

INFECTION CONTROL IN ENDOSCOPY

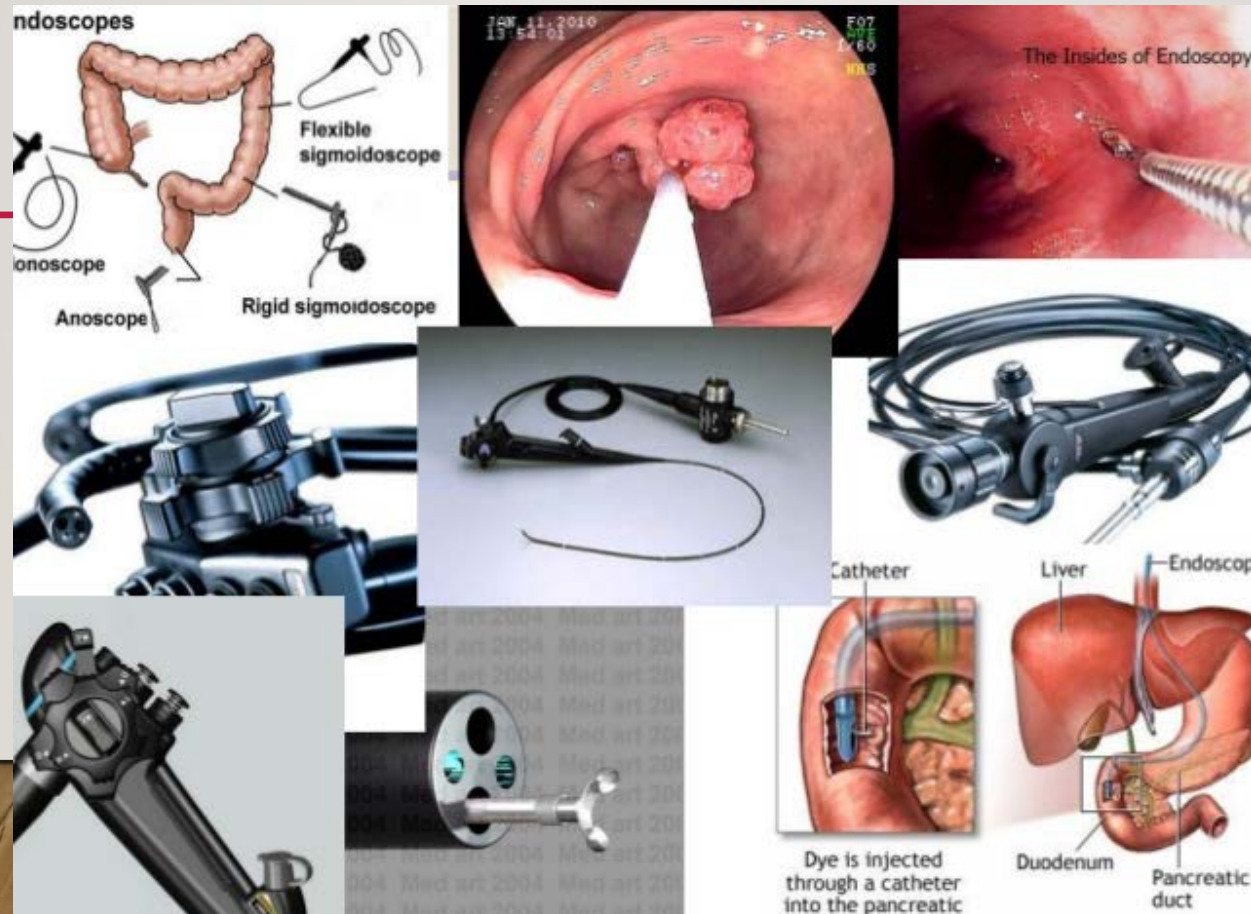
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2 INFECTION PREVENTION AND CONTROL IN THE ENDOSCOPY UNIT



3 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

4 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

BACKGROUND

Despite the large number and variety of GI endoscopic procedures performed, documented instances of infectious complications remain rare, with **an estimated frequency of 1 in 1.8 million procedures.**

Endoscopy-related infection may occur under the following circumstances:

(1) microorganisms may be spread from patient to patient by contaminated equipment (**exogenous**)

(2) microorganisms may spread from the GI tract through the bloodstream during an endoscopy to susceptible organs or prostheses, or may spread to adjacent tissues that are breached as a result of the endoscopic procedure (**endogenous infections**), or

(3) microorganisms may be transmitted from patients to endoscopy personnel and perhaps from endoscopy personnel to patients.

7 PATHWAY OF DISEASE TRANSMISSION

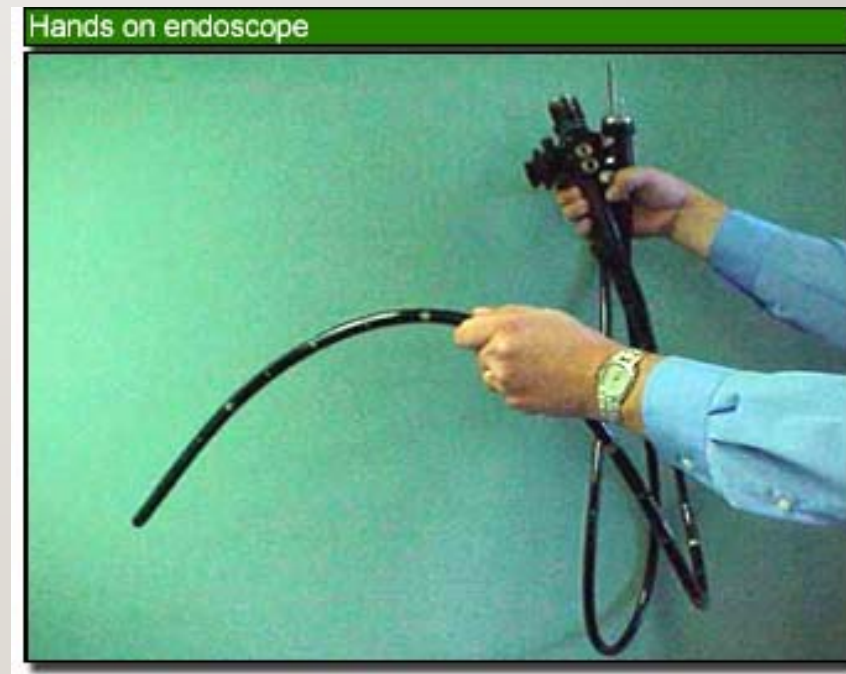
- ~~Transmission-based Precautions~~

- Contact Precautions

- Direct
- Indirect

- Droplet Precautions

- Airborne Precautions



8 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

9 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

10 DROPLET TRANSMISSION

- Droplet Transmission
 - Large droplet (most $\geq 5 \mu\text{m}$) 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

11 AIRBORNE TRANSMISSION

- Airborne Transmission
 - Droplet nuclei ($\leq 5 \mu\text{m}$) remain suspended for long distances or dust particles/spores containing microorganisms
 - Inhaled by another person
 - Requires special air handling
 - TB, Rubella, Varicella, Variola

COMPARISON OF PATHOGENS IN GI

- Prior to 1988, GI flora was considered as predictable as an endoscopy setting
- 1988 adoption of antibiotic prophylaxis
- Post 1988, 28 reported cases of GI flora
- Transmission of exogenous flora
- Transmission of endogenous flora

There is no place within a hospital or healthcare facility where encountering GI-borne bacteria and pathogens is as predictable as an endoscopy setting

Transmission of Infectious Agents via Flexible Endoscopy

Pathogens of Concern

- Salmonella species
- Escherichia coli
- Serratia marcescens
- Pseudomonas aeruginosa
- Mycobacterium tuberculosis
- Atypical mycobacterium
- Proteus species
- Helicobacter pylori*
- Hepatitis B virus (HBV)
- Hepatitis C virus (HCV)
- Human immunodeficiency virus (HIV)
- Creutzfeldt-Jakob disease (CJD)
- Microsporidia species
- Cryptosporidia species

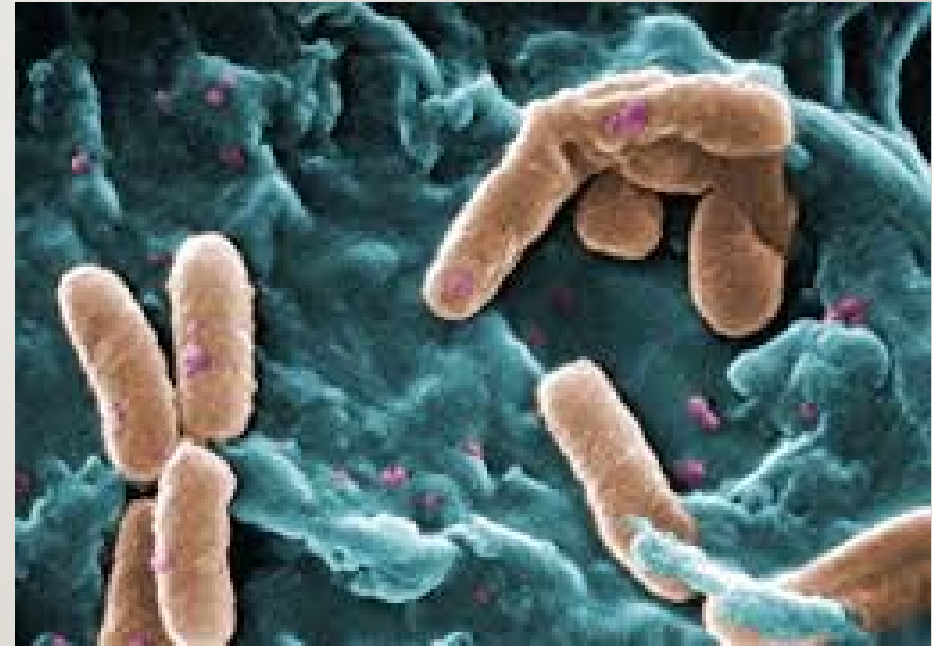
*known to have been transmitted by contaminated endoscopy biopsy forceps

COMMON PATHOGENS IN GI

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- 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



16 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

17 COMMON PATHOGENS

Salmonella

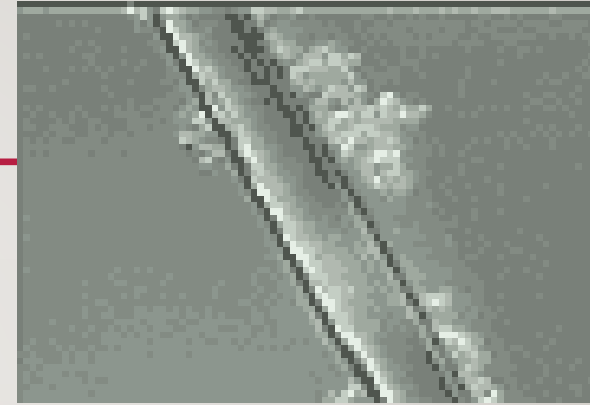
- ~3% chronic carrier state post infection
- Outbreaks due to improper cleaning of endoscopes and suite
- Infection usually small intestine, but can cause colitis
- Exogenous or endogenous



18 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



19 COMMON PATHOGENS

E. coli/Klebsiella spp.

- (Enterobacteriaceae)
- Normal GI flora
- Not associated with large outbreaks
- Common organism for endogenous transmission
- ESBL(extended spectrum beta lactamase) 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

A single report documented transmission of Strongyloides to 4 patients from a contaminated instrument. There are no other reports of transmission of parasites by endoscopy.

COMMON PATHOGENS

HIV/HBV

- No documented cases of transmission in endoscopy
- A few older questionable cases of HBV
- HIV very unstable
- HBV very stable
- Proper cleaning and disinfection
- OSHA (occupational safety and health administration) rule to protect you and HCW

There are no reports of transmission of HIV by endoscopy. Manual cleaning of the endoscope with detergent eradicates 99.0% of the virus from the instrument, and subsequent disinfection with glutaraldehyde for as little as 2 minutes was shown to eliminate the virus from endoscopes.

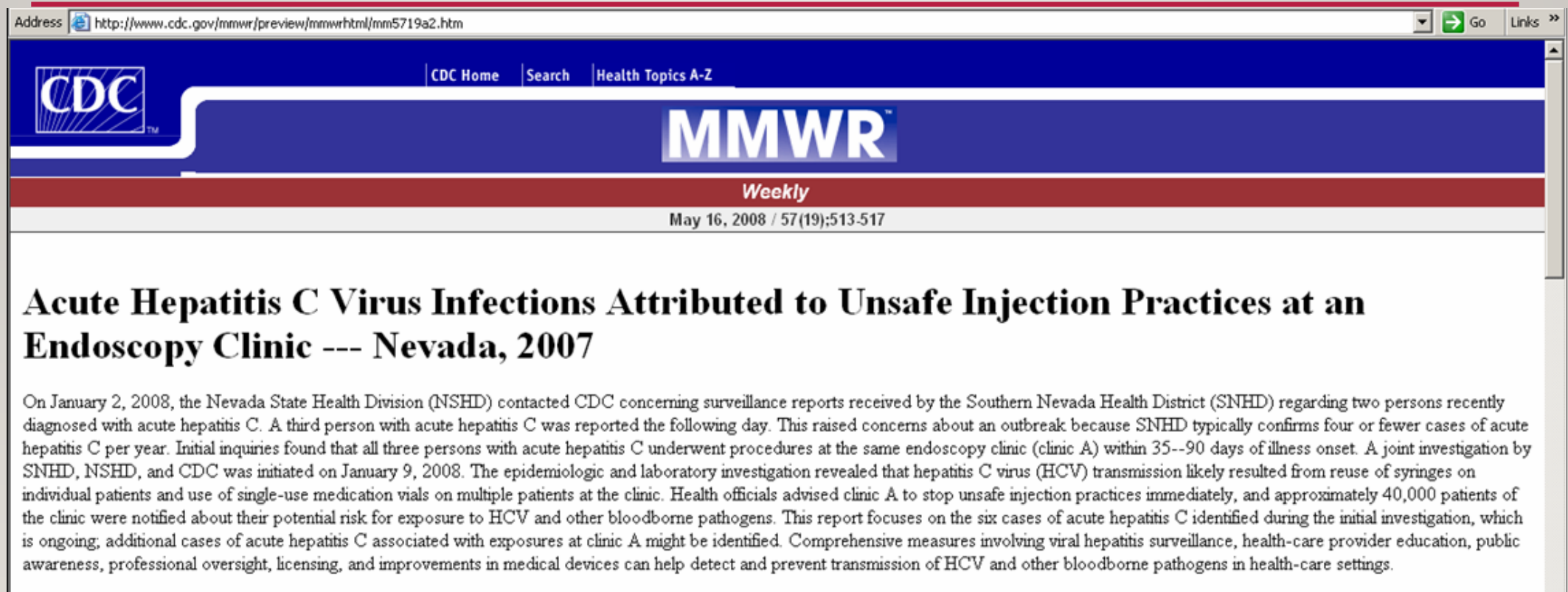
COMMON PATHOGENS

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

Two recent studies indicate that, when currently accepted reprocessing guidelines are followed, transmission of hepatitis C does not occur
ASGE

23 COMMON PATHOGENS



The image is a screenshot of a web browser displaying a page from the Centers for Disease Control and Prevention (CDC). The browser's address bar shows the URL: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5719a2.htm>. The page features the CDC logo on the left and navigation links for "CDC Home", "Search", and "Health Topics A-Z". The main header prominently displays "MMWR" in large white letters on a blue background, with "Weekly" written below it in a smaller font. The issue information "May 16, 2008 / 57(19);513-517" is centered below the header. The article title, "Acute Hepatitis C Virus Infections Attributed to Unsafe Injection Practices at an Endoscopy Clinic --- Nevada, 2007", is displayed in a large, bold, black font. The abstract text below the title describes a surveillance report from January 2008 regarding acute hepatitis C cases at an endoscopy clinic in Nevada, attributing the infections to unsafe injection practices such as syringe reuse.

Address <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5719a2.htm> Go Links »

CDC Home Search Health Topics A-Z

MMWR
Weekly
May 16, 2008 / 57(19);513-517

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

On January 2, 2008, the Nevada State Health Division (NSHD) contacted CDC concerning surveillance reports received by the Southern Nevada Health District (SNHD) regarding two persons recently diagnosed with acute hepatitis C. A third person with acute hepatitis C was reported the following day. This raised concerns about an outbreak because SNHD typically confirms four or fewer cases of acute hepatitis C per year. Initial inquiries found that all three persons with acute hepatitis C underwent procedures at the same endoscopy clinic (clinic A) within 35--90 days of illness onset. A joint investigation by SNHD, NSHD, and CDC was initiated on January 9, 2008. The epidemiologic and laboratory investigation revealed that hepatitis C virus (HCV) transmission likely resulted from reuse of syringes on individual patients and use of single-use medication vials on multiple patients at the clinic. Health officials advised clinic A to stop unsafe injection practices immediately, and approximately 40,000 patients of the clinic were notified about their potential risk for exposure to HCV and other bloodborne pathogens. This report focuses on the six cases of acute hepatitis C identified during the initial investigation, which is ongoing; additional cases of acute hepatitis C associated with exposures at clinic A might be identified. Comprehensive measures involving viral hepatitis surveillance, health-care provider education, public awareness, professional oversight, licensing, and improvements in medical devices can help detect and prevent transmission of HCV and other bloodborne pathogens in health-care settings.

(UN)COMMON PATHOGENS

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Variant Creutzfeldt-Jacob Disease (vCJD)

- Neurologic disease transmitted by protein
- Highly infectious: brain, dura mater, pituitary, lymphoid tissue
- Must less infectious in lymphoid tissue, tonsil, appendix
- European Society for Gastroenterologists recommends:
 - Dedicated scope
 - Destroy after use

“GI staff may encounter patients with *Clostridium difficile*, tuberculosis, Vancomycin-Resistant enterococci (VRE), carbapenem-resistant enterobacteriaceae (CRE), and other infections”
-SGNA 2015

25 COMMON PATHOGENS

Mycobacterium spp.

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



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WHAT CAUSES DISEASE TRANSMISSION



27 CAUSES OF TRANSMISSION

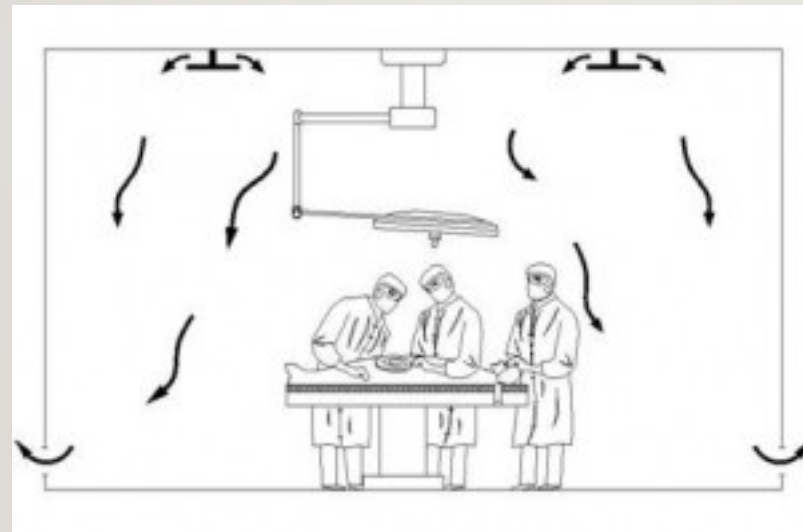
- Environmental contamination
- Equipment
 - Device integrity
 - Inadequate preprocessing
 - Failure in reprocessors
- Chemical failure
- Staff knowledge and training



Different Methods for Reprocessing Endoscopes



VENTILATION REQUIREMENTS FOR ENDOSCOPY PROCEDURE ROOMS



HOW OFTEN DO INFECTIONS OCCUR FROM UNDERGOING AN ENDOSCOPY?

- According to the recently updated guideline from the (ASGE) “**Infection control during GI endoscopy,**” despite the large number and variety of gastrointestinal (GI) endoscopic procedures performed, documented instances of infectious complications remain rare, with an estimated frequency of **1 in 1.8 million**.



Endoscope Reprocessing

Review of Terms

Biofilm – refers to a complex community of microorganisms that form a matrix of extracellular material composed of exopolysaccharides (EPS)

Minimum Effective concentration (MEC) – refers to the lowest concentration of active ingredient necessary to meet the label claim of a reusable high-level disinfectant / sterilant – chemical test strips should be used to determine whether and effective concentration of the active ingredient is present despite repeated use

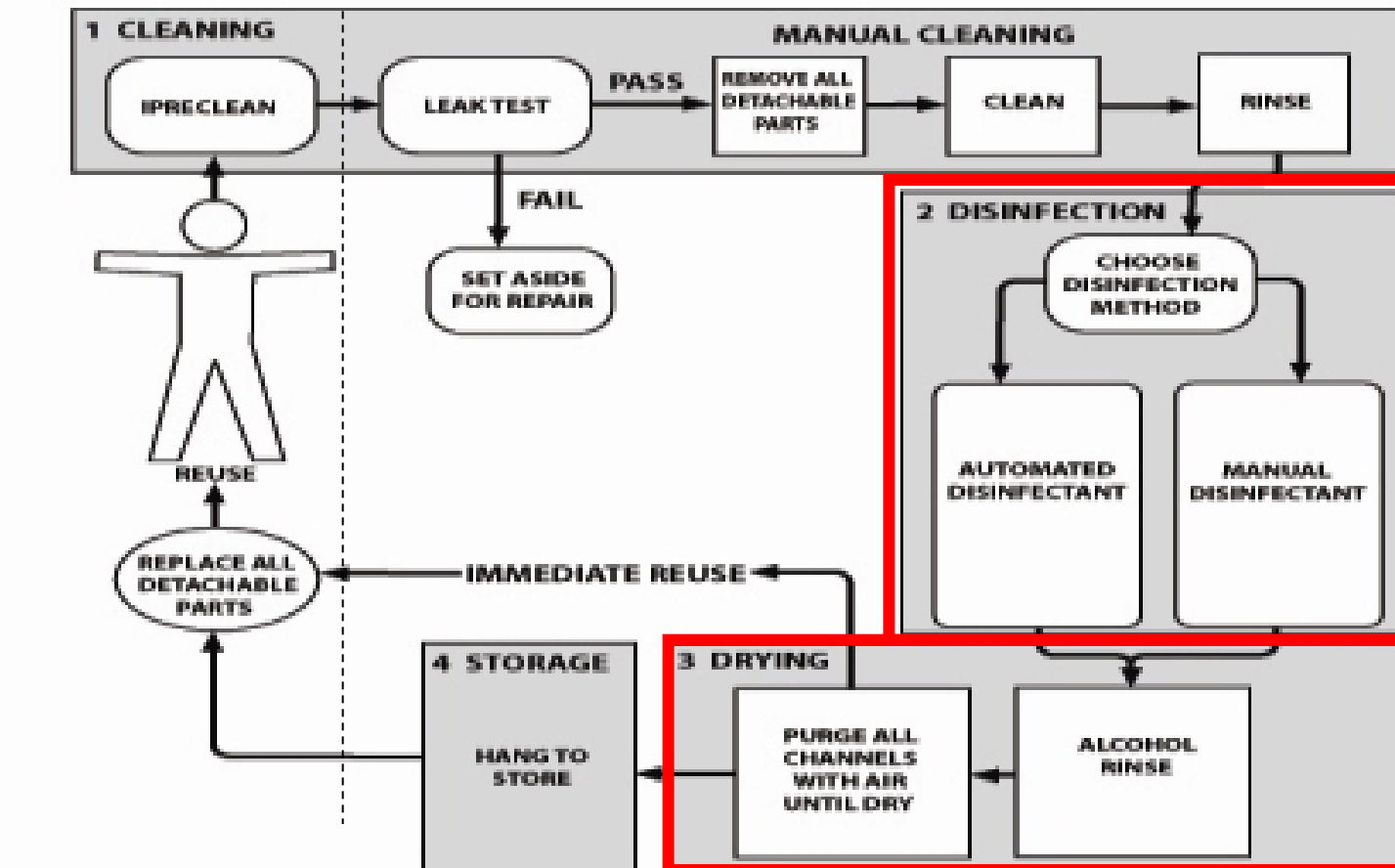
Reuse-life – refers to a statement by the manufacturer indicating the maximum number of days of a reusable high-level disinfectant / sterilant might be effective

Endoscope Reprocessing

- **Device Classification**
- **Manual Cleaning**
- **Personal Protective Equipment**
- **Biofilms within GI Endoscopy**
- **Reprocessing Room Standards**
- **Endoscope Reprocessing Protocols**
- **Leakage Testing**
- **Endoscope Handling**

Endoscope Reprocessing

ENDOSCOPE CLEANING AND DISINFECTION PROCESS:



Personal Protective Equipment

Personal Protective Equipment

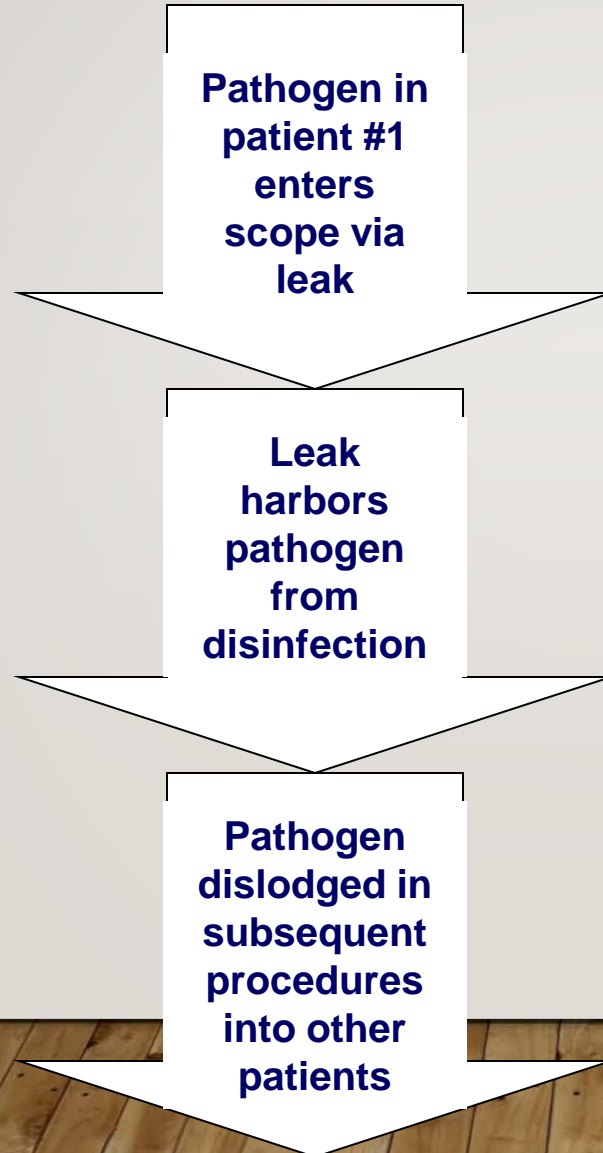
Gowns – impervious to fluid, long sleeves that fit snugly around the wrist, and wrap to cover as much of the body as possible. Dispose of or launder gowns if they become wet or are exposed to contaminated material

Gloves – inspect for tears or holes before use. Gloves should be long enough to extend up the arm to protect the forearm or clothing from splashes or seepage. To prevent cross-contamination, change gloves and wash hands whenever moving from a dirty to clean task or environment

Eye and / or face protection are necessary – contact lenses are not sufficient eye protection. A face shield is recommended. Do not use high filtration masks since they may actually trap vapours.



Fluid Invasion



e.g. Pseudomonas, Salmonella, HIV, Hepatitis B and C, Staph, E. coli, C. diff

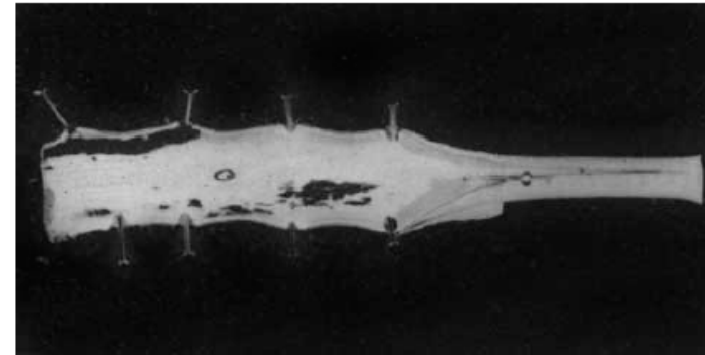


Fig 9. Interior surface of a flexible endoscope suction channel (2.8 mm in diameter) removed during leak repair

Cross-patient infection breakout

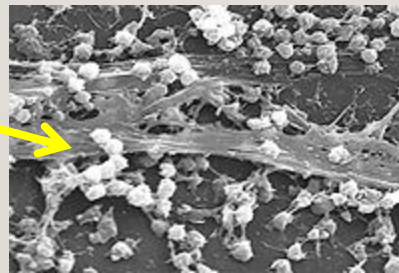
*APIC
Guideline for
infection
prevention and
control in
flexible
endoscopy
Volume 28,
number 2, p.145

Biofilms

Biofilms within GI Endoscopy

- A **biofilm** is a structured community of microorganisms encapsulated within a self-developed polymeric matrix and adherent to a living or inert surface.
- If the colonists are not immediately separated from the surface, they can anchor themselves more permanently using cell adhesion
- **Biofilms within endoscopy may form within endoscopes if proper manual pre-cleaning and CSGNA guidelines are not followed for endoscope reprocessing**

Staphylococcus aureus



Exopolysaccharide (EPS)

Staphylococcus aureus
biofilm

Reprocessing Room Standards

- The process and products used for cleaning, disinfection and or/sterilization of endoscopes must be compatible with the equipment being used
- Each health care setting in which endoscopic procedures are performed should have written detailed procedures for the cleaning and handling of endoscopes
- Reprocessing of contaminated patient equipment should be done in an area designated and dedicated for this function
- This room should be separate from where endoscopic procedures are performed
- Ventilation must be capable of removing toxic vapours generated by, or emitted from, cleaning or disinfectant agents – the vapour concentration of the chemical disinfectant being used should not exceed allowable limits (eg. 0.05 ppm for glutaraldehyde)
- Minimum of 10-12 air exchanges per hour in the reprocessing area

Endoscope Reprocessing Protocols

Basic steps to clean and perform high-level disinfection of gastrointestinal endoscopes

- 1) Pre-cleaning
- 2) Leakage testing
- 3) Cleaning
- 4) Rinsing
- 5) Disinfection
- 6) Rinsing
- 7) Drying
- 8) Storage

Endoscope Reprocessing Protocols

A. Pre-cleaning

- 4) Flush or blow out air and water channels in accordance with the endoscope manufacturer's instructions
- 5) Flush the auxiliary water channel
- 6) Detach the endoscope from the light source and suction pump
- 7) Attach protective video cap if using a video endoscope
- 8) Transport the Endoscope to the reprocessing area in an enclosed container

Note: *Containers, sinks, and basins should be large enough that the endoscope will not be damaged coiled too tightly*

Endoscope Reprocessing Protocols

B. Cleaning the Endoscope in the Reprocessing Area

Prepare the following:

- ✓ PPE
- ✓ Leakage testing equipment
- ✓ Channel cleaning adapters
- ✓ Large basin of endoscope detergent solution
- ✓ Channel cleaning brushes
- ✓ Sponge or lint-free cloth

C. Leak Testing

- Leak Testing detects damage to the interior or exterior of the endoscope
- The leak test is done before immersion of the endoscope in reprocessing solutions to minimize damage to parts of the endoscope not designed for fluid exposure.

Endoscope Reprocessing Protocols

C. Leak Testing

1. Manual Leak Testing

- Remove suction valves, air water valves, and biopsy valves
- Attached the leak tester and pressurize the scope before submerging it in water
- With the pressurized insertion tube completely submerged, flex the distal portion of the scope in all directions, observing for bubbles
- Submerge the entire endoscope and, observing the control head of the scope, depress the freeze and release buttons.
- Check the insertion tube and distal bending section as well as the universal cord for bubbles coming from the interior of the scope

Endoscope Reprocessing Protocols

C. Leak Testing

1. Computerized leak testing

- Remove suction valves, air water valves, and biopsy valves
- Attach the leak tester to the computer unit
- Input data including scope ID and user
- Move knobs and depress the freeze and release buttons when indicated
- Reprocess when test is complete

Follow the endoscope manufacturer's instructions if a leak or high humidity is detected or if the endoscope appears damaged

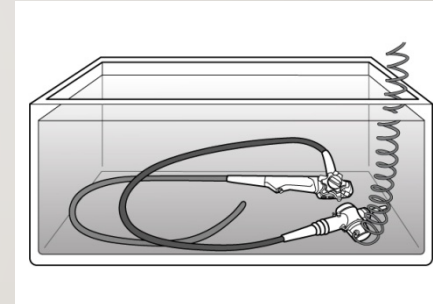


Endoscope Reprocessing Overview

■ Existing Manual Leak Test Methods

- Two Methods: **Wet Test & Dry Test**
 - Both methods should take ~3 minutes of uninterrupted technician time if done properly
- **Human Error Factors:**
 - Takes skill, commitment and dedication
 - Rushing
 - Leak detection problems
 - Lack of consistency and/or training
- **Manual Equipment Error Factors:**
 - No automated detection
 - 100% reliance on visual leak observation
 - Lack of procedure control
 - No record keeping

of

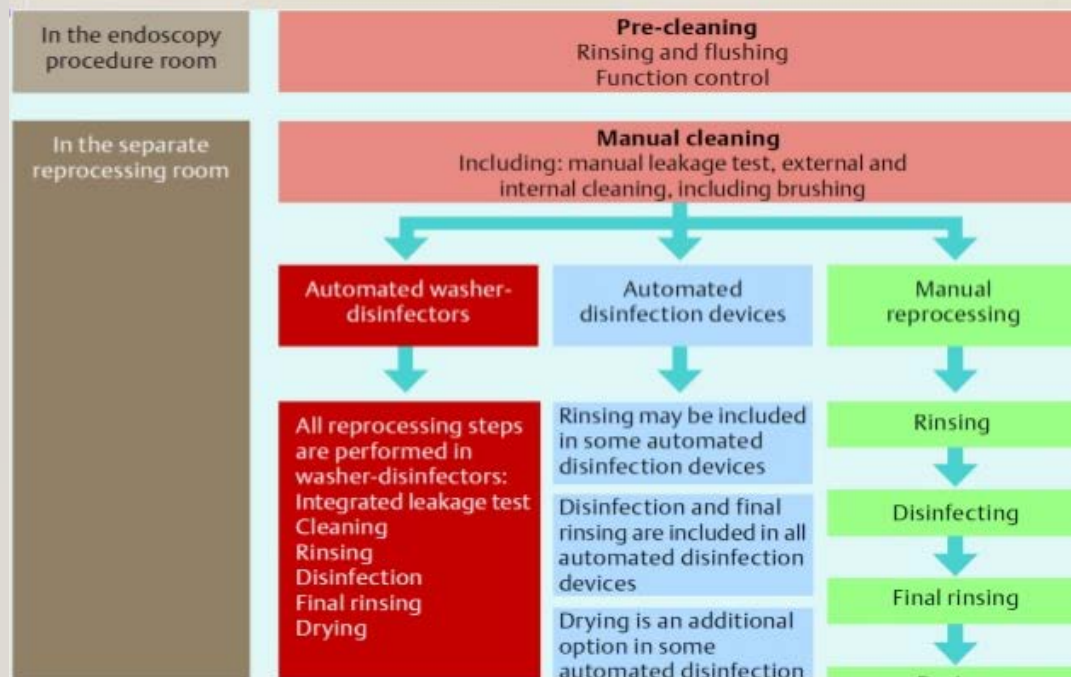


WHAT TYPES OF INFECTIONS CAN BE CONTRACTED DURING AN ENDOSCOPY?

- Breaches in following established reprocessing guidelines or general infection control principles have led to **transmission of blood borne pathogens**, most notably hepatitis B and C. **HIV has never been reported to have been transmitted related to gastrointestinal endoscopy.**



Different Methods for Reprocessing Endoscopes



46 CAUSES OF TRANSMISSION

Environmental contamination

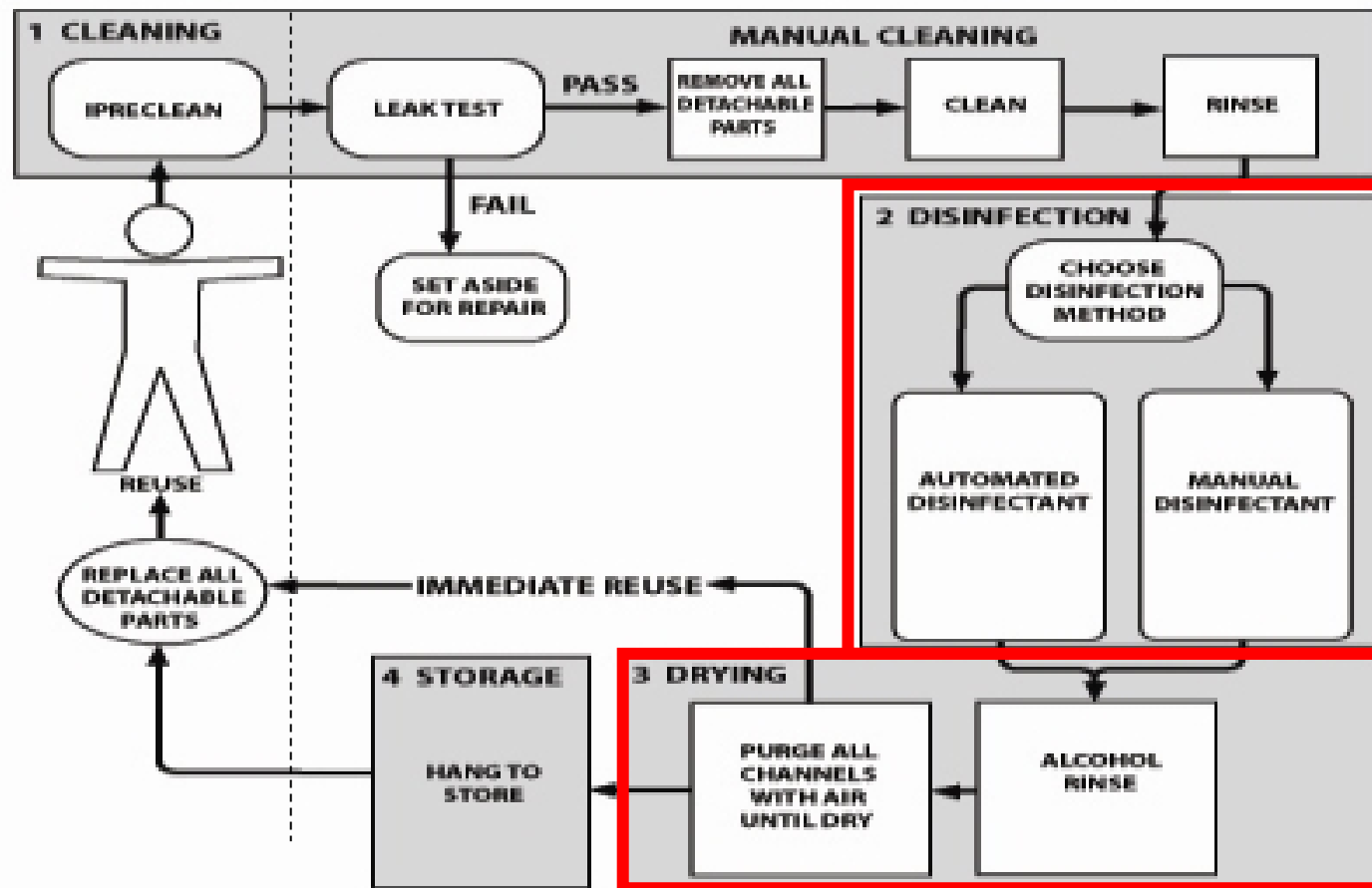
- Endoscopy suite ()
 - : The hospital reduces the risk of infections associated with medical equipment, devices, and supplies
 - Decontamination room separate from clean storage or patient care areas

HLD

- HLD is the standard of care recommended by governmental agencies and all pertinent professional organizations for the processing of flexible GI endoscopes.^{2,4,55,56} HLD is operationally defined by the FDA as a 6-log reduction of mycobacteria.

Endoscope Reprocessing

ENDOSCOPE CLEANING AND DISINFECTION PROCESS: PROCEDURE ROOM REPROCESSING AREA



TRANSMISSION OF INFECTIONS

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- Layout
 - 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 (80 ft²/pt)
- Storage of scopes
 - 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

50 CAUSES OF TRANSMISSION

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54 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



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56 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

57 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

58 CAUSES OF TRANSMISSION

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

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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.

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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.



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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 H₂O₂
- 0.2% peracetic acid
- 7.35% 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.

CLEANING, DISINFECTION AND STERILIZATION

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

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CLEANING, DISINFECTION AND STERILIZATION

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

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CLEANING, DISINFECTION AND STERILIZATION

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

CLEANING, DISINFECTION AND STERILIZATION

- 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

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

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

CLEANING, DISINFECTION AND STERILIZATION

- Steris System I Processor Advantages
 - Rapid cycle time
 - Instrument and material compatible
 - Sterilant vs HLD
- Steris System I Processor 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 I 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 I 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
- 

CLEANING, DISINFECTION AND STERILIZATION

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

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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

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CLEANING, DISINFECTION AND STERILIZATION

- H₂O₂ Advantages
 - No activation necessary
 - No odor or irritation
 - Does not fix residual organic materials
 - Inactivates *Cryptosporidium*
- 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

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CLEANING, DISINFECTION AND STERILIZATION

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

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

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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

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, DISINFECTION AND STERILIZATION

- Cleaning must be accomplished thoroughly prior to disinfection or sterilization
- Organic and inorganic materials remaining will interfere
- Decontamination \neq Cleaning
 - Decontamination is the process of removing microorganisms so objects are safe to handle, use or discard.
- Cleaning agents typically are phenolics or quats

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CLEANING, DISINFECTION AND STERILIZATION

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

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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

CLEANING, DISINFECTION AND STERILIZATION

- Final Drying process A MUST
 - Flush all channels with 70% alcohol
 - Purge with air
- position statement
 - HLD H₂O container, cap and tubing daily and dry completely
- Greatly reduces microbial recontamination from waterborne pathogens

ASGE ASPECTS

- There is evidence that Mycobacterium tuberculosis HBV, HCV, and HIV are readily inactivated by commonly used cleansing methods and appropriate (HLD/sterilant) LCGs.

CDC STATEMENT

- The Centers for Disease Control (CDC) states that currently recommended sterilization and disinfection procedures are adequate for endoscopes contaminated with pathogens, including HIV.

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- Patients with **severe neutropenia, immune deficiency syndromes,** and those patients who receive immunosuppressive agents may be at increased risk for local or systemic infection as a result of endoscopy-related translocation of gut organisms to deeper tissues or to the bloodstream.
 - **Endoscopes used in these patients should undergo standard reprocessing with HLD.**

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- Such practices should be avoided, and single-use drug vials are recommended. Similarly, use of gloves by health care workers was shown to decrease the incidence of Clostridium difficile associated diarrhea and the point prevalence of asymptomatic C difficile carriage in inpatients.⁹¹

ASGE STATEMENT

- TRANSMISSION OF INFECTION FROM PATIENTS TO ENDOSCOPY PERSONNEL
- There are several reports of documented transmission of infection from patients to health care personnel. Potential modes of transmission may include needlestick injury, blood splashes to the conjunctiva, inhalation of aerosolized microorganisms, and transfer from direct handling of patients.
- Studies demonstrated a higher prevalence of H pylori infection in endoscopy personnel,96-99 with an increased prevalence with increased years of practice. Appropriate use of personal protective equipment should minimize such infection risks.

ANTIBIOTIC PROPHYLAXIS FOR GI ENDOSCOPIC PROCEDURES

- The purpose of antibiotic prophylaxis during a GI endoscopy is to reduce the risk of significant endogenous infectious complications. Antibiotic prophylaxis against endoscopically induced local or systemic infections were previously discussed in detail in a guideline published by the **ASGE**, Antibiotic Prophylaxis for GI Endoscopy.

SUMMARY

Transmission of infection as a result of GI endoscopes is extremely rare, and recently reported cases are invariably attributable to lapses in currently accepted endoscope reprocessing protocols or to defective equipment.

SUMMARY

Endoscopes should undergo HLD as recommended by governmental agencies and all pertinent professional organizations for the reprocessing of GI endoscopes.

SUMMARY

Extensive training of staff involved in endoscopic re-processing is mandatory for quality assurance and for effective infection control.

SUMMARY

General infection control principles should be adhered to at the endoscopy unit.

SUMMARY

Transmission of infection from patients to endoscopy personnel can be avoided by application of standard precautions. ()

- **THANKS FOR YOUR ATTENTION**