000.00
REPROCESSING ROOM

- Separate from procedure room
- Adequate space for reprocessing activities
- Proper airflow and ventilation Requirements
  - 10 air exchanges per hour
  - Exhaust to outside not back into hospital air supply
  - Air return
- Eye wash station
- Tap water or water that has been filtered by passage through a 0.2 micron filter, bottled sterile water
- Air drying capabilities and storage
JC PERSPECTIVES: SCOPE ROOM CLARIFICATION March 2012

- High level disinfection standard for endoscopes – not sterile environment
- One Room-3 feet minimum separating clean from dirty
- No minimum size requirement – space to handle volume and equipment
- Must have sink(s)
- Eye wash station
- 10 air exchanges/hour, 2 must be fresh air, exhaust to outside
- No requirement for RH or temperature
LIQUID CHEMICAL GERMICIDES (LCG)
HIGH LEVEL DISINFECTANTS/STERILANTS

• Glutaraldehyde

• Cidex OPA

• Peracetic Acid (0.08%, 0.2%)

• Hydrogen Peroxide (1%, 7.5%)

• All cleared by FDA as HLD/sterilants

• See SGNA’s guidelines for use of HLD
MATERIAL SAFETY DATA SHEET (MSDS)

- Descriptive sheet that accompanies a chemical
  - Provides identity of the material, physical hazards, (i.e. flammability), acute and chronic health hazards associated with contact or exposure to the compound
HLD/sterilants Irritants to Staff and Patients

- **Staff**
  - Cough
  - Sneezing
  - Headaches
  - Asthma like symptoms
  - Dermatitis
  - Bronchitis

- **Patients**
  - Colitis
  - Abdominal cramping
  - Bloody diarrhea

Ryan 1995, K m 2012
HLD/sterilant Spill Containment Plan

- Specific for the HLD or sterilant used
- Incorporate MSDS information
- Written procedures for actions to contain the spill
- Communication and evacuation plan
REPROCESSING STEPS

- Pre-cleaning
- Leak test
- Manual cleaning (Most important step)
- Disinfection
- Rinsing
- Drying
- Storage
PRE-CLEANING

- Removal of gross debris (Revised manual 12-13-11)
- Performed in procedure room Immediately following procedure
- Follow OEM instructions for use of adapters
- Transport to reprocessing area in covered container
LEAKAGE TESTING

- Detects damage to scope
- Done prior to immersion following each procedure

- Alternative Methods
  - Wet Leak Test
    - Fresh, clear water
  - Computerized Leak Test
  - Hand held Leak Test
FAILED LEAKAGE TEST

- Wet leakage test
  - Leave leak tester running
  - Remove scope from water

- Know and follow specific OEM protocol for return
  - Most OEM mandate reprocessing prior to returning for repair

- ETO – without water cap
MANUAL CLEANING

- Most important step, removes 99.9% of bio burden
- Performed in the reprocessing room post leak test
- Retained debris may inactivate or interfere with the efficacy of HLD
- Biofilm – meticulous manual cleaning most effective process for inhibiting biofilm development
MANUAL CLEANING - Detergents

- Freshly prepare detergent solution for each endoscope to prevent cross-contamination
  - Dilute and use according to detergent manufacturer’s instructions
- SGNA recommends low-foaming detergent to
  - Clearly visualize each device
  - Allow for complete cleaning of lumen surfaces
    - Excessive foaming can inhibit good fluid contact with device surfaces
- Synthetic lipids (Olestra©) may require additional pre-cleaning with specifically formulated detergent
MANUAL CLEANING

Potential Errors

MH-974
No Valve

MAJ-855 One Way Valve

New York Society for Gastrointestinal Endoscopy
39th Annual New York Course
MANUAL CLEANING

- Follow endoscope OEM instructions
- Use OEM adapters
- Flush OEM recommended amounts detergent and clean water
- Use brushes of proper length and diameter
- Discard single-use brushes
- Follow OEM automated flushing pump IFU
- Reprocess reusable brushes after each use
- Reprocess “all channel” irrigator after each use
- Use germicide to disinfect sink between each use
HLD OF ENDOSCOPES WITH AER

- HLD standard for reprocessing scopes
- Sterile operative field
- Check HLD for MEC
- Disinfect, rinse, alcohol, air cycles
- Method to store and print data
- Elevator channels-small lumen
- Time and Temperature
- Follow AER and Scope manufacturer’s guidelines for HLD, Channel adapters
HLD Disinfection of Endoscopes without an AER (Manual)

- Test HLD for MEC
- Completely immerse scope and all removable parts in basin
- Inject disinfectant into ALL channels
- Cover Basin
- Follow HLD manufacturer’s instructions for scope soak time and temperature
- Timer
Rinse after AER or Manual Disinfection

- Rinse thoroughly all surfaces and removable parts (AER or manual with channel connectors)
- Sterile or filtered tap water using a 0.2 or 0.1 micron filter recommended
  - Reduces the potential for recontamination of waterborne microorganisms
- Fresh clean water used for each rinse
- 3 rinse cycles (GU/OPA Cidex)
- Rinsing prevents exposure and potential injury of skin and mucus membranes from HLD residue
ALCOHOL PURGE & DRYING

- Purge ALL channels with air until dry after the rinse cycle
  - Pseudomonas aeruginosa

- Air/alcohol flush ALL channels
  - 70% isopropyl alcohol (stored properly)
  - Alcohol mixes with the remaining water on surfaces and acts to encourage evaporation of residual water
STORAGE

- Do not store scope with removable parts, (valves, buttons, etc.)

- Hang scopes with all accessories removed

- Hang scopes vertically

- Storage in cabinet with good ventilation and dust-free environment

- Utilize scope protectors if they don’t interfere with scope hanging vertically
REPROCESSING ACCESSORIES

- **Accessories**
  - FDA requires manufacturer’s to provide instruction for cleaning reusable devices

- Refer to the Manufacturer’s guidelines for specifics

- Accessories classified as critical devices and therefore require sterilization

- SGNA’s position, critical items labeled for single use should not be reprocessed and or reused
QUALITY ASSURANCE

• Monitor HLD and sterilants daily and document
• Maintain logs
• Microbiological Surveillance tests
• Personnel Training and Education
• Competency
QUALITY ASSURANCE

- Monitor and document MEC prior to each use
- Conditions that may alter MEC
  - Organic matter
  - Dilution of rinse water
  - Number of uses
  - Test concentration prior to each use
- Maintain a logbook of results
  - By basin and / or AER
- Never extend LCG beyond the reuse life claim of the product
- Do not use strips beyond the date specified on activation
Joint Commission Checklist for an Environment of Care Survey

The list is a starting point for assessing the environment and verifying that it supports consistent and reliable endoscope cleaning and disinfection.

### Environmental tour checklist for endoscope reprocessing areas

**Physical space:**
- Is the area sized appropriately in relation to the volume of equipment processed?
- Do staff put on personal protective equipment (PPE) before entering the area?
- Are staff wearing suitable PPE?
- Is there sufficient work space?
- Are cleaning supplies, storage areas, and other critical items clearly labeled?
- Is there an appropriate hand washing station?
- Is there an appropriate eyewash station?
- Are “dirty” areas physically separated from “clean” ones?
- Are there suitable storage areas for cleaned endoscopes?
  - On visual inspection, do these areas look clean, free of debris and dry?
- If a cabinet serves as storage, does the cabinet have doors?
- Are endoscope storage containers dry and located off the ground?*
- What is the route from the processor to the cabinet? (The route should not cross through the soiled processing area.)*

**Ventilation:**
- Is there negative air pressure to surrounding areas?
- Are air exchange rates and filtration efficiencies appropriate? Are there a minimum of 10 exchanges per hour, with at least two being with fresh, outside air?
- Is exhaust vented directly outside?

**Documentation and training:**
- Are staff aware of the number of endoscopes in the department?
- Does staff know how frequently these are maintained and how that maintenance occurs?
- When staff members are questioned, can they show where evidence-based practices and guidelines are located?
- When staff are asked about their training, does it appear they were trained using the guidelines?
- Are staff given periodic refresher training?
Clarifications and Expectations Keeping It Clean: The EC professional's role in supporting thorough and reliable endoscope reprocessing

- Reprocessing Problematic
  - Failure to follow guidelines: lack of guideline awareness, poor training, limited accountability
  - Decentralized procedures: OR, GI, ENT, Bronch; standardize
  - Time pressures: Short cuts to meet demands
  - Poor Training: People don’t know what they don’t know

- What can EC professionals do to support effective scope reprocessing
  - Develop good working relationships
  - Visit areas during Environmental Rounds (checklist)
  - Verify suitable ventilation: alarms
  - Enable regular and effective endoscope maintenance
  - Remain vigilant: IC/EC/Clinical Staff
<table>
<thead>
<tr>
<th>Problem Area</th>
<th>Description</th>
<th>Strategy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Personal protective equipment (PPE)</td>
<td>Staff doesn’t follow the organization’s policy for wearing</td>
<td>• During the EC tour, verify that staff understand and consistently comply with the organization’s PPE policy. For more guidance on proper PPE for specific situations, see the Occupational Safety and Health Administration (OSHA) guidelines (for example, 29 CFR 1910.132).</td>
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<td></td>
<td>PPE is not in good working order.</td>
<td>• Have proper signage indicating when PPE is necessary.</td>
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<td></td>
<td></td>
<td>• Periodically evaluate lead aprons and other protective gear to ensure that there is no cracking or shielding material displacement.</td>
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<tr>
<td></td>
<td></td>
<td>• Periodically evaluate equipment used to protect patients, such as the collars placed on patients during an X-ray.</td>
</tr>
<tr>
<td>Problem Area</td>
<td>Description</td>
<td>Strategy</td>
</tr>
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<tr>
<td>Lighting</td>
<td>A burned-out light bulb in an exit sign can be a significant safety hazard. Appropriate lighting is important for patient care areas to ensure that staff can correctly read identification badges, charts, and information.</td>
<td>• The Joint Commission requires organizations to have two-bulb exit fixtures so that the loss of one bulb will not leave an area in total darkness. • Assess lighting conditions at various times to gauge whether lighting is suitable for the activities taking place. If lighting levels are not sufficient, explore ways to add lighting. • Ask staff members about their perceptions of lighting to see if there are any concerns about light level and intensity.</td>
</tr>
<tr>
<td>Problem Area</td>
<td>Description</td>
<td>Strategy</td>
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</table>
| Cleaning     | Accumulation of dust, dirt, and potential microbial contaminants on and under environmental surfaces serves as a potential reservoir for microorganisms. Odors from trash or cleaning products may be offensive to patients and staff. In order to clean, housekeeping staff may raise alarm pulls, display wet floor signs, open drawers, or in other ways alter the clinical environment so that it is not ready for use. | • Routine environmental cleaning is necessary to maintain a standard of overall organizational cleanliness. There are requirements, established by government regulation and guidelines issued by the Centers for Disease Control and Prevention (CDC), for maintaining the cleanliness of the health care environment.  
• Each health care organization must have and follow written policies and procedures for environmental cleaning.  
• Have processes in place for limiting and managing odors.  
• Check that these processes are consistently followed.  
• Empty trash more frequently or at different times. |
### Frequently occurring EC safety hazards and strategies for improvement

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<th>Problem Area</th>
<th>Description</th>
<th>Strategy</th>
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</thead>
</table>
| Lack of responsibility for environmental risks | Staff members ignore spills and other hazards                               | • Standard EC.03.01.01, elements of performance 1-3, require organization staff and licensed independent practitioners to remain vigilant about physical risks and take responsibility for addressing them.  
• Ensuring a safe environment requires commitment from all staff. When such a commitment is present, an organization can foster an environment that supports the best possible care for patients. |
INFECTION UPDATE:

THERE IS AN INCREASED PRESENCE OF ANTIBIOTIC RESISTANT ORGANISMS. (WHICH COULD RESULT IN AN INCREASED PRESENCE OF REGULATORY SURVEYS.)
Crash Cart-Laryngoscope

- Examples of compliant storage include, but are not limited to, a peel pack post steam sterilization (long-term) or wrapping in a sterile towel (short-term). Examples of noncompliant storage would include unwrapped blades in an anesthesia drawer, as well as unwrapped blades on top of a code cart.

- Processed via either sterilization or high-level disinfection. Packaged in some way. HICPAC guidelines do not specify the manner in Store in a way that will prevent recontamination.
Ceiling Tiles, Floors and Baseboards
Dilator Carts

- Cleaning policy-Cart
- Expiration Dates
Towels in Scope Cabinets

• Can towels be placed in scope cabinets to collect water, alcohol?
• Yes, as long as lint free
• No, infection control issues
Ventilation Requirements

- Negative or Positive Pressure Rooms??
- 1996-2010:
  - Air pressure for procedure rooms: neutral>negative>neutral>positive
  - Air changes per hour (ACH) 6-15
- JC adopted 2010 FGI EC.02.05.01, EP6 applies to new construction and is not enforceable to older designs.
- Reprocessing Room:  (JC Perspectives March 2012, volume 32, number 3)
  - The room’s air pressure must be negative to the surrounding spaces. For example, the air must move from a corridor into the endoscopy equipment processing room.
  - The air must exhaust directly outside; the air cannot be reused somewhere else in the building.
  - The air must be changed a minimum of 10 times per hour; 2 of the 10 air changes must be fresh, outside air.
  - There are no requirements for relative humidity (RH) or temperature.
Eye Wash Stations

- Eye wash stations are required wherever there is a possibility that caustic or corrosive chemicals can splash into the eye of health care provider. (ANSI standard Z358.1-2009)
- Blood and body fluids: not considered caustic or corrosive
- PPE/MSDS/15 minutes
- JC does not specify location-facility to perform risk assessment
- 10 seconds travel time or 55 feet of the hazard, path not obstructed
- Tepid water with weekly activation and testing (Bacteria)
- Caution portable eye wash bottles vs plumbed eye wash stations.
Soiled Linen and Trash Receptacle

• Is it acceptable to have containers that are designed with a capacity greater than 32 gallons in a healthcare or ambulatory occupancy?

• Yes, provided they are in a room designated as a hazardous area as defined in Life Safety Chapter (see also NFPA 101-2000 18/19.7.5.5; 18/19.3.2.1 and 20/21.7.5.5).
  – Container located outside of a hazardous room exceeds 32 gallons the following will need to occur:
  – A means to limit the internal capacity (such as an insert) to < 32gallons (.5 gallons per square foot in any 64 square foot area)
Under Sink Cabinet Storage

Do the Joint Commission standards prohibit use of under sink cabinets for storage?

No. The Environment of Care and Infection Control standards do not specifically address under sink storage.

- Conduct risk assessments
- Organizations should also check with applicable agencies, safety officers and building engineers
- Chemicals - quantities allowed by both OSHA and the fire protection Authorities Having Jurisdiction (AHJs)
- Chemicals - do not react with each other or with moisture.
ENDOSCOPE TESTING AND TRACEABILITY

- “In the setting of an outbreak caused by suspected infectious or chemical etiology, the environmental sampling should be performed according to standard outbreak procedure”
- The routine use of environmental microbiologic testing of endoscopes for quality assurance has not been established
  - Multi-society guideline, 2011
- New tools available
  - Allow user to test scopes for residual soils
  - Ensure that efforts to clean the unobservable, inside channels have been successful
- EndoCheck™ (Blood or protein residue)
- ChannelCheck™ (Blood, protein & carbohydrate residue)
- ATP (ATP is an enzyme that is present in all living cells, and an ATP monitoring system can detect the amount of organic matter on surfaces)
## ENDOSCOPE STORAGE

<table>
<thead>
<tr>
<th>Organization</th>
<th>Endoscope Type</th>
<th>Shelf-life</th>
</tr>
</thead>
<tbody>
<tr>
<td>AORN (2009)</td>
<td>Flexible endoscopes</td>
<td>&gt;5</td>
</tr>
<tr>
<td>AORN (2000)</td>
<td>Flexible endoscopes</td>
<td>None</td>
</tr>
<tr>
<td>ASGE</td>
<td>GI Endoscopes</td>
<td>Indefinite</td>
</tr>
<tr>
<td>BSG</td>
<td>GI Endoscopes</td>
<td>3 hours</td>
</tr>
<tr>
<td>BTS</td>
<td>Bronchoscopes</td>
<td>None</td>
</tr>
<tr>
<td>CHA</td>
<td>Flexible Endoscopes</td>
<td>12 hours</td>
</tr>
<tr>
<td>SGNA</td>
<td>GI Endoscopes</td>
<td>Indefinite</td>
</tr>
<tr>
<td>WGO</td>
<td>GI Endoscopes</td>
<td>Indefinite</td>
</tr>
<tr>
<td>VHA</td>
<td>GI Endoscopes</td>
<td>12 Days</td>
</tr>
</tbody>
</table>

- Organizational guidelines re: safe storage of flexible endoscopes
- AORN: Association of Peri-operative Registered Nurses; ASGE: American Society for Gastroenterology; Society of Gastroenterology Nurses and Associates; BSG: British Society of Gastroenterology; WGO: World Gastroenterology Organization; BTS: British Thoracic Society; CHA: Czech Hygiene Authorities; VHA: Veterans Health Administration
As a result of our increased use of antibacterials and antibiotics, strains of bacteria have evolved. And gotten stronger. Today, we call them superbugs – bacteria that are resistant to common antibiotics and are very hard to treat.

Superbugs, including CRE bacteria, Clostridium difficile and MRSA, are now one of the biggest health concerns of the 21st century. At least two million Americans suffer infections from antibiotic-resistant bacteria every year, and 23,000 die.
Inadequate Cleaning of Flexible Endoscopes before Disinfection Can Spread Deadly Pathogens

The failure to adequately reprocess 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 biologic debris and other foreign material from instruments before the disinfection or sterilization step. If this precleaning 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 series of fatal carbapenem-resistant Enterobacteriaceae (CRE) infections that attracted a lot of attention in 2014 and 2015 illustrates this concern: The deaths were associated with the use of duodenoscopes that had not been successfully disinfected between uses.

Facilities need to emphasize to their reprocessing staff that inattention to the cleaning steps within the reprocessing protocol can lead to deadly infections.
CRE Infections in Endoscopy

Current Understanding:
• 4 sites published in medical literature
• 5 more sites publicly disclosed
• 1 cluster before 2010, most exposures 2012-2014
• ~ 60 clinical infections and 20+ deaths
• >1000 pts notified for screening
• Some transmissions confirmed by endoscope culture others negative
• Occurrence with all three endoscope manufactures and multiple designs
• Attributed to persistent contamination at elevator region, cable, channel or both
CRE

- Increasingly prevalent in US
- Transmitted despite apparent optimal HLD
- Pts with multiple comorbidity or immunosuppression at greatest risk (infection/death)
- Silent carriage develops in many patients with risk of future infection or transmission
- Mortality of clinical infection is significant (up to 50%)

Gastrointestinal Endoscopy, 2015
Guidance Documents

• CDC
• FDA
• Content Experts
• Epidemiologists
• ASGE
• Olympus
Early Recommendations
FDA and ASGE

• FDA and ASGE
• Pts colonized with CRE, clinical warning and take scope out of service until verified to be free of pathogens
• Implement new manual cleaning and HLD in accordance with manufacturer’s reprocessing instructions
• Train appropriate staff on new instructions and implement ASAP
• Inform patients of benefits, risks associated with ERCP, including possible infection
• In addition to new manufacture’s guidelines take one or more of these additional steps to further reduce the risk of infection and increase safety
  – Microbiological Culturing
  – Ethylene Oxide Sterilization
  – Use of a Liquid Chemical Sterilant Processing System
  – Repeat HLD
Challenges

- Complex design-elevator channel
- Cleaning and HLD
- Pre procedure changes
- Manual cleaning changes

“We have two options...boldly tackle the challenges ahead, or hold off and hope an asteroid strikes.”
CONCLUSION

- Read and follow instructions for use (IFU) that should accompany all OEM medical devices

- Follow recognized industry Guidelines and Standards of Practice

- Stay current and competent

- Get certified
  - CGRN-SGNA
  - C.F.E.R - Certified Flexible Endoscope Reprocessor

http://www.sterileprocessing.org/gi.htm
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