Endoscopy, A Risky Business

Lynne A. Thomas, BSN RN CGER CFER
V.P. Education, Regulation, Compliance
Integrated Medical Systems International, Inc.
Birmingham, AL
Objectives

• Identify vulnerabilities of an endoscopy program
• List regulatory and statutory guidance related to endoscopes and their care
• Identify standardization strategies that can be implemented across the enterprise
Endoscopy Overview

• 20 Million annual endoscopies in the US

• “More health care acquired infections (HAIs) have been linked with the use of contaminated endoscopes than any other medical device.” W.A. Rutala, MD

• Flexible endoscopes listed as one of the top 10 technology hazards for several years. ECRI Institute

• The estimated patient risk of associated infections are considered to be rare at 1:1.8 million procedures. DL Carr-Locke, MD 1993

• Three recent studies have incident rates of 0.5%-3.4% CL Ofstead 2013
Where is Endoscopy Performed?

- GI Department
- Operating Room
- Urology
- General
- Anesthesia
- ENT
- Plastics
- Physician Clinics
- Thoracic
- Bariatric
- GYN
- Pulmonary Lab
- Emergency Depts.
- Intensive Care Units
- Radiation Oncology
- Outpatient Centers
Areas of Regulatory Review

- Facilities
- Supplies
- Equipment
- Management Program
  - Infection Preventionist
  - Risk Management
  - Clinical Engineering
- Safety and Effectiveness (audits)
- Inventory
- Documentation
Before receiving deeming authority for Medicare, an accreditation organization must apply and must demonstrate its ability to meet or exceed the Medicare conditions of participation/coverage specified in the CFR.
CFR §482.41 (c)(2)

“The hospital must ensure that supplies are maintained to produce an acceptable level of safety and quality for patients.”

- Required for day to day need
- Likely to be needed in an emergency
- Adequate provisions to support & maintain
- Stored to ensure safety
  - Theft
  - Damage
  - Contamination
  - Deterioration
CMS Requirements & National Standards

• Maintenance, inspection, and testing frequency and activities for facility and medical equipment is recommended by a risk-based assessment.
• Must develop policies and procedures and maintain documentation supporting practice.
• ANSI/AMMI EQ56:2013 Recommended practice for a medical equipment management program
• ANSI/AAMI EQ 89:2015 Guidance for the use of medical equipment maintenance strategies and procedures
Medical Equipment Management Plan

ANSI/AMMI EQ56 Create and maintain a medical equipment management plan that describes the functions and activities of the medical equipment management program.

TJC Minimize risk in facility: written plan for managing medical equipment.

DNV Establish a medical equipment management system.

AOA/HFAP Establish scheduled preventive maintenance programs for all biomedical equipment in accordance with manufacturer’s recommendations.
Equipment Selection & Acquisition

**ANSI/AAMI EQ56** Document selection process; demonstrate that organization’s experience is utilized.

**TJC** Input from users and servicers.

**DNV** Employ processes for acquisition and selection of equipment.
ANSI:AAMI ST 58 (2013)
Chemical Sterilization and High-Level Disinfection in Health Care Facilities

- Selection of FDA cleared liquid chemical sterilants (LCS) and high level disinfectants (HLD) and gaseous chemical sterilizers
- Safe & effective use of gaseous chemical sterilizing systems, LCSs/HLDs, and associated equipment

- Pre-cleaning, cleaning, packaging
- High-level disinfecting, and/or preferable sterilization of flexible gastrointestinal endoscopes, flexible bronchoscopes, surgical flexible scopes, and semi-rigid operative scopes
- Functional and physical design criteria for endoscope

- Staff qualifications, education, & other personnel considerations
- Processing recommendations
- Installation, care, and maintenance of automated reprocessing equipment
- Quality control
- Quality process improvement
Standard Critical Steps of Endoscope Reprocessing

• Precleaning at Point of Use
• Leak Testing > Rinsing
• Manual Cleaning > Rinsing > ~Drying
• High Level Disinfection > Sterilization
• Rinsing
• Drying
• Storage
• Cleaning verification
AAMI ST91 Verification

- Visual internal and external inspection
- Test cleaning efficacy of mechanical equipment
- Establish monitors of key cleaning parameters (e.g., temperature)
- Documentation of performing personnel and results of verification testing
- Markers for organic soil
  - Protein
  - Carbohydrate
  - Hemoglobin
  - Adenosine Triphosphate (ATP)
  - Bacteria specific enzymes
FDA Advisory August 2015

- Don’t stop using at risk devices
  - Adulterated – modified pre-market approved devices
  - Misbranded – lacked regulatory clearance 510(k)
- Microbial Culturing
- Ethylene Oxide Sterilization
- Liquid Chemical Sterilization Processing
- Repeated High Level Disinfection Cycles
Vulnerabilities

- Perceived risks are outdated
- Most outbreaks are not published
- Most outbreaks are not investigated
- It is difficult to link all issues to contaminated endoscopes
- Reviews of reprocessing practices show widespread lapses in essential steps
- Risks are greater than just infections (e.g., toxicity with aldehydes)

Reprocessing Lapses and Associated Outcomes
Endoscopy Associated Infections (EAI)

- No incentive to report EAI
- Nearly all result from failure to appropriately clean and reprocess
- Three recent studies have incident rates of 0.5%-3.4%
  - Fever
  - Diarrhea
  - Abdominal Pain
- Breaches historically focused on viruses
- Need to focus on EAI transmission by multi microorganisms

Tip of the Iceberg

- Failure to follow guidelines
- Failure to pre-clean
- Inadequate chemical exposure
- Dirty scopes allowed to dry
- Improper (use of) cleaning supplies
- Inadequate/skipped steps
- Improper storage
- Incorrect programming of AERs
- Failure to notice or report malfunctions
- Lack of employee competency
- Documentation lapses
Carbapenem-Resistant *Enterobacteriaceae*

- New-Delhi metallo-β-lactamase
- 48% - 71% mortality in high risk patients\(^7\)
- NDM reportable to state Public Health > CDC
- 2010 1\(^{st}\) reported endoscope associated transmission

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CDC Reported Cases of NDM CRE

This map was last updated on January, 2015

Total NDM-producing CRE = 118*
Consequently…

Infections with carbapenem-resistant *Enterobacteriaceae* (CRE) are on the rise.\(^8\)

- Florida
- Pennsylvania
- Illinois
- Wisconsin
- Minnesota
- Washington
- British Columbia
- California

<table>
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<th>Microorganism Types</th>
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<th>Non-enveloped viruses</th>
<th>Fungi</th>
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Spaulding EH, Chemical disinfection and antisepsis in the hospital. *J Hosp Res* 1957;9 5-31

**Spaulding Classification: Critical**

1. Purchased Sterile or Steam Sterilized
2. EtO ~ H₂O₂
3. Liquid Chemical Germicide
Spaulding Classification: Semi-Critical

- Free from Microorganisms
- Few Spores Permitted
- Contact Mucous Membranes or Nonintact Skin

Glutaraldehyde
Hydrogen Peroxide
Ortho-phthalaldehyde
Peracetic Acid
Peracetic Acid + Hydrogen Peroxide
Spaulding Classification: Non-Critical
Patient Care and Non Patient Care

Contacts Intact Skin But Not Mucous Membranes

Usually Decontaminated at Point of Use
Low Level Disinfectant
Effectiveness of Reprocessing
Carbapenem-Resistant Enterobacteriaceae

Infections with carbapenem-resistant *Enterobacteriaceae* (CRE) are on the rise.

- Florida
- Pennsylvania
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47/50
Endoscopic Retrograde Cholangio Pancreatography

Scope

Esophagus

Stomach

Gallbladder

Duodenum

Pancreas

Viewing major papilla

Catheter
ERCP Scopes     Duodenoscopes
Devices Thread over a Wireguide
Root Causes of Issues with CRE and Duodenoscopes

- Number, location, and resistance of microorganisms
- No incentive to report EALs
- Device design
- Inadequate processes
- Culture
  - Abbreviated processes
  - Delayed processes > biofilm development
Biofilm Development

- Reversible
- Irreversible

- Seconds
- Seconds to Minutes
- Hours
- Hours to Days
- Days to Months
Open Wire System  Closed Wire System
Pre-clean at Point of Use
Immediately

Suction Facility Approved Cleaning Fluid
30 seconds liquid, lift tip, 10 second air

Move Elevator Forward
Suction Facility Approved Cleaning Fluid
30 seconds liquid, lift tip, 10 second air

Flush Open Elevator Wire Channel
Leak Test
Manual Cleaning

Brush In Front of & Behind Elevator at a $45^0$ Angle
Manual Cleaning

Kink in channel
High Level Disinfection or Liquid Chemical Sterilization

All Chemicals Must Have Contact

Set the elevator to the intermediate, 45° position, to maximize contact to all surfaces, including the recessed elevator chamber.
Dry With Air > Alcohol > Air

79 psi
Tip of the Iceberg

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Citation Trends
2014 Regulatory Reviews CMS & TJC

Failure of the governing body to
• Oversee clinical practice
• Ensure ICP had control and management of patient care/clinical practice
• Ensure processes were in place to ensure safe patient care

Failure of the clinical staff to
• Appropriately perform HLD
• Document processes
2014 Recommendation Trends of CMS & TJC

Recommendations for ICP control

- Oversight, approval and audit development and implementation of policy for clinical practices
- Audit clinical processes daily/weekly
- Ensure training to best practice and hospital policy are complementary and comprehensive

Recommendations for department

- Audit documentation
- Clean in a negative pressure environment
- Confirm procedure-based HLD competencies
- Completed, trained on, documented, filed
Physical Space  TJC Online 4/2013

• Is space appropriate for volume?
• Is appropriate PPE donned before entering a room?
• Is there sufficient work space?
• Are critical supplies and areas labeled?
• Are there appropriate hand washing stations?
• Is there an appropriate eyewash station?
Physical Space  

TJC Online 4/2013

- Are dirty areas separated from clean ones?
- Is there clean and appropriate storage of scopes?
- In cabinets with doors?
- Supported dry and off the ground?
- What is the route from the processor to storage?
• 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 2 being with fresh outside air?
• Is exhaust vented directly outside?
Documentation and Training

- Are staff aware of the number of scopes in the department?
- Do they know how frequently they are maintained and how that maintenance occurs?
- Can staff show where there are evidenced based practices?
- Is training based on evidenced based guidelines?
- Is there periodic refresher training?
Impact of Regulations

- Leadership ~ chain of command
- Oversight
- Locations of services
- Variable policies, procedures, and practices
Leadership

- VP of Ancillary Services
- Nursing Service
- Surgical Services
Oversight

- Inconsistent and variable
- Absentee director
- Outsourced services (anesthesia)
Location of Services

• GI Endoscopy Department
• OR – Urology, General, Anesthesia, ENT, Plastics, Thoracic, Bariatric, GYN
• Respiratory – Pulmonary lab, ER, ICU
• Ambulatory Centers
• Radiation Oncology
• Physician Clinics
• Centralized vs. Decentralized Reprocessing
Polices, Procedures, and Practices

• Policies
  • What is to be done
  • Standardized across the enterprise/facility

• Procedures
  • How the policy is to be carried out
  • Unique to each group of providers

• Practices
  • What actually does occur
Standardization Opportunities

- Oversight
- Employee Standardization
- Process Standardization
- Device and Supply Procurement
- Precleaning Chemicals
- Transportation Containers
- Leak Testers
- Automated Flushing Units
- Verification of Cleaning Products
- Capacity to Sterilize
Consultative and Outsourced Solutions

- Equipment
- Processes
- Personnel