INFECTION PREVENTION AND CONTROL IN THE ENDOSCOPY UNIT

Kathy Zegarski BS, CIC
Kettering Medical Center
Infection Prevention and Control
March 6, 2010

1

NO DISCLOSURES

2

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

3

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

4

Pathway of Disease Transmission

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

5

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

6

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 ≥ 5 µm) usually ≤ 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

13

Common Pathogens

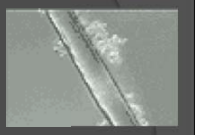
Salmonella

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

14

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

15

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)

16

Common Pathogens

Staphylococcus aureus/Enterococcus

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

17

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

18

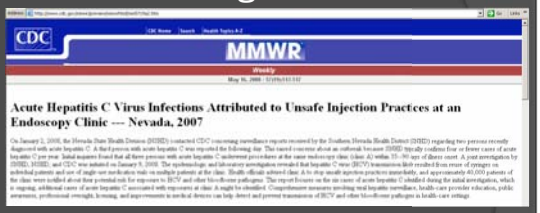
Common Pathogens

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

19

Common Pathogens


CDC

MMWR

Weekly

Acute Hepatitis C Virus Infections Attributed to Unsafe Injection Practices at an Endoscopy Clinic --- Nevada, 2007

20

(Un)Common Pathogens

Variant Creutzfeldt-Jacob Disease (vCJD)

- Neurologic disease transmitted by proteinacous 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

21

Common Pathogens

Mycobacterium spp.

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

22

WHAT CAUSES DISEASE TRANSMISSION

23

Causes of Transmission

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

24

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

25

Transmission of Infections

- Layout (AIA)
  - Endoscopy suites may be divided into 3 major functional areas:
    - Procedure Room (200 ft^2)
    - Instrument processing room(s)
      - Ventilation (10 Air exchanges/hr, negative pressure, no recirculation)
      - 2 sinks (handwashing, equipment)
    - Patient holding/preparation and recovery room/area (80 ft^2/pt)
- Storage of scopes(AORN)
  - Closed, well ventilated cabinet not touching one another
  - Adequate height to allow scope to hang vertically and not touch bottom
  - Internal walls must be surface cleanable (weekly or monthly), preferably with scope protectors separating scopes

26

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

27

Causes of Transmission

Chemical Failure

- Failure to replace solutions (most 14-28 days)

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofSingle-UseDevices/UCM133514

- Improper solution dilution/outdated solution
  - Must monitor reuse
  - Visually inspect
- Wrong solution

28

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

29

Causes of Transmission

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

30

PREVENTION OF TRANSMISSION

Cleaning, Disinfection and Sterilization

- All items in healthcare facilities are subject to cleaning, disinfection or sterilization.
- CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008.
- EH Spaulding believed that an object's intended use determined how to disinfect it.
  - Classification scheme designed based on risk of infection for an items' intended use.

Cleaning, Disinfection and Sterilization

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

Cleaning, Disinfection and Sterilization

- 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.

Cleaning, Disinfection and Sterilization

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

Cleaning, Disinfection and Sterilization

- 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 H_2O_2
- 0.2% peracetic acid
- 7.35% H_2O_2 with 0.23% peracetic acid
- 0.08% peracetic acid with 1.0% H_2O_2

(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.

37

Cleaning, Disinfection and Sterilization

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

38

Cleaning, Disinfection and Sterilization

- Disadvantages
  - Potential for burns to staff
  - Heat labile instruments
  - May leave instruments wet

39

Cleaning, Disinfection and Sterilization

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

40

Cleaning, Disinfection and Sterilization

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

41

Cleaning, Disinfection and Sterilization

- 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

42

Cleaning, Disinfection and Sterilization

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

43

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

44

Cleaning, Disinfection and Sterilization

- Peracetic Acid Disadvantages
  - Point of use; no sterile storage
  - Material incompatibility
  - Small load capacity
  - Potential hazards
    - Eye and skin damage

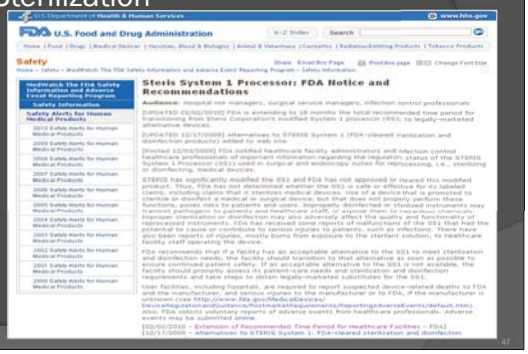
45

Cleaning, Disinfection and Sterilization

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

46

Cleaning, Disinfection and Sterilization



47

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
  - 12/3/2009 FDA pulled claim for sterilization
  - 12/10/2009 FDA gave 3-6 months to replace
  - 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

48

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

49

Cleaning, Disinfection and Sterilization

- HLD kill all microorganisms except a small number of spores
- HLD include:
  - Glutaraldehyde (Cidex, Metricide)
  - H_2O_2 (Sterrad)
  - Ortho-phthalaldehyde (Cidex OPA, Opaciden)
  - Peracetic acid with H_2O_2 (Peract, Endospore Plus)
- Cleared by the Food and Drug Administration (FDA) and are dependable high-level disinfectants provided the factors influencing germicidal procedures are met .

50

Cleaning, Disinfection and Sterilization

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

51

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

52

Cleaning, Disinfection and Sterilization

- H_2O_2 Advantages
  - No activation necessary
  - No odor or irritation
  - Does not fix residual organic materials
  - Inactivates Crytosporidium
- H_2O_2 Disadvantages
  - Material compatibility concerns
  - Serious eye damage with contact

53

Cleaning, Disinfection and Sterilization

- Ortho-phthalaldehyde Advantages
  - Fast acting
  - No activation
  - Odor not significant
  - Excellent materials compatibility
  - Does not fix organic materials

54

Cleaning, Disinfection and Sterilization

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

55

Cleaning, Disinfection and Sterilization

- Peracetic acid with H_2O_2 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

56

Cleaning, Disinfection and Sterilization

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

57

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

58

Cleaning, Disinfection and Sterilization

- 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)

59

Cleaning, Disinfection and Sterilization

- 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

60

Cleaning, Disinfection and Sterilization

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

61

Cleaning, Disinfection and Sterilization

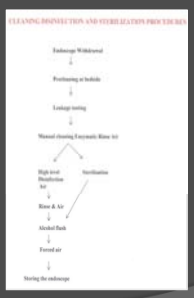
- Mechanically and meticulously clean internal and external surfaces, including brushing internal channels and flushing each internal channel with water and a detergent or enzymatic cleaners (leak testing is recommended for endoscopes before immersion).
- HLD or sterilize

62

Cleaning, Disinfection and Sterilization

- Final Drying process A MUST
  - Flush all channels with 70% alcohol
  - Purge with air
- SGNA position statement
  - HLD H_2O container, cap and tubing daily and dry completely
- Greatly reduces microbial recontamination from waterborne pathogens

63



64

"Our bravest and best lessons are not learned through success, but through misadventure."

-Amos Bronson Alcott

65

Thank You!

Kathy.Zegarski@khnetwork.org

66