Objectives

- Discuss issues and standards associated with infection prevention in the endoscopy setting
- Identify possible sources of infection in the endoscopy setting
- Discuss the categories and use of cleaning and disinfecting agents in reprocessing endoscopy equipment

Hopefully you will learn.....

- How infections are transmitted
- Common pathogens
- Common modes of transmission in endoscopy suites
- Cleaning, disinfection and sterilization of equipment and environment
- Levels of disinfection and their specific use
- Recommended guidelines for endoscopy equipment

Pathway of Disease Transmission

- Transmission-based Precautions
  - Contact Precautions
    - Direct
    - Indirect
  - Droplet Precautions
  - Airborne Precautions

Contact Transmission

- Direct Contact Transmission
  - Transfer of microorganisms from one person to another without and intermediary object
  - Occupational exposure without a device
  - Herpetic whitlow or scabies
Contact Transmission

- Indirect Contact Transmission
  - Transfer of microorganisms from one person to another by means of a contaminated intermediary object
  - Contaminated hands
  - Improperly cleaned endoscopes, equipment or environment
  - Contaminated medication vials

Droplet Transmission

- Droplet Transmission
  - Large droplet (most $\geq$ 5 μm) usually $\leq$ 3 feet but may be 6-10 feet
  - Mostly respiratory agents (Influenza, Pertussis GAS, Bacterial Meningitis)
  - Also proven mode of transmission for Norovirus and Rotavirus

Airborne Transmission

- Airborne Transmission
  - Droplet nuclei (< 5 μm) remain suspended for long distances or dust particles/spores containing microorganisms
  - Inhaled by another person
  - Requires special air handling
  - TB, Rubeola, Varicella, Variola

Common Pathogens in GI

- Prior to 1988, not uncommon (253 reported)
- 1988 adoption of 1st endoscope reprocessing guidelines
- Post 1988, 28 reported cases
- Transmission of exogenous flora
- Transmission of endogenous flora

Common Pathogens in GI

- GI Pathogens
  - GI Viruses (Noro, Rota)
  - C. difficile
  - Salmonella
  - Gram Negative Rods (GNR)
    - Pseudomonas
    - E. coli
  - S. aureus
  - Enterococcus
- Non-GI Pathogens
  - HIV, HBV, HCV
  - vCJD
  - Mycobacterium

Common Pathogens

- Gastrointestinal viruses
  - Norovirus “Cruise ship virus”
    - Can not be grown in culture
    - Modes of transmission
      - Can be resistant to > 10 ppm chlorine
      - Phenolics are usually effective virucidal
  - Rotavirus
    - Typically pediatric outbreaks
    - Very stable
    - Mode of transmission
    - Disinfectants
  - Not identified as attributable to outbreaks from endoscopes
Common Pathogens

C. difficile
- Pathogenicity
- Mode of transmission
- Spore-forming bacteria (Ubiquitous)
- Vegetative vs. spore state
- Special environmental cleaning recommendations
- Hand hygiene considerations
- Colonization vs. infection
- Potential pathogen for outbreaks

Common Pathogens

Salmonella
- ~3% chronic carrier state post infection
- Outbreaks due to improper cleaning of endoscopes and suite
- Infection usually small intestine, but can cause colitis
- Exogenous vs. endogenous

Common Pathogens

Pseudomonas spp.
- Ubiquitous in soil and water
- Large producer of Biofilm
- Associated with several endoscopy outbreaks
- Proper cleaning and final rinsing imperative to reduce the risk of infection
- Commonly resistant to multiple antibiotics
- Mostly exogenous spread

Common Pathogens

E. coli/Klebsiella spp.
- (Enterobacteriaceae)
- Normal GI flora
- Not associated with large outbreaks
- Common organism for endogenous transmission
- ESBL producers (3rd generation cephalosporins)
- Klebsiella also a Carbapenemase producer (Carbapenems)

Common Pathogens

Staphylococcus aureus/Enterococcus
- Both GI flora
- Enterococcus 100%, Staph 30-50%
- Endogenous or exogenous
- MRSA/VRSA
- VRE
- Both susceptible to disinfectants

Common Pathogens

HIV/HBV
- No documented cases of transmission in endoscopy for HIV
- A few older questionable cases of HBV
- HIV very unstable
- HBV very stable
- Proper cleaning and disinfection
- OSHA BBP rule to protect you the HCW
**Common Pathogens**

**HCV**
- Primarily spread blood-to-blood
- Documented cases of transmission of HCV due to high level disinfection (HLD) lapsed
  - Failure to sterilize biopsy forceps between patients
  - Failure to mechanically clean working channel of endoscope prior to disinfection
- Identified in inadequate aseptic techniques
  - Contaminated IV tubing or bags, syringes, multi-dose vials
- Las Vegas Endoscopy Suites

**Variant Creutzfeldt-Jacob Disease (vCJD)**
- Neurologic disease transmitted by proteinaceous agent called prions
- Highly infectious: brain, dura mater, pituitary, eye
- Must less infectious in lymphoid tissue, tonsil, appendix, ileum, rectum
- European Society for Gastroenterologists recommendations
  - Dedicated scope
  - Destroy after use

**Mycobacterium spp.**
- Tuberculosis
  - Documented transmission due to inadequate HLD
  - Lapses in Automatic Endoscope Reprocessors (AERs)
- Intracellulare
  - Lapses in AERs

**Causes of Transmission**
- Environmental contamination
- Equipment
  - Device integrity
  - Inadequate preprocessing
  - Failure in reprocessors
- Chemical failure
- Staff knowledge and training
Causes of Transmission

Environmental contamination
- Endoscopy suite (TJC)
  - IC.02.02.01: The hospital reduces the risk of infections associated with medical equipment, devices, and supplies
  - Decontamination room separate from clean storage or patient care areas

Transmission of Infections

- Layout (AIA)
  - Endoscopy suites may be divided into 3 major functional areas:
    - Procedure Room (200 ft²)
    - Instrument processing room(s)
    - Ventilation (10 Air exchanges/hr, negative pressure, no recirculation)
    - 2 sinks (handwashing, equipment)
  - Patient holding/preparation and recovery room/area

Causes of Transmission

Equipment
- Inadequate pre-cleaning
- Inadequate HLD
- Inadequate drying; no use of alcohol and/or air
- Reusable brushes
- Defaults or breakdown in scopes
- AER or reprocessor malfunctions

Causes of Transmission

Chemical Failure
- Failure to replace solutions (most 14-28 days)
- Improper solution dilution/outdated solution
  - Must monitor reuse
  - Visually inspect
  - Wrong solution

Causes of Transmission

Staff knowledge and training
- Personnel must demonstrate ongoing competency in the use, care and processing of flexible endoscopes and related equipment
  - Education specific to type and design of scopes used and procedures performed
  - Periodically and before new scopes or other equipment are introduced into the practice
  - Understanding of cleaning, disinfection and sterilization

Causes of Transmission

Training MUST include:
- Set up/Breakdown
- Cleaning
- Disinfection/sterilization
- Storage
- SUDs
- Periodically retrain and assess competence
- Follow manufacturer recommendations
Cleaning, Disinfection and Sterilization

All items in healthcare facilities are subject to cleaning, disinfection or sterilization.


EH Spaulding believed that an object’s intended use determined how to disinfect it.
- Classification scheme designed based on risk of infection for an item’s intended use.

EH Spaulding Scheme
- Critical
- Sterilization
- Semicritical
  - High Level Disinfection
- Noncritical
  - Intermediate or Low Level Disinfection

Cleaning
- the removal of visible soil (e.g., organic and inorganic material) from objects and surfaces and normally is accomplished manually or mechanically using water with detergents or enzymatic products.

Disinfection
- a process that eliminates many or all pathogenic microorganisms, except bacterial spores, on inanimate objects.

Sterilization
- a process that destroys or eliminates all forms of microbial life and is carried out in health-care facilities by physical or chemical methods.

CRITICAL – Objects which enter normally sterile tissue or the vascular system must be subjected to sterilization because these objects if contaminated can transmit disease.
- Surgical Equipment
- Endoscopes entering sterile body sites
- Cardiac and urinary catheters
- Implantable items
- Ultrasound probes used in sterile body sites

Sterilization Methods kill all microorganisms including all spores.
- Methods include:
  - Steam
  - Ethylene Oxide (Gas)
  - Hydrogen Peroxide Plasma (Gas Plasma)
  - Ozone
  - VHP
  - Chemical
Cleaning, Disinfection and Sterilization

Chemical sterilants include:
- >2.4% glutaraldehyde-based formulations
- 0.95% glutaraldehyde with 1.64% phenol/phenate
- 7.5% stabilized H₂O₂
- 0.2% peracetic acid
- 7.95% H₂O₂ with 0.23% peracetic acid
- 0.08% peracetic acid with 1.0% H₂O₂
(Follow manufacturer exposure times)

Liquid chemical sterilants reliably produce sterility only if cleaning precedes treatment and if proper guidelines are followed regarding concentration, contact time, temperature, and pH.

Steam Sterilization Advantages
- Inexpensive
- Non-toxic
- QC easy
- Rapid effective microbicidal
- Rapid cycle times
- Excellent medical packaging penetration

Ethylene Oxide (ETO) Advantages
- Effective microbicidal
- Excellent package penetration
- Inexpensive
- Operation and QC easy

ETO Disadvantages
- Potentially hazardous to patients and staff
- Lengthy cycles
- CFC banned post 1985
- Efforts to reduce ETO emissions
- Flush all endoscope channels with air
- Can only run full loads (EPA)
- Can not transfer abator to separate aerating cabinet

Hydrogen Peroxide Gas Plasma Advantages
- Safe
- Fast (28-75 minutes cycle time)
- Good choice for heat sensitive items
- Simple to install, operate and monitor

Disadvantages
- Small sterilization chamber
- Paper linens liquids
- Restrictions for endoscope lumen size
Cleaning, Disinfection and Sterilization

- **Hydrogen Peroxide Gas Plasma**
  - Disadvantages
    - Small sterilization chamber
    - Paper, linens, liquids
    - Restrictions for endoscope lumen size
    - Potential toxicity

Cleaning, Disinfection and Sterilization

- **Peracetic Acid**
  - Advantages
    - Rapid cycle time
    - Low temperature sterilization
    - Safe (Environment, patients, staff)
    - Sterilant flows through endoscope which facilitates salt, protein and microbe removal

- **Steris System 1 Processor**
  - Advantages
    - Rapid cycle time
    - Instrument and material compatible
    - Sterilant vs HLD
  - Disadvantages
    - Small processing chamber
    - Lack of good biological for routine monitoring
    - Expensive
    - Patented system - must use their sterilants
    - FDA Issues

Cleaning, Disinfection and Sterilization

- **Steris**
  - Made changes to their System 1 Processor
  - Did not obtain FDA approval
  - FDA sent warning letter to Steris May 15, 2008
  - 2/19/2009 Steris sent letter to customers to ease fears
  - 12/10/2009 FDA pulled claim for sterilization
  - 12/17/2009 FDA published alternatives
  - 2/2/2010 FDA extended to 18 months
  - 2/22/2010 FDA Endoscope manufacturers remove system 1 as approved reprocessing method

http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm194429.htm
Cleaning, Disinfection and Sterilization

SEMICRITICAL – Items which contact mucous membranes or nonintact skin must be subject minimally to high level disinfection (HLD) with a chemical disinfectant. These devices should be free from all microorganisms except a small number of bacterial spores

- Respiratory therapy and anesthesia equipment
- Some endoscopes
- Laryngoscope blades
- Cystoscopes
- Esophageal manometry probes
- Anorectal manometry catheters
- Diaphragm fitting rings

HLD kill all microorganisms except a small number of spores

HLD include:

- Glutaraldehyde (Cidex, Metricide)
- H₂O₂ (Sterrad)
- Ortho-phthalaldehyde (Cidex OPA, Opaciden)
- Peracetic acid with H₂O₂ (Peract, Endospor Plus)

Cleared by the Food and Drug Administration (FDA) and are dependable high-level disinfectants provided the factors influencing germicidal procedures are met.

Cleaning, Disinfection and Sterilization

Glutaraldehyde Advantages

- Inexpensive
- Excellent materials compatibility
- Need pH 7.5-8.5

Cleaning, Disinfection and Sterilization

Glutaraldehyde Disadvantages

- Some organisms resistant
- Efficacy decreases after few days in AERs
- Respiratory irritation from vapors
- Residual organic materials fixed to surfaces
- Test strips expire
- Exposure can cause colitis
- Need to monitor exposure

Cleaning, Disinfection and Sterilization

H₂O₂ Advantages

- No activation necessary
- No odor or irritation
- Does not fix residual organic materials
- Inactivates Cryptosporidium

Cleaning, Disinfection and Sterilization

H₂O₂ Disadvantages

- Material compatibility concerns
- Serious eye damage with contact

Cleaning, Disinfection and Sterilization

Ortho-phthalaldehyde Advantages

- Fast acting
- No activation
- Odor not significant
- Excellent materials compatibility
- Does not fix organic materials
Cleaning, Disinfection and Sterilization

Ortho-phthalaldehyde

Disadvantages
- Stains skin, mucous membranes, clothing, surfaces
- Hypersensitivity with repeated exposure
- Eye irritant
- Slow sporicidal activity

Peracetic acid with H₂O₂

Advantages
- No activation necessary
- No odor/irritation

Disadvantages
- Material compatibility concerns
- Potential for eye skin damage
- Limited clinical experience
- Need longer exposure times for certain organisms
- Poor rinsing is associated with PMC-like enteritis

NONCRITICAL – Items which only come into contact with intact skin. Intact skin is an effective barrier to most microorganisms, therefore sterility is “not critical.”

Two types:
- noncritical patient care items
- noncritical environmental surfaces

Noncritical items are subject to intermediate or low level disinfection.

EPA Contact time = 10 minutes
- Phenolics (Intermediate or low)
- Quaternary Ammonium Compounds (Quats) - Low
- Ethyl or Isopropyl alcohol (70-90%) – (Intermediate)
- Household bleach (5.25-6.15%) (Low 1:10 dilution, Intermediate 1:100)
- Iodophors (low)

Cleaning, Disinfection and Sterilization

Noncritical patient care:
- Bedpans
- Blood pressure cuffs
- Crutches
- Computers

Noncritical environmental surface:
- Bed rails
- Some food utensils
- Bedside tables
- Patient furniture
- Floors

Cleaning must be accomplished thoroughly prior to disinfection or sterilization.

Organic and inorganic materials remaining will interfere.

Decontamination ≠ Cleaning
- Decontamination is the process of removing microorganisms so objects are safe to handle, use or discard.
- Cleaning agents typically are phenolics or quats.
Cleaning, Disinfection and Sterilization

Endoscope cleaning
- All endoscopes must be decontaminated and cleaned immediately after use and prior to HLD

Mechanically and meticulously clean internal and external surfaces, including brushing internal channels and flushing each internal channel with water and a detergent or enzymatic cleaners (leak testing is recommended for endoscopes before immersion).
- HLD or sterilize

Final Drying process A MUST
- Flush all channels with 70% alcohol
- Purge with air

SGNA position statement
- HLD H₂O container, cap and tubing daily and dry completely
- Greatly reduces microbial recontamination from waterborne pathogens

"Our bravest and best lessons are not learned through success, but through misadventure."
- Amos Bronson Alcott

Thank You!

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