Endoscope Reprocessing and Infection Prevention

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Louisville, KY
Trina VanGuilder, RN, BSN, CGRN, CFER
Clinical Education Consultant
Objectives

• Identify standards relevant to processing of flexible endoscopes

• List potential errors that can occur during both manual and automated reprocessing

• Discuss current unresolved issues relevant to flexible endoscope reprocessing
GI Endoscope Reprocessing Standards

Cleaning followed by High-Level Disinfection is the minimum standard:

- American Society for Gastrointestinal Endoscopy (ASGE)
- American College of Gastroenterology (ACG)
- Society of Gastroenterology Nurses Association (SGNA)
- Association for Professionals in Infection Control (APIC)
- Centers for Disease Control (CDC)
- Food and Drug Administration (FDA)
- Association of Peri-Operative Registered Nurses (AORN)
- American Society for Testing and Materials (ASTM)
- Association for the Advancement of Medical Instrumentation (AAMI)
Standards for Reprocessing

**EH Spaulding** - How an item is processed is dependent upon the intended use

**Critical Items** - Items that penetrate skin or mucous membranes, enter an area of the body that is normally sterile

- These items must be sterilized
- Examples: Biopsy forceps, angioscope
Standards for Reprocessing

**Semi-critical** - Items that touch intact mucous membranes

- These items require a minimum of high-level disinfection
- Example: flexible bronchoscope

**Noncritical** – Items that touch intact skin, or environmental surfaces

- These items require low- or intermediate-level disinfection
- Examples: blood pressure cuff, OR table
Sterilization

Kills all microorganisms, including high numbers of spores

Sterility Assurance Level (SAL) used in the sterile device and drug industry is $10^{-6}$

- Probability of an item being contaminated is equal to or less than one in a million
Disinfectant Categories – High Level

**High level** – kills vegetative bacteria, viruses, fungi and most bacterial spores

**Examples** – Glutaraldehyde, hydrogen peroxide, peracetic acid, ortho-phthalaldehyde
Disinfectant Categories – Intermediate Level

Intermediate level- kills bacteria, viruses, fungi. Includes TB, HBV, HCV, HIV. Does not kill bacterial spores.

Examples – Phenolics (amphyl), Iodophors (betadine), chlorine compounds (bleach), Alcohol (70 – 90%)
Disinfectant Categories – Low Level

Low-level disinfectants- kills most bacteria, viruses and fungi. No bacterial spores.

Examples- Hexachlorophene (hand soap), alcohol (70%)
Transmission of Infection

More than 15 million flexible endoscopic procedures a year

American Society for Gastrointestinal Endoscopy (ASGE) estimate

- Chance of a serious infection being transmitted by an endoscope is 1 in 1.8 million

Actual number is unknown

- Infections difficult to recognize
- Increase in ambulatory procedures
- Fear of litigation and bad press
Transmission of Infections

Infection Control Lapses at Ambulatory Surgery Centers (ASC) (2010)

68 ASCs audited by Center for Medicare & Medicaid Services (CMS) - 67.6% had at least one lapse in infection control, e.g., not precleaning scopes, not using HLD properly, not maintaining documentation

North Carolina Hospital Reprocessing and Documentation Breaches (2010)

Tech did not push button on AER and removed scope without verifying that HLD was met, unprocessed scope used on another patient
Transmission of Infections

St Louis VA Multiple Breaks with GI Endoscope Reprocessing (2010)

Lapses from late 2008 to Feb 2010 – no defined area for clean/dirty, rags and disposable gloves thrown everywhere, not using correct connectors, filters & test strips not changed or used correctly, improper placement of scope in reprocessors

Las Vegas Surgery Center (2008)

Disinfection cycle set on one minute, instead of five as recommended by the manufacturer
Importance of disinfection in reprocessing flexible endoscopes:

- Mycobacteria remaining in inadequately cleaned flexible bronchoscopes persisted after a full 60 min disinfection in 2% glutaraldehyde.

- Transmission of *Serratia marcescens* by an inadequately cleaned flexible bronchoscope, after 24 hr ethylene oxide “sterilization” process- causing several deaths.

(Gillespie 2008)
Infection and Endoscope Reprocessing

Source of contamination for infections transmitted by GI endoscopes from 1974-2001:

- Cleaning-3 (12%)
- Disinfection-19 (73%)
- Rinsing, Drying, Storage-3 (12%)
- Etiology unknown-11 (3%)
Infection and Endoscope Reprocessing

Identified factors:

• Improper use/connection with AER

• Faulty filters leading to waterborne contamination

• Endoscope design

• Inadequate cleaning and/or processing
What Can Go Wrong?

Failure to:

• Leak test or test correctly
• Clean all channels
• Flush all channels with disinfectant
• Fully immerse endoscope
• Time disinfectant contact (no clock in processing area)
• Perform MEC test
• Discard outdated disinfectant
• Maintain standard for reprocessing
Endoscope Channels and Capacity

- Air channel: Ø 0.7 mm
- Water channel: Ø 0.7 mm
- Biopsy channel: Ø 4.2 mm
- Suction channel: Ø 4.2 mm
- CO₂ channel: Ø 0.7 mm
- Water jet channel: Ø 0.7 mm
- Elevator channel: Ø 0.15 mm
Cleaning Studies

Study on the Impact of Human Factors

Manual high-level disinfection (MHLD)

Endoscope cleaning and reprocessing machine (ECR)

By Cori Ofstead – Gastroenterology Nursing July/Aug 2010
Summary of Results: Types of Nonadherence with Guidelines

• MHLD
  o 57% Did not brush all channels & components
  o 55% Did not dry with forced air
  o 22% Tested for leaks using sudsy water
  o 16% Skipped air purge after detergent flush
  o 14% Did not flush with alcohol
  o 10% Skipped final wipe down

• ECR
  o 25% Skipped final wipe down
EVOTECH® ECR

• Received FDA clearance for cleaning claims for manual cleaning prior to High-Level Disinfection

• SGNA – alerted users in 2007 and 2009, manual cleaning should be continued until clinical testing data is available

• Study by Dr Alfa et al. demonstrated that the cleaning cycle provided bioburden removal and was superior to optimal manual cleaning

What is Clean?

No specific standard

Recommendations for washing the endoscope:

• Meticulous cleaning immediately after use with an approved enzymatic detergent

• Use a validated cleaning protocol

• Do not let debris dry on endoscope
Washing the Endoscope

Criteria in selecting a cleaner:

- Contains one or more enzymes
  *Breaks down complex proteins, carbohydrates, and fats*
- Low foaming
- Works at room temperature
- Has a mild/neutral pH
- Rinses easily
- Acts rapidly
Cleaning Solutions

• **Surfactants lower surface tension, emulsify oily soils – can be more readily rinsed away**
  - Many cleaning solutions contain two or more surfactants
  - Molecules of surfactants can be charged or neutral
  - Ionic surfactants – negatively charged – create lots of suds (dishwashing)
  - Nonionic - do not form ions in solutions
  - Low sudsing (automatic dishwasher)
Use of Enzymatic Detergents

Common Misuses:

• Failure to dilute the enzymatic detergent
• Overdilution of detergent
• Use of expired enzymatic
• Inadequate exposure time
• Failure to adequately rinse
• Failure to change after each use
Cleaning (results in dramatic decrease in bioburden, 4-5 log\textsubscript{10} reduction)

- No brushing biopsy channel. (Schousboe M. *NZ Med J* 1980;92:275)

- No precleaning before AER. (Hawkey PM. *J Hosp Inf* 1981;2:373)

- Biopsy-suction channel not cleaned with a brush. (Bronowicki JP. *NEJM* 1997;337:237)

(WA Rutala)
## Bacterial Bioburden Associated with Endoscopes (WA Rutala)

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<th>Gastroscope, $\log_{10}$ CFU</th>
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Bioburden on Flexible Endoscopes

• Cleaning removes all visible soil and significantly reduces the bioburden in order to facilitate the biocidal process.

• Devices should be cleaned promptly following the procedure to prevent bioburden from drying, which makes it more difficult to remove.

• Retained debris may inactivate or interfere with the capability of the active ingredient of the chemical solution to effectively kill and/or inactivate microorganisms.
Automated Reprocessing

Timed cleaning
Consistent exposure to cleaning agent
Timed contact with liquid chemical germicide
Air flush to remove moisture

Filtered rinse water
Copious and consistent rinse
Validated and consistent process
Minimizes personnel exposure to chemicals

Note: Not all automated reprocessors have all of the features
Do We Have Two Levels of Care?

Can say YES:

• If procedure driven

• If inconsistent practice

➢ Disinfect throughout the day, sterilize at end of day

• If variation between departments

• If sterilize semi-critical items in OR and disinfect in Endoscopy
Two Levels of Care?

Can argue NO according to:

**Joint Commission**

Sterilizing some endoscopes while disinfecting others “creates no problem in the survey process” - there is no significant difference in nosocomial infection rate

**APIC**

“...not a double standard of patient care to sterilize endoscopes in one area and disinfect in another because the outcome is equivalent...”
Liquid chemical sterilization

“FDA believes that sterilization with liquid chemical sterilants does not convey the same sterility assurance as sterilization using thermal or gas/vapor/plasma low temperature sterilization methods.”

U.S. Food and Drug Administration (FDA) has updated the “General Hospital Devices and Supplies” Web site with new guidance related to liquid chemical sterilization (2011).
Question...

An endoscope has been processed and hung overnight to dry ...

*Does it need to be processed in the morning just before use?*
Yes – Reasons to Reprocess

• Could minimize likelihood of patient contamination if environmental bacteria proliferated overnight in scope channels

• No proof scope was properly processed/dried yesterday

• AORN recommends high-level disinfection immediately before use, if HLD used for critical items

• Media inferences
No – Reasons Not to Reprocess

- Increases processing costs
- Time consuming
- No data demonstrating clinical benefit to the patient
Decision Criteria

Consider reprocessing if:

• Endoscope channels are not routinely flushed with alcohol
• Moisture is noted when endoscope is removed from storage
• Potentially pathogenic bacteria have been noted in tap rinse water
How often should flexible devices be processed even if they aren’t used?

• According to AAMI – no set times
• AORN Recommended Practices - “Flexible endoscopes should be reprocessed before use if unused for more than five days.” (2009 – Cleaning and Processing Endoscopes)
• Urological Association – White Paper (2009) – Flexible cystoscopes that undergo HLD and then are stored overnight should repeat HLD prior to use.
How often should flexible devices be processed even if they aren’t used?

• According to the multi-society guideline for reprocessing flexible gastrointestinal endoscopes –

 ➢ Healthcare facilities should ensure that users can readily identify whether and when an endoscope has been reprocessed. (2011)

 ➢ In the interest of utmost caution, AORN and APIC espouse maximal storage intervals without reprocessing of 5 and 7 days, respectively. (2011)
What About the ERCP Channel?

• Must fill the lumen

• Can the AER automatically clean and disinfect?

• What must you do to ensure germicide contact during AER processing?
Alcohol Flush and Air Dry Every Time?

Alcohol kills bacteria and promotes drying

Rinse water not sterile

• Even “bacteria-free filtered water” does not prevent microorganisms less than 0.2 microns from entering

Bacteria filters known to fail

• Allow bacteria to re-contaminate scope

*Pseudomonas aeruginosa* implicated in a number of nosocomial infections

• Flush and air dry documented to terminate outbreak
Unresolved Issues

Must air dry between procedures?
How long can you wait before air drying?
What is the definition of sterile water?

- USP - Sterile water is water filtered through a 0.2 micron filter
- Differs from bottled sterile water that is produced in an aseptic environment
Periodic Surveillance?

• Defined as monitoring during a specific time period

• Periodic microbiologic sampling not generally recommended

➢ Not enough data to relate number of microorganisms on a surface with nosocomial infection rates
If You Decide To Sample

- Consult microbiology lab and infection prevention practitioner to develop protocol

- Culture the rinse water

- Process endoscope then use sterile brush to obtain sample from internal channels
What Can We Do?

- Proper training
- Performing procedure to maintain competency
- Understanding National standards
- Compliance with National standards
- Time-saving measures (cutting corners)
- Cost savings
- Mixed messages from different manufacturers
- Quality improvement initiatives
Quality Improvement Steps

• Monitoring program in place to track compliance
• Provide feedback results to team
• Identify and reduce high-risk events
• Confidence reprocessing standards are followed EVERY TIME
• Understand the consequences of an improperly processed scope
References


Questions/Slides: www.disinfectionandsterilization.org (WA Rutala)


References


Alfa, M.J., DeGangne, P., Olson, N., Fatima, I. Evotech endoscope cleaner and reprocessor (ECR) simulated-use and clinical-use evaluation of cleaning efficacy, *BMC Infectious Diseases* 2010, 10:200.

References


