ENDOSCOPE REPROCESSING IN HEALTHCARE FACILITIES: BEST PRACTICES AND RECOMMENDATIONS

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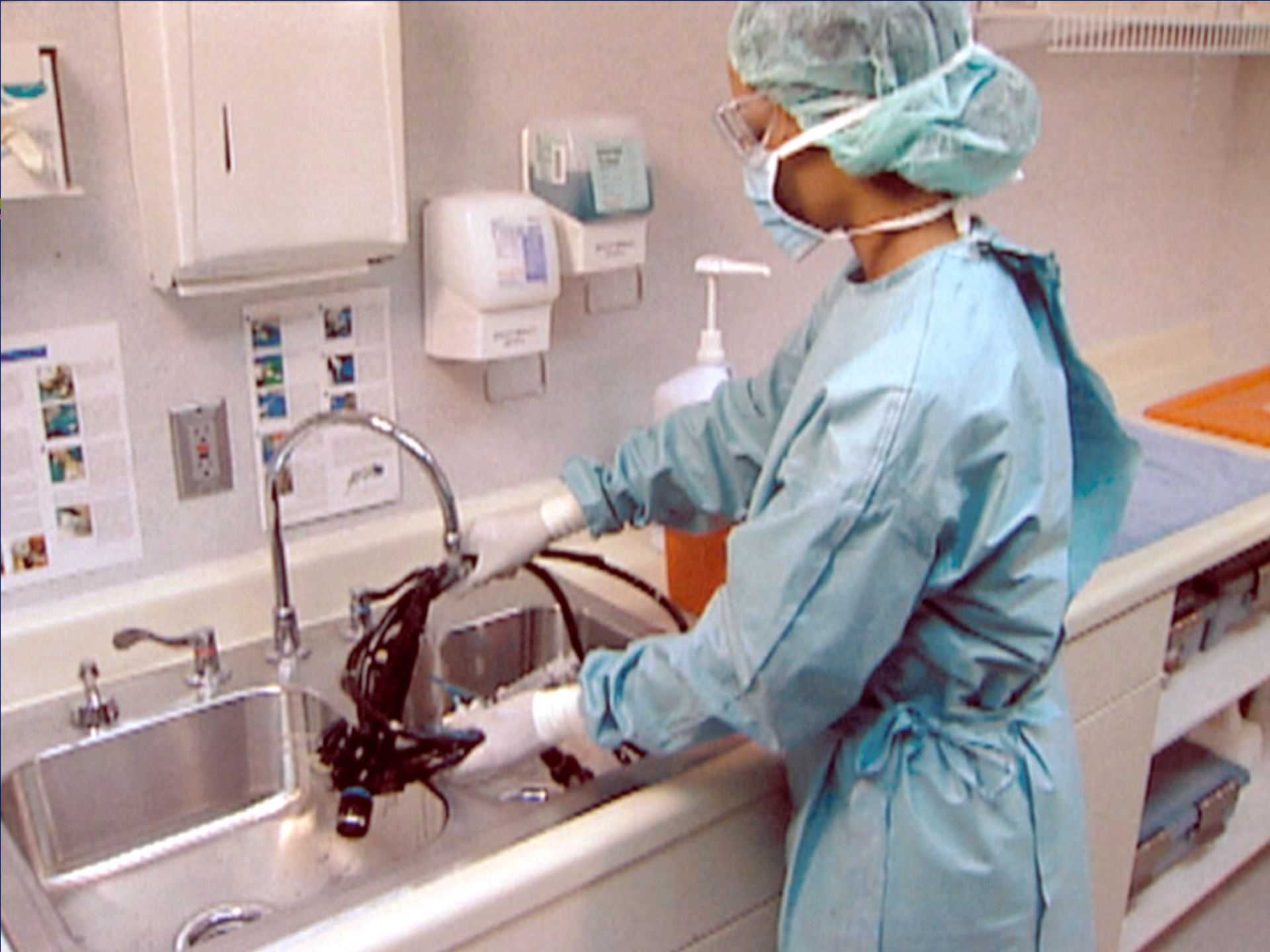
LECTURE GOALS

- Risks associated with reprocessing flexible endoscopes
- Causes of contamination and infection
- Gaps in current reprocessing standards
- Establish scientific rationale and evidence requirements for enhancing safe practices

DISINFECTION AND STERLIZATION

- EH Spaulding believed that how an object will be disinfected depended on the object's intended use.
  - CRITICAL - objects which enter normally sterile tissue or the vascular system or through which blood flows should be **sterile.**
  - SEMICRITICAL - objects that touch mucous membranes or skin that is not intact require a disinfection process (**high-level disinfection[HLD]**) that kills all microorganisms but high numbers of bacterial spores (e.g., GI endoscopes).
  - NONCRITICAL -objects that touch only intact skin require **low-level disinfection.**

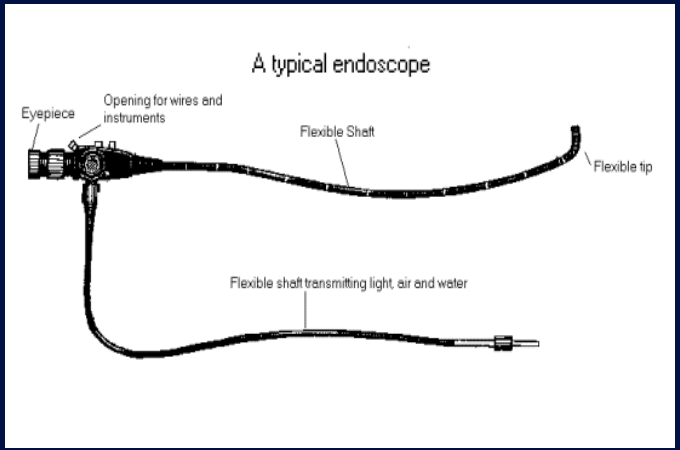


ENDOSCOPES

- Widely used diagnostic and therapeutic procedure (>10 million GI procedures annually in the US)
- GI endoscope contamination following use (~10^9 internal channel and ~10^5 external surface)
- Semicritical items require high-level disinfection minimally
- Inappropriate cleaning and disinfection has led to cross-transmission and multiple outbreaks
- Concern now raised that even with adherence to current cleaning/disinfection guidelines and properly operating equipment, patient-to-patient transmission of multidrug-resistant pathogens may occur
- Although the incidence remains very low, endoscopes represent a significant risk of disease transmission

FEATURES OF ENDOSCOPES THAT IMPAIR CLEANING AND DISINFECTION

- Usually heat sensitive: Require low temperature disinfection
- Long narrow lumens
- Sharp angles (right angle bends)
- Cross-connections
- Mated surfaces
- Springs and valves
- Occluded dead ends
- Absorbent material
- Rough or pitted surfaces
- Heavily contaminated with use



GI ENDOSCOPES: NARROW MARGIN OF SAFETY WITH HLD

Narrow margin of safety associated with high-level disinfection of GI endoscopes

- Internal channels of GI endoscopes contaminated with 10^{8-10} enteric bacteria
  - Cleaning eliminates 10^{4-6} microbes
  - High-level disinfection inactivates 10^{4-6} microbes
  - Total elimination = 10^{8-12} microbes
- Margin of safety = 0-2 $\log_{10}$ potential pathogens (margin of safety with surgical instruments is 17 $\log_{10}$). Thus person-to-person transmission possible if reprocessing protocol is not followed precisely

Nosocomial Infections via GI Endoscopes

- Infections traced to deficient practices
  - Inadequate cleaning (clean all channels)
  - Inappropriate/ineffective disinfection (time exposure, perfuse channels, test concentration, ineffective disinfectant, inappropriate disinfectant)
  - Failure to follow recommended disinfection practices (tapwater rinse)
  - Flaws in design of endoscopes or AERs

ENDOSCOPE REPROCESSING

- Source of contamination for infections (36 outbreaks) transmitted by GI endoscopes from 1974-2001:
  - Cleaning-3 (12%)
  - Disinfection-19 (73%)
  - Rinse, Dry, Store-3 (12%)
  - Etiology unknown-11

Weber DJ, Rutala WA, DiMarino Jr. 2002. Prevention of infection following gastrointestinal endoscopy: The importance of prophylaxis and reprocessing. In DiMarino AJ, Benjamin SB, editors. Gastrointestinal Diseases: An Endoscopic Approach. Slack, Thorofare, NJ, pp. 87-106.

DISINFECTION OF ENDOSCOPES

INFECTION CONTROL AND HOSPITAL EPIDEMIOLOGY JUNE 2011, VOL. 32, NO. 6

ASGE-SHEA GUIDELINE

Multisociety Guideline on Reprocessing Flexible GI Endoscopes: 2011

Bret T. Petersen, MD, FASGE; Jennifer Chennat, MD; Jonathan Cohen, MD, FASGE; Peter B. Cotton, MD, FASGE; David A. Greenwald, MD, FASGE; Thomas E. Kowalski, MD; Mary L. Krinsky, DO; Walter G. Park, MD; Irving M. Pike, MD, FASGE; Joseph Romagnuolo, MD, FASGE; for the ASGE Quality Assurance in Endoscopy Committee; and William A. Rutala, PhD, MPH; for the Society for Healthcare Epidemiology of America

ENDOSCOPE REPROCESSING

CDC and Multi-Society Guideline on Endoscope Reprocessing

- PRECLEAN-point-of-use (bedside) remove debris by wiping exterior and aspiration of detergent through air/water and biopsy channels. Transport to reprocessing within an hour before soil dries; perform pressure/leak testing.
- CLEAN-mechanically cleaned with water and enzymatic/detergent cleaner
- HLD/STERILIZE-immerse scope and perfuse HLD/sterilant through all channels for exposure time (>2% glut at 20m at 20^{o}C). If AER used, review model-specific reprocessing protocols from both the endoscope and AER manufacturer
- RINSE-scope and channels rinsed with sterile water, filtered water, or tap water. Flush channels with alcohol and dry
- DRY-use forced air to dry insertion tube and channels
- STORE-hang in vertical position to facilitate drying; stored in a manner to protect from contamination

Viral Bioburden from Endoscopes Used with AIDS Patients

	Dirty	Cleaned	Disinfected
Gastroscopes			
HIV (PCR)	7/20	0/20	0/20
HBsAg	1/20	0/20	0/7
Bronchoscopes			
HIV (cDNA)	7/7	0/7	0/7
HBsAg	1/10	0/10	0/10

Hanson et al. Lancet 1989;2:86; Hanson et al. Thorax 1991;46:410

High-Level Disinfection of "Semicritical Objects"

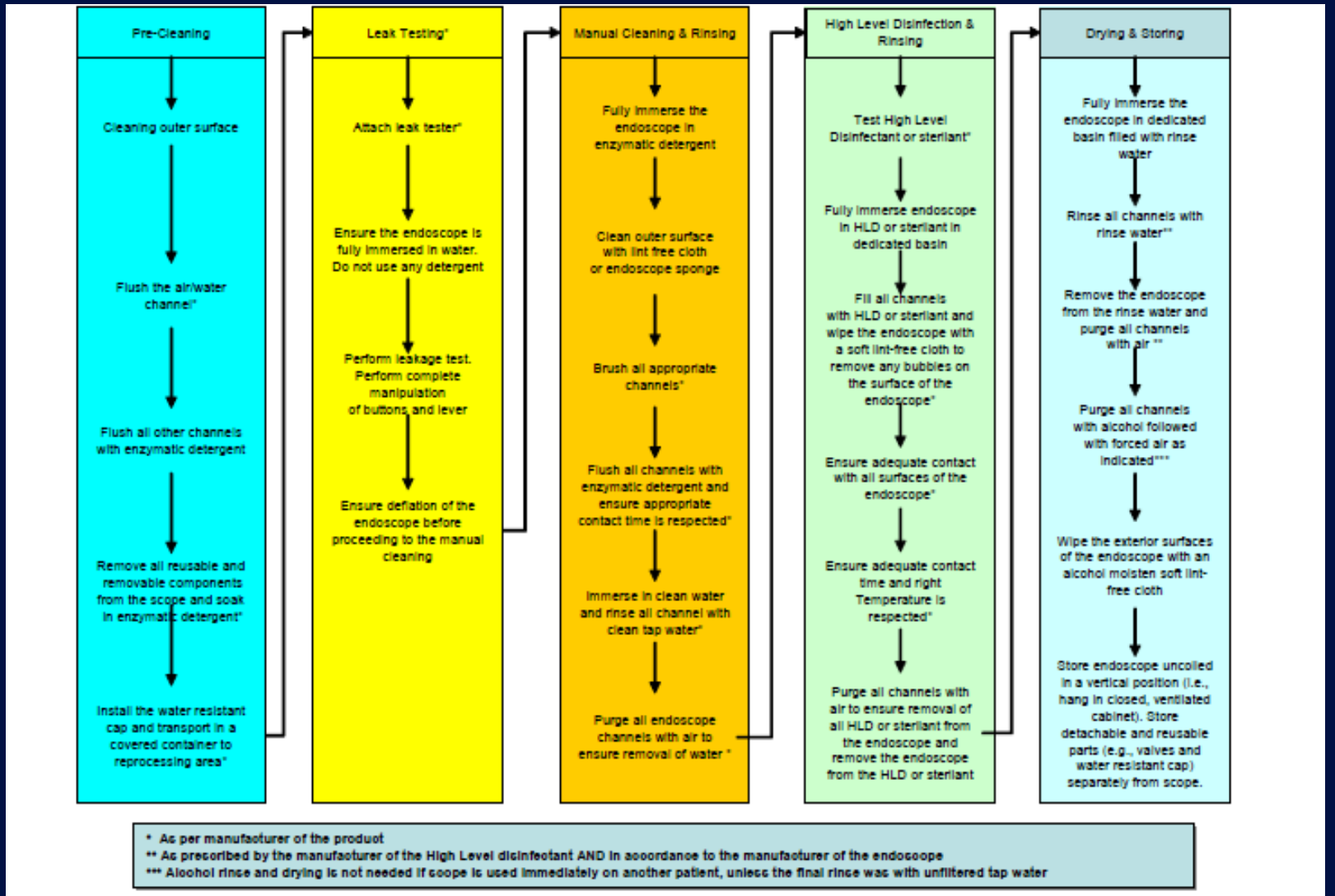
Exposure Time ≥ 8m-45m (US), 20°C

Germicide	Concentration
Glutaraldehyde	≥ 2.0%
Ortho-phthalaldehyde	0.55%
Hydrogen peroxide*	7.5%
Hydrogen peroxide and peracetic acid*	1.0%/0.08%
Hydrogen peroxide and peracetic acid*	7.5%/0.23%
Hypochlorite (free chlorine)*	650-675 ppm
Accelerated hydrogen peroxide	2.0%
Peracetic acid	0.2%
Glut and isopropanol	3.4%/26%
Glut and phenol/phenate**	1.21%/1.93%

*May cause cosmetic and functional damage; **efficacy not verified

Flow Chart for Endoscope Reprocessing

Endoscope Reprocessing Guideline: Health Canada 2010



ENDOSCOPE DISINFECTION

- Cleaning (results in dramatic decrease in bioburden, 4-5 $\log_{10}$ 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)

ENDOSCOPE REPROCESSING

- Inappropriate disinfectants
  - Benzalkonium chloride (Greene WH. Gastroenterol 1974;67:912)
  - 70% alcohol (Elson CO. Gastroenterol 1975;69:507)
  - QUAT (Tuffnell PG. Canad J Publ Health 1976;67:141)
  - Hexachlorophene (Dean AG. Lancet 1977;2:134)
  - Hexachlorophene (Beecham HJ. JAMA 1979;1013)
  - 70% alcohol (Parker HW. Gastro Endos 1979;25;102)
  - Povidone-iodine (Low DE. Arch Intern Med 1980;1076)
  - Cetrimonium bromide. (Schliessler KH. Lancet 1980;2:1246)

ENDOSCOPE REPROCESSING

- Inappropriate disinfectants
  - 3% hexachlorophene. (Schousboe M. NZ Med J 1980;92:275)
  - 0.5% CHG in alcohol, 0.015% CHG and 0.15% cetrimide; 87 s exposure to 2% glut. (Hawkey PM. J Hosp Inf 1981;2:373)
  - 1% Savlon (cetrimide and CHG).(O'Connor BH. Lancet 1982;2:864)
  - 0.0075% iodophor. (Dwyer DM. Gastroint Endosc 1987;33:84)
  - 0.13% glut with phenol. (Classen DC. Am J Med 1988;84:590)
  - 70% ethanol for 3 min. (Langenberg W. J Inf Dis 1990;161:507

Endoscope Reprocessing Methods

Ofstead , Wetzler, Snyder, Horton, Gastro Nursing 2010; 33:204

Performed all 12 steps with only 1.4% of endoscopes using manual versus 75.4% of those processed using AER

TABLE 3. Documented Completion of Steps During Manual Cleaning With High-Level Disinfection Reprocessing

Observed Activity	Steps Completed (%) (n = 69)
Leak test performed in clear water	77
Disassemble endoscope completely	100
Brush all endoscope channels and components	43
Immerse endoscope completely in detergent	99
Immerse components completely in detergent	99
Flush endoscope with detergent	99
Rinse endoscope with water	96
Purge endoscope with air	84
Load and complete automated cycle for high-level disinfection	100
Flush endoscope with alcohol	86
Use forced air to dry endoscope	45
Wipe down external surfaces before hanging to dry	90

TABLE 2. Steps in the Disinfection Process and Mechanisms of Failure

Disinfection step	Reason for disinfection step	Mechanism for failure
Cleaning	Remove bioburden Remove substances that might interfere with disinfection: blood, salt, protein	Inadequate policies; Inadequate training or supervision; failure to clean immediately (ie, allowing body fluids to dry); failure to brush all channels; damaged internal channel(s); poorly mated internal components
Appropriate disinfectant	Inactivation of contaminating microbes	Ineffective disinfectant (eg, iodides); inadequate concentration; inadequate duration; inadequate temperature
Contact between disinfectant and contaminating microbes	Requirement for killing	AER: failure to use channel connectors; AER: wrong channel connectors; occluded lumen; torn or damaged lumen
Rinse	Remove potentially toxic chemicals (eg, glutaraldehyde, hydrogen peroxide)	Mucous membrane damage to subsequent patient (eg, colitis); contaminated rinse water
Prevention of recontamination	Prevent contamination with environmental microbes	Tap water rinse without subsequent alcohol rinse; failure to air-dry endoscope; contaminated AER; reassembly of valves before storage; placement of endoscope in contaminated container; storage in coiled position (rather than hanging straight)

Automated Endoscope Reprocessors (AER)

- Manual cleaning of endoscopes is prone to error. AERs can enhance efficiency and reliability of HLD by replacing some manual reprocessing steps
- AER Advantages: automate and standardize reprocessing steps, reduce personnel exposure to chemicals, filtered tap water, reduce likelihood that essential steps will be skipped
- AER Disadvantages: failure of AERs linked to outbreaks, may not eliminate precleaning BMC Infect Dis 2010;10:200
- Problems: incompatible AER (side-viewing duodenoscope); biofilm buildup; contaminated AER; inadequate channel connectors; used wrong set-up or connector MMWR 1999;48:557
- Must ensure exposure of internal surfaces with HLD/sterilant

AUTOMATED ENDOSCOPE REPROCESSORS

Automated Endoscope Reprocessors

Gastro Endoscopy 2010;72:675

- All AERs have disinfection and rinsing cycles; some detergent cleaning; alcohol flush and/or forced-air drying
- Additional features may include: variable cycle times; printed documentation; HLD vapor recovery systems; heating; automated leak testing; automated detection of channel obstruction, MEC
- Not all AERs compatible with all HLDs or endoscopes; some models designed with specific HLDs
- Some AERs consume and dispose of HLD and other reuse HLD
- Some AERs have an FDA-cleared cleaning claim (eliminates soil and microbes equivalent to optimal manual cleaning-<6.4$\mu g/cm^2$ protein)

Multi-Society Guideline for Reprocessing Flexible Gastrointestinal Endoscopes, 2011

- Unresolved Issues
  - Interval of storage after which endoscopes should be reprocessed before use
    - Data suggest that contamination during storage for intervals of 7-14 days is negligible, unassociated with duration, occurs on exterior of instruments and involves only common skin organisms
    - Data are insufficient to proffer a maximal outer duration for use of appropriately cleaned, reprocessed, dried and stored endoscopes
    - Without full data reprocessing within this interval may be advisable for certain situations (endoscope entry to otherwise sterile regions such as biliary tree, pancreas)

Endoscopes Reprocessed If Unused 5 Days

AORN, 2010

Provided all channels thoroughly reprocessed and dried, reuse within 10-14 appears safe. Data are insufficient to offer maximum duration for use.

Investigator	Shelf Life	Contamination Rate	Recommendation
Osborne, Endoscopy 2007	18.8h median	15.5% CONS, Micrococcus, *Bacillus*	Environmental /process contamination
Rejchrt, Gastro Endosc 2004	5 days	3.0% (4/135), skin bacteria (CONS, diphteroids)	Reprocessing before use not necessary
Vergis, Endoscopy 2007	7 days	8.6% (6/70), all CONS	Reprocessing not necessary for at least 7d
Riley, GI Nursing, 2002	24,168h	50% (5/10), <3 CFU CONS, *S. aureus, P. aeurginosa, Micrococcus*	Left for up to 1 week

Multi-Society Guideline for Reprocessing Flexible Gastrointestinal Endoscopes, 2011

- Unresolved Issues
  - Optimal frequencies for replacement of: clean water bottles and tubing for insufflation of air and lens wash water, and waste vacuum canisters and suction tubing
    - Concern related to potential for backflow from a soiled endoscope against the direction of forced fluid and air passage into clean air/water source or from tubing/canister against a vacuum into clean instruments
  - Microbiologic surveillance testing after reprocessing
    - Detection of non-environmental pathogens indicator of faulty reprocessing equipment, inadequate solution, or failed human process

Audit Manual Cleaning of Endoscopes

Establishing Benchmarks

- Lack of consensus regarding the clinical value of routine microbiological monitoring of endoscopes. We perform to assess the efficacy of reprocessing.
  - Alfa et al. Am J Infect Control 2012;40:233. Recommends a bioburden residual of <100 CFU/ml.
  - Beilenhoff et al. Endoscopy; 2007;39: 175. ESGE-ESGENA allows bioburden count of <20 CFU/ channel.
  - Heeg et al. J Hosp Infect; 2004;56:23. Contamination should not exceed 1 CFU/ml. Certain organisms should not be detected in any amount (e.g., *P. aeruginosa*, *E. coli*, S. aureus)

FUTURE DIRECTIONS III: Problems with using ATPase measurements

- What cut-off to use for concern
- Lack of validation (ATP may be related to markers (e.g., protein) but may have no relationship to microbial burden, likelihood of developing infection, or providing patient a safe instrument)
- Sampling scheme (All scopes? Selected scopes?)
- What should be done if trigger reached (ETO sterilization of all vs contaminated scopes; 2nd disinfection process; assess scope for internal damage)

PATHOGEN	MICROBIAL LOAD	ATP
C. difficile	10^6	<100
Acinetobacter baumannii	~10^4	<100
MRSA	~10^4	<100

Rutala WA, Gergen M, Weber DJ. Unpublished, 2014

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ORIGINAL ARTICLE

How to Assess Risk of Disease Transmission to Patients When There Is a Failure to Follow Recommended Disinfection and Sterilization Guidelines

William A. Rutala, PhD, MPH; David J. Weber, MD, MPH

BACKGROUND. Disinfection and sterilization are critical components of infection control. Unfortunately, breaches of disinfection and sterilization guidelines are not uncommon.

OBJECTIVE. To describe a method for evaluating a potential breach of guidelines for high-level disinfection and sterilization of medical devices.

METHODS. The appropriate scientific literature was reviewed to determine the frequency of failures of compliance. A risk assessment model was constructed.

RESULTS. A 14-step protocol was constructed to aid infection control professionals in the evaluation of potential disinfection and sterilization failures. In addition, a model is presented for aiding in determining how patients should be notified of the potential adverse event. Sample statements and letters are provided for communicating with the public and individual patients.

CONCLUSION. Use of a protocol can guide an institution in managing potential disinfection and sterilization failures.

Infect Control Hosp Epidemiol 2007; 28:146-155

In the United States in 1996, there were approximately 46,500,000 surgical procedures and a much larger number of

infection failure on record involved the distribution of an inactive lot of glutaraldehyde disinfectant solution that had

1. Confirm disinfection or sterilization reprocessing failure
2. Impound any improperly disinfected/sterilized items
3. Do not use the questionable disinfection/sterilization unit (e.g., sterilizer, automated endoscope reprocessor) until proper functioning can be assured
4. Inform key stakeholders
5. Conduct a complete and thorough evaluation of the cause of the disinfection/sterilization failure
6. Prepare a line listing of potentially exposed patients
7. Assess whether disinfection/sterilization failure increases patient risk for infection
8. Inform expanded list of stakeholders of the reprocessing issue
9. Develop a hypothesis for the disinfection/sterilization failure and initiate corrective action
10. Develop a method to assess potential adverse patient events
11. Consider notification of state and federal authorities
12. Consider patient notification
13. Develop long-term follow-up plan
14. Perform after-action report

FIGURE 1. Protocol for exposure investigation after a failure of disinfection and sterilization procedures

Failure to Follow Disinfection and Sterilization Principles

- Can estimate the per patient risk for HIV as follows:
  - HIV prevalence in the US population: 0.37%, ~4:1000, ~$4x10^{-3}$
  - Risk of transmission (via mm): 0.09%, 1:1000, $1x10^{-3}$
  - Efficacy of AER without HLD: 99.99%, 1:10,000, $1x10^{-4}$
  - Efficacy or OPA against HIV in 2m: 99.999%, 1:100,000, $1x10^{-5}$
  - Effect of HIV drying: 99%, 1:100, $1x10^{-2}$
  - Individual risk = ~$.4 \times 10^{-17}$ o ~4×10^{-16} (4 in 10 quadrillion)

TABLE 1. Reprocessing Failures of Semicritical or Critical Medical Instruments Resulting in Patient Notification

Location or institution, year	Instrument involved	No. of persons exposed
Sacramento, CA, 2002	Endoscope	750
Toronto, ON, 2003	Endoscope	146
Seattle, WA, 2004	Endoscope	600
Sacramento, CA, 2004	Endoscope	1,331
San Francisco, CA, 2004	Endoscope	2,000
Long Island, NY, 2004	Endoscope	177
Charleston, NC, 2004	Endoscope	1,383
Toronto, ON, 2003	Prostate biopsy probe	900
Pittsburgh, PA, 2005	Endoscope	200
Leesburg, VA 2005	Endoscope	144
San Diego, CA, 2006	Endoscope	300
Augusta, ME, 2006	Prostate biopsy needle	481
Dept Veterans Affairs, 2006	Prostate biopsy equipment	2,075
San Diego, CA, 2006	Surgical instrument	82

NOTE. Modified from a presentation by Douglas Nelson, MD, at the 33rd Annual Conference and International Meeting of the Association for Professionals in Infection Control and Epidemiology; Tampa, Florida, 2006.

CONCLUSIONS

- Endoscopes represent a nosocomial hazard. Narrow margin of safety associated with high-level disinfection of semicritical items. Guidelines must be strictly followed.
- AERs can enhance efficiency and reliability of HLD of endoscopes by replacing some manual reprocessing steps and reducing the likelihood that essential steps are not skipped
- Urgent need to better understand the gaps in endoscope reprocessing-CRE, *C. difficile* spores, HPV, biofilms, etc. Industry must support research to answer questions.
- Data are insufficient to recommend ATP monitoring
- Data suggest that contamination during storage for 7-14 days is negligible.

THANK YOU!!