Disinfection, Sterilization and Antisepsis

William A. Rutala, Ph.D., M.P.H., C.I.C.
Director, Statewide Program for Infection Control and Epidemiology
and Professor of Medicine, University of North Carolina at Chapel Hill, NC, USA
Former Director, Hospital Epidemiology, Occupational Health and Safety, UNC Health Care, Chapel Hill, NC

Disinfection, Sterilization and Antisepsis

- Provide overview of disinfection and sterilization principles
- Current Issues
  - Low-Level disinfection
    - Emerging pathogens
  - High-level disinfection
    - Endoscopes, endocavitary probes, etc
    - HPV
    - Failure to follow disinfection/sterilization principles and patient exposures
  - Antisepsis
Overview

- Last Centers for Disease Control and Prevention guideline in 1985
- 158 pages (>82 pages preamble, 34 pages recommendations, glossary of terms, tables/figures, >1000 references)
- Evidence-based guideline
- Cleared by HICPAC February 2003; delayed by FDA
- Published in November 2008
Efficacy of Disinfection/Sterilization
Influencing Factors

Cleaning of the object
Organic and inorganic load present
Type and level of microbial contamination
Concentration of and exposure time to disinfectant/sterilant
Nature of the object
Temperature and relative humidity
Disinfection and Sterilization

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.

NONCRITICAL - objects that touch only intact skin require **low-level disinfection**.
DISINFECTION AND STERILIZATION

- 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
  - NONCRITICAL - objects that touch only intact skin require low-level disinfection

Critical Medical/Surgical Devices

- Critical
  - Transmission: direct contact
  - Control measure: sterilization
  - Surgical instruments
    - Enormous margin of safety, rare outbreaks
    - ~85% of surgical instruments <100 microbes
    - Washer/disinfector removes or inactivates 10-100 million
    - Sterilization kills 1 trillion spores
Critical Objects

- Surgical instruments
- Cardiac catheters
- Implants

Sterilization
Enormous Margin of Safety!

100 quadrillion ($10^{17}$) margin of safety

Sterilization kills 1 trillion spores, washer/disinfector removes or inactivates 10-100 million; ~100 microbes on surgical instruments
Processing “Critical” Patient Care Objects

Classification: Critical objects enter normally sterile tissue or vascular system, or through which blood flows.

Object: Sterility.

Level germicidal action: Kill all microorganisms, including bacterial spores.

Examples: Surgical instruments and devices; cardiac catheters; implants; etc.

Method: Steam, gas, hydrogen peroxide plasma, ozone plus hydrogen peroxide, VHP or chemical sterilization.
Chemical Sterilization of “Critical Objects”

Glutaraldehyde (> 2.0%)
Hydrogen peroxide-HP (7.5%)
HP (1.0%) and PA (0.08%)
HP (7.5%) and PA (0.23%)
Glut (1.12%) and Phenol/phenate (1.93%)

Exposure time per manufacturers’ recommendations

Semicritical Medical Devices
Rutala et al. AJIC 2016;44:e47

- Semicritical
  - Transmission: direct contact
  - Control measure: high-level disinfection
  - Endoscopes top ECRI list of 10 technology hazards, >100 outbreaks (GI, bronchoscopes)
    - 0 margin of safety
    - Microbial load, $10^7$-10$^{10}$
    - Complexity
    - Biofilm
  - Other semicritical devices, rare outbreaks
    - ENT scopes, endocavitary probes (prostate, vaginal, TEE), laryngoscopes, cystoscopes
    - Reduced microbial load, less complex
Microbiological Disinfectant Hierarchy
Rutala WA, Weber DJ, HICPAC. www.cdc.gov

Most Resistant

Spores (C. difficile)
Mycobacteria (M. tuberculosis)
Non-Enveloped Viruses (norovirus, HAV, polio)
Fungi (Candida, Trichophyton)
Bacteria (MRSA, VRE, Acinetobacter)

Most Susceptible

Enveloped Viruses (HIV, HSV, Flu)

HLD
Processing “Semicritical” Patient Care Objects

Classification: Semicritical objects come in contact with mucous membranes or skin that is not intact.
Object: Free of all microorganisms except high numbers of bacterial spores.
Level germicidal action: Kills all microorganisms except high numbers of bacterial spores.
Examples: Respiratory therapy and anesthesia equipment, GI endoscopes, thermometer, etc.
Method: High-level disinfection

Semicritical Items

- Endoscopes
- Respiratory therapy equipment
- Anesthesia equipment
- Endocavitary probes
- Tonometers
- Laryngoscopes
High-Level Disinfection of “Semicritical Objects”

Exposure Time ≥ 8m-45m (US), 20°C

<table>
<thead>
<tr>
<th>Germicide</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glutaraldehyde</td>
<td>&gt; 2.0%</td>
</tr>
<tr>
<td>Ortho-phthalaldehyde</td>
<td>0.55%</td>
</tr>
<tr>
<td>Hydrogen peroxide*</td>
<td>7.5%</td>
</tr>
<tr>
<td>Hydrogen peroxide and peracetic acid*</td>
<td>1.0%/0.08%</td>
</tr>
<tr>
<td>Hydrogen peroxide and peracetic acid*</td>
<td>7.5%/0.23%</td>
</tr>
<tr>
<td>Hypochlorite (free chlorine)*</td>
<td>650-675 ppm</td>
</tr>
<tr>
<td>Accelerated hydrogen peroxide</td>
<td>2.0%</td>
</tr>
<tr>
<td>Peracetic acid</td>
<td>0.2%</td>
</tr>
<tr>
<td>Glut and isopropanol</td>
<td>3.4%/26%</td>
</tr>
<tr>
<td>Glut and phenol/phenate**</td>
<td>1.21%/1.93%</td>
</tr>
</tbody>
</table>

*May cause cosmetic and functional damage; **efficacy not verified
Environmental Contamination Leads to HAIs

- Evidence environment contributes
- Role-MRSA, VRE, C. difficile
- Surfaces are contaminated--~25%
- EIP survive days, weeks, months
- Contact with surfaces results in hand contamination; contaminated hands transmit EIP to patients
- Disinfection reduces contamination
- Disinfection (daily) reduces HAIs
- Rooms not adequately cleaned

Processing “Noncritical” Patient Care Objects

Classification: Noncritical objects will not come in contact with mucous membranes or skin that is not intact.
Object: Can be expected to be contaminated with some microorganisms.
Level germicidal action: Kill vegetative bacteria, fungi and lipid viruses.
Examples: Bedpans; crutches; bed rails; EKG leads; bedside tables; walls, floors and furniture.
Method: Low-level disinfection
Microbiological Disinfectant Hierarchy
Rutala WA, Weber DJ, HICPAC. www.cdc.gov

Most Resistant

Spores (C. difficile)
Mycobacteria (M. tuberculosis)
Non-Enveloped Viruses (norovirus, HAV, polio) LLD
Fungi (Candida, Trichophyton)
Bacteria (MRSA, VRE, Acinetobacter)
Enveloped Viruses (HIV, HSV, Flu)

Most Susceptible

LOW-LEVEL DISINFECTION FOR NONCRITICAL EQUIPMENT AND SURFACES

Exposure time ≥ 1 min

<table>
<thead>
<tr>
<th>Germicide</th>
<th>Use Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethyl or isopropyl alcohol</td>
<td>70-90%</td>
</tr>
<tr>
<td>Chlorine</td>
<td>100ppm (1:500 dilution)</td>
</tr>
<tr>
<td>Phenolic</td>
<td>UD</td>
</tr>
<tr>
<td>Iodophor</td>
<td>UD</td>
</tr>
<tr>
<td>Quaternary ammonium (QUAT)</td>
<td>UD</td>
</tr>
<tr>
<td>QUAT with alcohol</td>
<td>RTU</td>
</tr>
<tr>
<td>Improved hydrogen peroxide (HP)</td>
<td>0.5%, 1.4%</td>
</tr>
<tr>
<td>Peracetic acid with HP (C. difficile)</td>
<td>UD</td>
</tr>
</tbody>
</table>

UD=Manufacturer’s recommended use dilution; others in development/testing-electrolyzed water; polymeric guanidine; cold-air atmospheric pressure plasma (Boyce Antimicrob Res IC 2016. 5:10)
Disinfection of Noncritical Surfaces Bundle

NL Havill AJIC 2013;41:S26-30

- Develop policies and procedures
- Select cleaning and disinfecting products
- Educate staff-environmental services and nursing
- Monitor compliance (thoroughness of cleaning, product use) and feedback
- Implement “no touch” room decontamination technology and monitor compliance

PROPERTIES OF AN IDEAL DISINFECTANT


- Broad spectrum-wide antimicrobial spectrum
- Fast acting-should produce a rapid kill
- Remains Wet-meet listed kill/contact times with a single application
- Not affected by environmental factors-active in the presence of organic matter
- Nontoxic-not irritating to user
- Surface compatibility-should not corrode instruments and metallic surfaces
- Persistence-should have sustained antimicrobial activity
- Easy to use
- Acceptable odor
- Economical-cost should not be prohibitively high
- Soluble (in water) and stable (in concentrate and use dilution)
- Cleaner (good cleaning properties) and nonflammable
### Key Considerations for Selecting the Ideal Disinfectant for Your Facility


<table>
<thead>
<tr>
<th>Consideration</th>
<th>Question to Ask</th>
<th>Score (1-10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kill Claims</td>
<td>Does the product kill the most prevalent healthcare pathogens</td>
<td></td>
</tr>
<tr>
<td>Kill Times and Wet-Contact Times</td>
<td>How quickly does the product kill the prevalent healthcare pathogens. Ideally, contact time greater than or equal to the kill claim.</td>
<td></td>
</tr>
<tr>
<td>Safety</td>
<td>Does the product have an acceptable toxicity rating, flammability rating</td>
<td></td>
</tr>
<tr>
<td>Ease-of-Use</td>
<td>Odor acceptable, shelf-life, in convenient forms (wipes, spray), water soluble, works in organic matter, one-step (cleans/disinfects)</td>
<td></td>
</tr>
<tr>
<td>Other factors</td>
<td>Supplier offers comprehensive training/education, 24-7 customer support, overall cost acceptable (product capabilities, cost per compliant use, help standardize disinfectants in facility)</td>
<td></td>
</tr>
</tbody>
</table>

Note: Consider the 5 components shown, give each product a score (1 is worst and 10 is best) in each of the 5 categories, and select the product with the highest score as the optimal choice (maximum score is 50).

### Decreasing Order of Resistance of Microorganisms to Disinfectants/Sterilants

- **Most Resistant**
  - Prions
  - Spores (*C. difficile*)
  - Mycobacteria
  - Non-Enveloped Viruses (*norovirus, adenovirus*)
  - Fungi
  - Bacteria (*MRSA, VRE, Acinetobacter*)

- **Most Susceptible**
  - Enveloped Viruses
C. difficile spores

DISINFECTANTS
No measurable activity (1 C. difficile strain, J9; spores at 20 min)

- Vesphene (phenolic)
- 70% isopropyl alcohol
- 95% ethanol
- 3% hydrogen peroxide
- Clorox disinfecting spray (65% ethanol, 0.6% QUAT)
- Lysol II disinfecting spray (79% ethanol, 0.1% QUAT)
- TBQ (0.06% QUAT); QUAT may increase sporulation capacity- (Lancet 2000;356:1324)
- Novaplus (10% povidone iodine)
- Accel (0.5% hydrogen peroxide)

DISINFECTANTS AND ANTISEPSIS

*C. difficile* spores at 10 and 20 min, Rutala et al, 2006

- ~4 log\(_{10}\) reduction (3 *C. difficile* strains including BI-9)
  - Clorox, 1:10, ~6,000 ppm chlorine (but not 1:50)
  - Clorox Clean-up, ~19,100 ppm chlorine
  - Tilex, ~25,000 ppm chlorine
  - Steris 20 sterilant, 0.35% peracetic acid
  - Cidex, 2.4% glutaraldehyde
  - Cidex-OPA, 0.55% OPA
  - Wavicide, 2.65% glutaraldehyde
  - Aldahol, 3.4% glutaraldehyde and 26% alcohol

A Targeted Strategy for *C. difficile*

Orenstein et al. 2011. ICHE;32:1137

Daily cleaning with bleach wipes on high incidence wards reduced CDI 85% (24.2 to 3.6 cases/10,000 patient days and prolonged median time between HA CDI from 8 to 80 days

![Graph showing infection incidence before and after intervention](image-url)
C. difficile CONTROL MEASURES
Orenstein et al. ICHE 2011;32:1137

- In units with high endemic C. difficile infection rates or in an outbreak setting, use dilute solutions of 5.25-6.15% sodium hypochlorite (e.g., 1:10 dilution of bleach) for routine disinfection. (Category II).
- We now use chlorine solution in all CDI rooms for routine daily and terminal cleaning (use to use QUAT in patient rooms with sporadic CDI). One application of an effective product covering all surfaces to allow a sufficient wetness for > 1 minute contact time. Chlorine solution normally takes 1-3 minutes to dry.
- For semicritical equipment, glutaraldehyde (20m), OPA (12m) and peracetic acid (12m) reliably kills C. difficile spores using normal exposure times.

INACTIVATION OF MURINE AND HUMAN NOROVIRUSES

<table>
<thead>
<tr>
<th>Disinfectant, 1 min</th>
<th>MNV Log$_{10}$ Reduction</th>
<th>HNV Log$_{10}$ Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>70% Ethanol</td>
<td>&gt;4 (3.3 at 15sec)</td>
<td>2</td>
</tr>
<tr>
<td>70% Isopropyl alcohol</td>
<td>4.2</td>
<td>2.2</td>
</tr>
<tr>
<td>65% Ethanol + QUAT</td>
<td>&gt;2</td>
<td>3.6</td>
</tr>
<tr>
<td>79% Ethanol + QUAT</td>
<td>3.4</td>
<td>3.6</td>
</tr>
<tr>
<td>Chlorine (5,000ppm)</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Chlorine (24,000ppm)</td>
<td>2.4</td>
<td>4.3</td>
</tr>
<tr>
<td>Phenolic, QUAT, Ag, 3% H$_2$O$_2$</td>
<td>≤1</td>
<td>≤1 (2.1 QUAT)</td>
</tr>
<tr>
<td>0.5% Accel H$_2$O$_2$</td>
<td>3.9</td>
<td>2.8</td>
</tr>
</tbody>
</table>

GUIDELINE FOR THE PREVENTION OF NOROVIRUS OUTBREAKS IN HEALTHCARE, HICPAC, 2011

- Avoid exposure to vomitus or diarrhea. Place patients with suspected norovirus on Contact Precautions in a single room (IB)
  - Continue Precautions for at least 48 hours after symptom resolution (IB)
  - Use longer isolation times for patients with comorbidities (II) or <2 yrs (II)
- Consider minimizing patient movements within a ward (II)
  - Consider restricting movement outside the involved ward unless essential (II)
  - Consider closure of wards to new admissions (II)
- Exclude ill personnel (IB)
- During outbreaks, use soap and water for hand hygiene (IB)
- Clean and disinfect patient care areas and frequently touched surfaces during outbreaks 3x daily using EPA approved healthcare product (IB)
- Clean surfaces and patient equipment prior to disinfection. Use product with an EPA approved claim against norovirus (IC)


Glutaraldehyde

- Advantages
  - Numerous use studies published
  - Relatively inexpensive
  - Excellent materials compatibility
- Disadvantages
  - Respiratory irritation from vapor
  - Pungent and irritating odor
  - Relatively slow mycobactericidal activity
  - Coagulate blood and fix tissues to surfaces
  - Allergic contact dermatitis
Ortho-phthalaldehyde

Advantages
- Fast acting HLD
- No activation
- Excellent materials compatibility
- Not a known irritant to eyes and nasal passages
- Weak odor

Disadvantages
- Stains protein gray
- Cost ($30/gal); but lower reprocessing costs-soak time, devices per gal)
- Slow sporicidal activity
- Eye irritation with contact
- Exposure may result in hypersensitivity

Comparison of Glutaraldehyde and OPA

>2.0% Glutaraldehyde
- HLD: 45 min at 25°C
- Needs activator
- 14 day use life
- 2 year shelf life
- ACGIH ceiling limit, 0.05ppm
- Strong odor
- MEC, 1.5%
- Cost - $10/gallon

0.55% Ortho-phthalaldehyde
- HLD: 12 min at 20°C
- No activator needed
- 14 day use life
- 2 year shelf life
- No ACGIH or OSHA limit
- Weak odor
- MEC, 0.3%
- Cost - $30/gallon
Ortho-phthalaldehyde (OPA)
Contraindications for OPA

- Repeated exposure to OPA, following manual reprocessing of urological instruments, may have resulted in hypersensitivity in some patients with a history of bladder cancer undergoing repeated cystoscopy.
- Out of approximately 1 million urological procedures, there have been reports of 24 patients who have experienced ‘anaphylaxis-like’ reactions after repeated cystoscopy (typically after 4-9 treatments).
- Risk control measures: residues of OPA minimized; and contraindicated for reprocessing of urological instruments used on patients with history of bladder cancer.
Hydrogen Peroxide


- **Advantages**
  - No activation required
  - Enhanced removal of organisms
  - No disposal issues
  - No odor or irritation issues
  - Does not coagulate blood or fix tissues to surfaces
  - Use studies published

- **Disadvantages**
  - Material compatibility concerns for brass, zinc, copper, and nickel/silver plating (cosmetic and functional damage)
  - Eye damage with contact

Peracetic Acid/Hydrogen Peroxide


- **Advantages**
  - No activation required
  - No odor or irritation issues
  - Effective in the presence of organic matter

- **Disadvantages**
  - Material compatibility issues for lead, brass, copper, zinc (cosmetic and functional damage)
  - Limited clinical use
  - Potential for eye and skin damage
Critical Medical/Surgical Devices
Rutala et al. ICHE 2014;35:883; Rutala et al. ICHE 2014;35:1068; Rutala et al. AJIC 2016;44:e47

- Critical
  - Transmission: direct contact
  - Control measure: sterilization
  - Surgical instruments
    - Enormous margin of safety, rare outbreaks
    - ~85% of surgical instruments <100 microbes
    - Washer/disinfector removes or inactivates 10-100 million
    - Sterilization kills 1 trillion spores

Sterilization

The complete elimination or destruction of all forms of microbial life and is accomplished in healthcare facilities by either physical or chemical processes
Methods in Sterilization

Sterilization of “Critical Objects”

Steam sterilization
Hydrogen peroxide gas plasma
Ethylene oxide
Ozone and hydrogen peroxide
Vaporized hydrogen peroxide
Steam formaldehyde
“Ideal” Sterilization Method

- Highly efficacious
- Rapidly active
- Strong penetrability
- Materials compatibility
- Non-toxic
- Organic material resistance
- Adaptability
- Monitoring capability
- Cost-effective

Schneider PM. Tappi J. 1994;77:115-119
Cleaning

- Items must be cleaned using water with detergents or enzymatic cleaners (single use) before processing.
- Cleaning reduces the bioburden and removes foreign material (organic residue and inorganic salts) that interferes with the sterilization process.
- Cleaning and decontamination should be done as soon as possible after the items have been used as soiled materials become dried onto the instruments.

Cleaning

- Mechanical cleaning machines-automated equipment may increase productivity, improve cleaning effectiveness, and decrease worker exposure
  - Utensil washer-sanitizer
  - Ultrasonic cleaner
  - Washer sterilizer
  - Dishwasher
  - Washer disinfector
- Manual
Inadequate Cleaning and Sterilization of Cataract Surgery

- May result in an adverse event after cataract surgery
  - Toxic Shock
  - Posterior Segment Syndrome
  - Anterior Syndrome
  - Toxic Anterior Segment Syndrome
Five Chambers

- Pre-wash: water/enzymatic is circulated over the load for 1 min
- Wash: detergent wash solution (150°F) is sprayed over load for 4 min
- Ultrasonic cleaning: basket is lowered into ultrasonic cleaning tank with detergent for 4 min
- Thermal and lubricant rinse: hot water (180°F) is sprayed over load for 1 min; instrument milk lubricant is added to the water and is sprayed over the load
- Drying: blower starts for 4 min and temperature in drying chamber 180°F
Washer/Disinfector
Removal/Inactivation of Inoculum (Exposed) on Instruments

<table>
<thead>
<tr>
<th>WD Conditions</th>
<th>Organism</th>
<th>Inoculum</th>
<th>Log Reduction</th>
<th>Positives</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routine</td>
<td>MRSA</td>
<td>2.6x10^7</td>
<td>Complete</td>
<td>0/8</td>
</tr>
<tr>
<td>Routine</td>
<td>VRE</td>
<td>2.6x10^7</td>
<td>Complete</td>
<td>0/8</td>
</tr>
<tr>
<td>Routine</td>
<td><em>P. aeruginosa</em></td>
<td>2.1x10^7</td>
<td>Complete</td>
<td>0/8</td>
</tr>
<tr>
<td>Routine</td>
<td><em>M. terrae</em></td>
<td>1.4x10^8</td>
<td>7.8</td>
<td>2/8</td>
</tr>
<tr>
<td>Routine</td>
<td>GS spores</td>
<td>5.3x10^6</td>
<td>4.8</td>
<td>11/14</td>
</tr>
<tr>
<td>No Enz/Det</td>
<td>VRE</td>
<td>2.5x10^7</td>
<td>Complete</td>
<td>0/10</td>
</tr>
<tr>
<td>No Enz/Det</td>
<td>GS spores</td>
<td>8.3x10^6</td>
<td>5.5</td>
<td>8/10</td>
</tr>
</tbody>
</table>

Washer/disinfectors are very effective in removing/inactivating microorganisms from instruments.
Mechanical Cleaning Equipment in CP

- When tested to verify adequate cleaning
  - Should be carried out weekly
  - Upon installation of the equipment
  - After major repairs

IS THERE A STANDARD TO DEFINE WHEN A DEVICE IS CLEAN?

- There is currently no standard to define when a device is “clean”, cleanliness controlled by visual
- Potential methods: level of detectable bacteria; protein (6µg/cm²); endotoxin; ATP; lipid
- This is due in part to the fact that no universally accepted test soils to evaluate cleaning efficiency and no standard procedure for measuring cleaning efficiency
- At a minimum, a cleaning process should: reduce the natural bioburden; remove organic/inorganic contaminants; provide devices that when sterilized have a SAL $10^{-6}$
Steam Sterilization
Rutala, Weber AJIC 2016;44:e1-e6

- Advantages
  - Non-toxic
  - Cycle easy to control and monitor
  - Inexpensive
  - Rapidly microbicidal
  - Least affected by organic/inorganic soils
  - Rapid cycle time
  - Penetrates medical packing, device lumens

- Disadvantages
  - Deleterious for heat labile instruments
  - Potential for burns
**Minimum Steam Sterilization Times**

Time at 132°C in Prevacuum Sterilizer

<table>
<thead>
<tr>
<th>Item</th>
<th>Minimum exposure</th>
<th>Minimum drying time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wrapped instruments</td>
<td>4 min</td>
<td>30 min</td>
</tr>
<tr>
<td>Textile packs</td>
<td>4 min</td>
<td>5 min</td>
</tr>
</tbody>
</table>

**Immediate Use Steam Sterilization**

- “Flash” originally defined as sterilization of an unwrapped object at 132°C for 3 min at 27-28 lbs pressure in gravity
- “Flash” used for items that must be used immediately and cannot be packaged, sterilized and stored before use
- “Flash” is an antiquated term and replaced by “immediate use steam sterilization
- The same critical reprocessing steps (such as cleaning, decontaminating, and transporting) must be followed
Immediate Use Steam Sterilization

- “Immediate Use” is defined as the shortest possible time between a sterilized item’s removal from sterilizer and aseptic transfer to sterile field
- A sterilized item intended for immediate use is not stored for future use.
- Sterilization process monitoring is essential
- Instruments inventories should be adequate to meet surgical volumes and permit the time to complete all critical elements of reprocessing
Sterilization of “Critical Objects”

Steam sterilization
Hydrogen peroxide gas plasma
Ethylene oxide
Ozone and hydrogen peroxide
Vaporized hydrogen peroxide
Steam formaldehyde
Ethylene Oxide (ETO)
Rutala, Weber AJIC 2016;44:e1-e6

- Advantages
  - Very effective at killing microorganisms
  - Penetrates medical packaging and many plastics
  - Compatible with most medical materials
  - Cycle easy to control and monitor
- Disadvantages
  - Some states (CA, NY, TX) require ETO emission reduction of 90-99.9%
  - CFC (inert gas that eliminates explosion hazard) banned after 1995
  - Potential hazard to patients and staff
  - Lengthy cycle/aeration time
Hydrogen Peroxide Gas Plasma Sterilization
Rutala, Weber AJIC 2016;44:e1-e6

Advantages
- Safe for the environment and health care worker; it leaves no toxic residuals
- Fast - cycle time is 28-52 min and no aeration necessary
- Used for heat and moisture sensitive items since process temperature 50°C
- Simple to operate, install, and monitor
- Compatible with most medical devices

Disadvantages
- Cellulose (paper), linens and liquids cannot be processed
- Sterilization chamber is small, about 3.5ft³ to 7.3ft³
- Endoscopes or medical devices restrictions based on lumen internal diameter and length (see manufacturer’s recommendations); expanded claims with NX
- Requires synthetic packaging (polypropylene) and special container tray
Ozone and Hydrogen Peroxide

- Sterizone VP4, 510(k) FDA clearance, TSO3 Canada
- Sterilizer has a 4.4 ft³ chamber
- Low temperature (41°C); uses VHP and ozone in multiple phases
- Can sterilize multi-channeled flexible endoscopes (max 4) having internal lumens ≥1.45 mm in inner diameter and ≤3,500 mm and ≥1.2 mm in inner diameter and ≤ 1,955 mm in overall length (commonly found in video colonoscopies and gastroscopes)
- Advantages/Disadvantages - limited information in peer-review literature

V-PRO™1, Vaporized Hydrogen Peroxide
Rutala, Weber AJIC 2016;44:e1-e6

- Advantages
  - Safe for the environment and health care worker; it leaves no toxic residuals
  - Fast - cycle time is 55 min and no aeration necessary
  - Used for heat and moisture sensitive items (metal and nonmetal devices)
- Disadvantages
  - Sterilization chamber is small, about 4.8 ft³
  - Medical devices restrictions based on lumen internal diameter and length - see manufacturer's recommendations, e.g., SS lumen 1mm diameter, 125mm length
  - Not used for liquid, linens, powders, or any cellulose materials
  - Requires synthetic packaging (polypropylene)
  - Limited use and limited comparative microbicidal efficacy data
Steris System 1E

FDA cleared April 2010

UNC Health Care Policy-SS1E

• As a general rule, the Steris System 1E will not be used to reprocess critical items unless the item cannot be sterilized by other legally marketed sterilization methods (e.g., SS, ETO, HP gas plasma, VHP, ozone) validated for that type of device
Steris System 1E

- SS1E-liquid chemical sterilant processing system (LCSPS)
  - All LCSPS have the same limitation in that final devices emerge wet and unwrapped from the processor (not terminally sterilized)
  - The SS1E rinse water is not described as sterile
  - FDA consider steam sterilization, HP gas plasma, VHP, ETO, and ozone sterilizers (which the agency has cleared) to be fully validated terminal sterilizers which provide terminally sterilized products

Recommendations
Methods of Sterilization

- Steam is preferred for critical items not damaged by heat
- Follow the operating parameters recommended by the manufacturer
- Use low temperature sterilization technologies for reprocessing critical items damaged by heat
- Use immediately critical items that have been sterilized by peracetic acid immersion process (no long term storage)
Conclusions

- All sterilization processes effective in killing spores
- Cleaning removes salts and proteins and must precede sterilization
- Failure to clean or ensure exposure of microorganisms to sterilant (e.g. connectors) could affect effectiveness of sterilization process

Sterilization Practices
Objectives of Monitoring the Sterilization Process

- Assures probability of absence of all living organisms on medical devices being processed
- Detect failures as soon as possible
- Removes medical device involved in failures before patient use

Sterilization Monitoring

Sterilization monitored routinely by combination of mechanical, chemical, and biological parameters

- Physical - cycle time, temperature, pressure
- Chemical - heat or chemical sensitive inks that change color when germicidal-related parameters present
- Biological - Bacillus spores that directly measure sterilization
### Sterility Indicators Table

<table>
<thead>
<tr>
<th>Method</th>
<th>Before Exposure (Do not use)</th>
<th>After Exposure (Sterile) (Ok if package is intact)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam Autoclave</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tape</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Strip</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peel Pack</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ethylene Oxide (ETO, gas)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tape</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Strip</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peel Pack</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sterrad</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tape</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Strip</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Steris</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Strip</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6/23/97</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Biological Indicators

![Image of biological indicators](image-url)
Biological Monitors

- Steam - Geobacillus stearothermophilus
- Dry heat - B. atrophaeus (formerly B. subtilis)
- ETO - B. atrophaeus
- New low temperature sterilization technologies
  - HP gas plasma (Sterrad) - G. stearothermophilus
  - Ozone-G. stearothermophilus

Biological Indicators

- Select BIs that contain spores of Bacillus atrophaeus
- Rationale: BIs are the only sterilization process monitoring device that provides a direct measure of the lethality of the process
Rapid Readout BIs for Steam Now Require a 1-3h Readout Compared to 24-48h

Super Rapid Readout Biological Indicators
Commercially available

1491 BI (blue cap)
• Monitors 270°F and 275°F gravity –displacement steam sterilization cycles
• 30 minute result (from 1hour)

1492V BI (brown cap)
• Monitors 270°F and 275°F dynamic-air-removal (pre-vacuum) steam sterilization cycles
• 1 hour result (from 3 hours)
Biological Indicators

- Select BIs that contain spores of *B. atrophaeus* or *Geobacillus steroothermophilus*

- Rationale: BIs are the only sterilization process monitoring device that provides a direct measure of the lethality of the process
Recommendations
Monitoring of Sterilizers

- Monitor each load with mechanical and chemical (internal and external) indicators.
- Use biological indicators to monitor effectiveness of sterilizers at least weekly with spores intended for the type of sterilizer.
- Use biological indicators for every load containing implantable items.
Recommendations
Monitoring of Sterilizers

- Following a single positive biological indicator used with a method other than steam, treat as non-sterile all items that have been processed in that sterilizer, dating back to last negative biological indicator.
- Following a positive biological indicator with steam sterilization, objects, other than implantable objects, do not need to be recalled because of a single positive spore test unless the sterilizer or procedure is defective or inappropriate cycle settings. If additional spore tests remain positive, consider the items nonsterile and recall and reprocess the items from the suspect load.

Recommendations
Storage of Sterile Items

- Sterile storage area should be well-ventilated area that provides protection against dust, moisture, and temperature and humidity extremes.
- Sterile items should be stored so that packaging is not compromised
- Sterilized items should be labeled with a load number that indicates the sterilizer used, the cycle or load number, the date of sterilization, and the expiration date (if applicable)
Recommendations
Storage of Sterile Items

- Event-related shelf life recognizes that the product remains sterile until an event causes it to become contaminated (e.g., tear, wetness). Packages should be evaluated before use for lose of integrity.

- Time-related shelf life (less common) considers items remain sterile for varying periods depending on the type of material used to wrap the item/tray. Once the expiration date is exceeded the pack should be reprocessed.
Proper Storage of Sterile, Reprocessed Items

- Items stored
  - At least 18 inches below the ceiling
  - 8 inches above the floor
  - 2 Inches from the wall
  - If rack used, it should be solid bottom to avoid contamination of items from dust on the floor
  - Room should be positive pressure, <75F and RH <70% (30-60%)

Sterile, Reprocessed Item

- Prior to opening a sterile package, the end user should inspect the package for
  - Signs of contamination such as moisture, tears, or discoloration in addition to the expiration date
Ultrasonic Cleaners

- Use sound waves to create bubbles that disrupt small particles that may exist in hard-to-clean places on instruments (fine cleaning)
- Used after initial cleaning that cleaning that removes all visible and accessible soiling is carried out and before sterilization

OR, CSS

- Report of an:
  - Infestation of fruit flies in the sterile instrument storage room
  - Steam intrusion and wetness
  - Significant construction debris
- OR staff want to know whether they can use the sterile packs. These conditions can affect the integrity of the packaging and contaminate the contents
  - The instruments should be unwrapped, visibly inspected, cleaned if necessary, and reprocessed
DISINFECTION AND STERILIZATION

- 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
  - NONCRITICAL - objects that touch only intact skin require low-level disinfection

Semicritical Medical Devices
Rutala et al. AJIC 2016;44:e47

- Semicritical
  - Transmission: direct contact
  - Control measure: high-level disinfection
  - Endoscopes top ECRI list of 10 technology hazards, >130 outbreaks (GI, bronchoscopes)
    - 0 margin of safety
    - Microbial load, $10^7$-$10^{10}$
    - Complexity
    - Biofilm
  - Other semicritical devices, rare outbreaks
    - ENT scopes, endocavitary probes (prostate, vaginal, TEE), laryngoscopes, cystoscopes
    - Reduced microbial load, less complex
Reprocessing Reusable Medical/Surgical Devices

- Shift from HLD to sterilization dependent on technology
- Most infections associated with endoscopes
- Perfuse channeled scopes
- Reprocessing laryngoscopes
- Endocavitary probes
- Ultrasound probe reprocessing

GI Endoscopes: Shift from Disinfection to Sterilization

Gastrointestinal Endoscopes
A Need to Shift From Disinfection to Sterilization?
William A. Rutala, PhD, MPH; David J. Weber, MD, MPH

More than 10 million gastrointestinal endoscopic procedures are performed annually in the United States for diagnostic purposes, therapeutic interventions, or both.1 Because gastrointestinal endoscopes contact mucosal surfaces, use of a contaminated endoscope may lead to patient-to-patient transmission of potential pathogens with a subsequent risk of infection.

In this issue of JAMA, Epstein and colleagues2 report findings from their investigation of a cluster of New Delhi metallo-
\-lactamase (NDM)-producing Escherichia coli associated with gastrointestinal endoscopy that occurred from March 2013 to July 2013 in a single hospital in northeastern Illinois. During the 5-month period, 9 pa-

1. First, endoscopes are semicritical devices, which contact mucous membranes or nonintact skin, and require at least high-

level disinfection.3,4 High-level disinfection achieves complete elimination of all microorganisms, except for small numbers of bacterial spores. Because flexible gastrointestinal endoscopic instruments are heat labile, only high-level disinfection with chemical agents or low-temperature sterilization technologies are possible.3 However, no low-temperature sterilization tech-

2. Second, more health care-associated outbreaks and clusters of infection have been linked to contaminated endo-

nologies are US Food and Drug Administration (FDA)-cleared for gastrointestinal endoscopes such as duodenoscopes.

3. Related article page 1447

However, until now,
Evidence-Based Recommendation for Sterilization of Endoscopes

(FDA Panel Recommendation for Duodenoscopes, May 2015; more peer-reviewed publications (>150) for the need for shifting from disinfection to sterilization than any other recommendation of AAMI, CDC [HICPAC], SHEA, APIC, SGNA, ASGE)

>130 plus endoscope-related outbreaks

GI endoscope contamination rates of 20-40% after HLD
Scope commonly have disruptive/irregular surfaces
>50,000 patient exposures involving HLD

Where are we?
Potential Future Methods to Prevent Endoscope-Related Outbreaks

- Optimize current low temperature sterilization methods or new LTST proving SAL $10^{-6}$ achieved (2 LTS technologies, FDA-cleared)
- Disposable sterile GI endoscopes/bronchoscopes (4 manufacturers)
- Steam sterilization for GI endoscopes (1 bronchoscope manufacturer)
- Use of non-endoscope methods to diagnosis or treat disease (e.g., capsule endoscopy, stool or blood tests to detect GI cancer, stool DNA test)
- Improved GI endoscope design (to reduce or eliminate reprocessing challenges-based on 50y of experience unlikely to resolve problem; closed channel duodenoscopes increased risk)

Reprocessing Reusable Medical/Surgical Devices

- Shift from HLD to sterilization dependent on technology
- Most infections associated with endoscopes
- Perfuse channeled scopes
- Reprocessing laryngoscopes
- Endocavitary probes
- Ultrasound probe reprocessing
### Infections/Outbreaks Associated with Semicritical Medical Devices

**Rutala, Weber, AJIC, In preparation**

<table>
<thead>
<tr>
<th>Medical Device</th>
<th>No. Outbreaks/Infections</th>
<th>No. Outbreaks/Infections with Bloodborne Pathogens</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaginal Probes</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Ear-Nose-Throat Endoscopes</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Cystoscopes</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>Hysteroscopes</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Laryngoscopes</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Ureteroscopes</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Prostate Probes</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>TEE-Transesophageal echocardiogram</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>GI Endoscopes/Bronchosopes</td>
<td>~130</td>
<td>4 (HBV-1 GI; HCV-3 GI; HIV-0)</td>
</tr>
</tbody>
</table>

HBV and HCV transmission during endoscopy and use of semicritical medical devices can occur, but it is rare.

Four reports of HCV and HBV transmission related to breaches involved in GI endoscope reprocessing.

No articles related to possible transmission of HIV via medical device.

Greatest evidence of transmission associated with GI endoscopes/bronchoscopes (~130 outbreaks) likely due to microbial load and complexity.

Other semicritical medical devices are rarely associated with infections related to inadequate reprocessing.
High-Level Disinfection of "Semicritical Objects"

Exposure Time > 8m-45m (US), 20°C

<table>
<thead>
<tr>
<th>Germicide</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glutaraldehyde</td>
<td>&gt; 2.0%</td>
</tr>
<tr>
<td>Ortho-phthalaldehyde</td>
<td>0.55%</td>
</tr>
<tr>
<td>Hydrogen peroxide*</td>
<td>7.5%</td>
</tr>
<tr>
<td>Hydrogen peroxide and peracetic acid*</td>
<td>1.0%/0.08%</td>
</tr>
<tr>
<td>Hydrogen peroxide and peracetic acid*</td>
<td>7.5%/0.23%</td>
</tr>
<tr>
<td>Hypochlorite (free chlorine)*</td>
<td>650-675 ppm</td>
</tr>
<tr>
<td>Accelerated hydrogen peroxide</td>
<td>2.0%</td>
</tr>
<tr>
<td>Peracetic acid</td>
<td>0.2%</td>
</tr>
<tr>
<td>Glut and isopropanol</td>
<td>3.4%/26%</td>
</tr>
<tr>
<td>Glut and phenol/phenate**</td>
<td>1.21%/1.93%</td>
</tr>
</tbody>
</table>

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

Microbiological Disinfectant Hierarchy

Rutala WA, Weber DJ, HICPAC. www.cdc.gov

Most Resistant

- Spores (C. difficile)
- Mycobacteria (M. tuberculosis)
- Non-Enveloped Viruses (norovirus, HAV, polio)
- Fungi (Candida, Trichophyton)
- Bacteria (MRSA, VRE, Acinetobacter)
- Enveloped Viruses (HIV, HSV, Flu)

HLD
Reason for Endoscope-Related Outbreaks

- Margin of safety with endoscope reprocessing minimal or non-existent
- Microbial load
  - GI endoscopes contain $10^7$-$10^{10}$
  - Cleaning results in 2-6 log$_{10}$ reduction
  - High-level disinfection results in 4-6 log$_{10}$ reduction
  - Results in a total 6-12 log$_{10}$ reduction of microbes
  - Level of contamination after processing: 4log$_{10}$ (maximum contamination, minimal cleaning/HLD)

- Complexity of endoscope and endoscope reprocessing
- Biofilms—could contribute to failure of endoscope reprocessing

Endoscope Reprocessing Methods
Ofstead, Wetzler, Snyder, Horton, Gastro Nursing 2010; 33:204
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>
<thead>
<tr>
<th>Observed Activity</th>
<th>Steps Completed (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leak test performed in clear water</td>
<td>77</td>
</tr>
<tr>
<td>Disassemble endoscope completely</td>
<td>100</td>
</tr>
<tr>
<td>Brush all endoscope channels and components</td>
<td>43</td>
</tr>
<tr>
<td>Immerse endoscope completely in detergent</td>
<td>99</td>
</tr>
<tr>
<td>Immerse components completely in detergent</td>
<td>99</td>
</tr>
<tr>
<td>Flush endoscope with detergent</td>
<td>99</td>
</tr>
<tr>
<td>Rinse endoscope with water</td>
<td>96</td>
</tr>
<tr>
<td>Purge endoscope with air</td>
<td>84</td>
</tr>
<tr>
<td>Load and complete automated cycle for high-level disinfection</td>
<td>100</td>
</tr>
<tr>
<td>Flush endoscope with alcohol</td>
<td>86</td>
</tr>
<tr>
<td>Use forced air to dry endoscope</td>
<td>45</td>
</tr>
<tr>
<td>Wipe down external surfaces before hanging to dry</td>
<td>90</td>
</tr>
</tbody>
</table>

Microbial Surveillance of GI Endoscopes

<table>
<thead>
<tr>
<th>Characteristics of Sample</th>
<th>Action Level (TCU&gt;100/scope) or EIP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastroscope</td>
<td>26.6%</td>
</tr>
<tr>
<td>Colonoscope</td>
<td>33.7%</td>
</tr>
<tr>
<td>Duodenoscope</td>
<td>34.7%</td>
</tr>
<tr>
<td>Echo-endoscope</td>
<td>31.9%</td>
</tr>
<tr>
<td>AER</td>
<td>27.2%</td>
</tr>
<tr>
<td>Manual</td>
<td>39.3%</td>
</tr>
<tr>
<td>Age of endoscope &lt;2 years</td>
<td>18.9%</td>
</tr>
<tr>
<td>Age of endoscope &gt;2 years</td>
<td>38.8%</td>
</tr>
</tbody>
</table>
Visual Inspection of GI Endoscopes and Bronchoscopes

- All endoscopes (n=20) had visible irregularities (e.g., scratches)
- Researchers observed fluid (95%), discoloration, and debris in channels
- 60% scopes with microbial contamination

Bronchoscopes, Ofstead et al. Chest. 2018
- Visible irregularities were observed in 100% (e.g., retained fluid, scratches, damaged insertion tubes)
- Microbial contamination in 58%
- Reprocessing practices deficient at 2 of 3 sites

Duodenoscope Lever Position
Alfa et al. AJIC 2018;46:73-75

- Bacteria will survive if the elevator lever was improperly positioned (in horizontal position instead of 45°) in AER
- *E. faecalis* (7 log inoculum, 2-6 log recovered) and *E. coli* (0-3 log) survived disinfection of sealed and unsealed elevator wire channel duodenoscopes in 2 different AERs
- Ensure proper lever position when placed in AERs with PA
ENDOSCOPE REPROCESSING


- PRECLEAN- point-of-use (bedside) remove debris by wiping exterior and aspiration of detergent through air/water and biopsy channels; leak testing
- CLEAN- mechanically cleaned with water and enzymatic cleaner
- HLD/STERILIZE- immerse scope and perfuse HLD/sterilant through all channels for exposure time (>2% glut at 20m at 20°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

Automated Endoscope Reprocessors

AERs automate and standardize endoscope reprocessing steps
Minimum Effective Concentration
Chemical Sterilant

- Dilution of chemical sterilant occurs during use
- Test strips are available for monitoring MEC
- Test strips for glutaraldehyde monitor 1.5%
- Test strip not used to extend the use-life beyond the expiration date (date test strips when opened)
- Testing frequency based on how frequently the solutions are used (used daily, test at least daily)
- Record results
Reprocessing Reusable Medical/Surgical Devices

- Shift from HLD to sterilization dependent on technology
- Most infections associated with endoscopes
- Perfuse channeled scopes
- Reprocessing laryngoscopes
- Endocavitary probes
- Ultrasound probe reprocessing
Reprocessing Channeled Endoscopes
Cystoscope- “completely immerse” in HLD (J Urology 2008.180:588)

Reprocessing Channeled Endoscopes
Cystoscope-HLD perfused through lumen with syringe (luer locks onto port and syringe filled and emptied until no air exits the scope nor air in barrel of syringe-syringe and lumen filled with HLD)
Reprocessing Channeled Endoscopes

<table>
<thead>
<tr>
<th>Exposure Method</th>
<th>CRE (K. pneumoniae) Inoculum before HLD (glutaraldehyde)</th>
<th>CRE (K. pneumoniae) Contamination after HLD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Passive HLD (immersed, not perfused)</td>
<td>3.2x10^8 1.9x10^9 4.1x10^8</td>
<td>3.1x10^8 4.6x10^8 1.0x10^8</td>
</tr>
<tr>
<td>Active HLD (perfused HLD into channel with syringe)</td>
<td>3.0x10^8 9.2x10^8 8.4x10^8</td>
<td>0 0 0</td>
</tr>
</tbody>
</table>

- Pathogens must have exposure to HLD for inactivation
- Immerse channeled flexible scope into HLD will not inactivate channel pathogens
- Completely immerse the endoscope in HLD and ensure all channels (e.g., hysteroscopes, cystoscopes) are perfused
- Air pressure in channel stronger than fluid pressure at fluid-air interface

Reprocessing Reusable Medical/Surgical Devices

- Shift from HLD to sterilization dependent on technology
- Most infections associated with endoscopes
- Perfuse channeled scopes
- Reprocessing laryngoscopes
- Endocavitary probes
- Ultrasound probe reprocessing
Disposable vs Reusable Laryngoscopes

- Many hospitals transitioning to disposable laryngoscopes
- Saves time
- Virtually eliminates risk of cross contamination
- Reduces likelihood on non-performing equipment
- Possibly cost-effective when considering reprocessing costs
Reprocessing of Rigid Laryngoscopes

- Limited guidelines for reprocessing laryngoscope’s blades and handles
- For years, many hospitals consider blade as semicritical (HLD) and handle as noncritical (LLD)
- Blades linked to HAIs; handles not directly linked to HAIs but contamination with microbes/blood/OPIM suggest its potential and blade and handle function together
- Ideally, clean then HLD/sterilize blades and handles (UNCH-blades and handles sterilized).
Contamination of Laryngoscope Handles

J Hosp Infect 2010;74:123
- 55/64 (86%) of the handles deemed “ready for patient use” positive for HA pathogens (S. aureus, enterococci, Klebsiella, Acinetobacter)

Anesth Analg 2009;109:479
- 30/40 (75%) samples from handles positive (CONS, Bacillus, Streptococcus, S. aureus, Enterococcus) after cleaning

AANA J 1997;65:241
- 26/65 (40%) of the handles and 13/65 (20%) of the blades were positive for occult blood. These blades and handles were identified as ready for patient use.

Reprocessing Reusable Medical/Surgical Devices

- Shift from HLD to sterilization dependent on technology
- Most infections associated with endoscopes
- Perfuse channeled scopes
- Reprocessing laryngoscopes
- Endocavitary probes
- Ultrasound probe reprocessing
Endocavitary Probes

- Probes-Transesophageal echocardiography probes, vaginal/rectal probes used in sonographic scanning
- Probes with contact with mucous membranes are semicritical
- Guideline recommends that a new condom/probe cover should be used to cover the probe for each patient and since covers may fail (1-80%), HLD (semicritical probes) should be performed
Endocavitary Probe Covers

- Sterile transvaginal probe covers had a very high rate pf perforations before use (0%, 25%, 65% perforations from three suppliers)
- A very high rate of perforations in used endovaginal probe covers was found after oocyte retrieval use (75% and 81% from two suppliers) but other investigators found a lower rate of perforations after use of condoms (0.9-2.0%)
- Condoms superior to probe covers for ultrasound probe (1.7% condom, 8.3% leakage for probe covers)

Research and Technology
Five-Year Plan to Prevent Exposures/Infections

- Human Papilloma Virus (HPV)
  - HPV is transmitted through sexual contact
  - Medical devices can become contaminated
  - If adequate disinfection of devices does not occur, the next patient may be at risk for HPV infection
  - Based on one publication, there are currently no FDA-cleared HLDs that are effective against HPV
ENDOSCOPE/ENDOCAVITARY PROBES REPROCESSING: CHALLENGES
Susceptibility of Human Papillomavirus

- Most common STD
- In one study, FDA-cleared HLD no effect on HPV
- Finding inconsistent with other small, non-enveloped viruses such as polio, rhino, echo
- Further investigation needed: test methods unclear; glycine; organic matter; comparison virus
- Conversation with CDC: validate and use HLD consistent with FDA-cleared instructions (no alterations)

Hydrogen Peroxide Mist
(uses HP mist to achieve HLD in 7m)
Effectiveness of HP Mist System in Inactivating Healthcare Pathogens on Probes

Rutala, Gergen, Sickbert-Bennett. ICHE 2016;37:613-614

- Automated, closed system that uses HP mist for HLD of ultrasound probes
- >10^6 pathogens inoculated onto probe at 2-3 sites
- Inactivated bacteria and good but not complete kill of mycobacteria, spores
- Alternative to high-level disinfection by high-level disinfectants

Efficacy of HP Mist Against HPV

Meyers C et al. SHEA Poster, 2015

- HLD widely used to reprocess semicritical items including endocavitary probes
- Tested OPA, hypochlorite and HP mist
- HP mist system and hypochlorite >4 log_{10} reduction, OPA achieved <1 log_{10} reduction
Reprocessing Reusable Medical/Surgical Devices

- Shift from HLD to sterilization dependent on technology
- Most infections associated with endoscopes
- Perfuse channeled scopes
- Reprocessing laryngoscopes
- Endocavitary probes
- Ultrasound probe reprocessing

Do ultrasound transducers used for placing peripheral or central venous access devices require HLD/sterilization?
Transducer Disinfection for Insertion of Peripheral and Central Catheters
Association of Vascular Access Guideline. June 2018; AIUM 2017

- “All transducers/probes used for peripheral VAD insertion will undergo, at a minimum, low-level disinfection….” Clean (step 1) the probe prior to disinfection (step 2).
- “During assessment, consider using a single-use condom or commercially manufactured transducer sheath (excluded: transparent dressing, gloves) during all use where there is the possibility of contact with blood/body fluids or non-intact skin”
- “Perform ALL ultrasound guided vascular access device insertions (PIV, Midline, PICC, CVC, arterial line) with the use of a sterile sheath and single-use sterile gel”.
  - After the procedure, the used sheath should be inspected for tears and the transducer inspected for potential compromise
  - Once inspected, the probe should be cleaned and then disinfected.

Transducer Disinfection for Insertion of Peripheral and Central Catheters
Association of Vascular Access (AVA) Guideline. June 2018; AIUM 2017

- All clinicians involved in ultrasound guidance should undergo comprehensive training on disinfection of the US transducers
- The AVA recommendations are similar to guidelines from the American Institute for Ultrasound in Medicine (AIUM): that is, internal probes-HLD; “interventional percutaneous procedure probes that are used for percutaneous needle or catheter placement…should be cleaned using LLD and be used in conjunction with a single-use sterile probe cover”, if probe cover compromised HLD the probe.
- Some publications have interpreted CDC and AIUM recommendations differently (AJIC 2018:46:913-920): ultrasound guided CVC insertion (critical-sterilize or HLD with sterile sheath and sterile gel); scan across unhealthy skin (semicritical-HLD and use with clean sheath and clean gel)
Transducer Disinfection for Insertion of Peripheral and Central Catheters

**Comments**

- Blood contamination of probe is infrequent
- Sheath plus cleaning plus LLD should eliminate HBV, HCV, HIV
- Likelihood of transmission, even if probe still contaminated, very remote – would require contaminating virus gaining entry via contact with the actual injection site
- Transmission of HIV, HBV, HCV via a probe using on external body surface never demonstrated
- Only semicritical medical device to transmit HBV or HCV is GI endoscope (HIV not transmitted)
- If all devices that could contact non-intact skin or be blood contaminated require HLD prior to reuse that would include linen/mattresses (Burn Center), stethoscopes, BP cuffs, xray cassettes, etc

---

Reuse of Single Use Devices
FDA Developments

- August 2000, FDA issued final SUD Enforcement Guidance. Hospitals and TPR regulated the same as original equipment manufacturer (OEM).
- A device labeled for single-use only that is reprocessed is considered as a new device. Hospital is considered the manufacturer.
- As a new device, all federal controls regarding the manufacture and marketing of the device apply.

Hospital’s Options: USA

- Option 1-Comply with enforcement guidance (August 14, 2000) and continue to reprocess SUDs
- Option 2-Use Third Party Reprocessor (premarket requirements new for TPR as they have been using non-premarket requirements)
- Option 3-avoid reuse of SUDs
Do Not Reuse Single-Use Devices

- Federal judge convicted a urologist who reused needle guides meant for single use during prostate procedures (Sept 2014)
- Third party reprocessor OK
- Criminal prosecution (based on conspiracy to commit adulteration)

Disinfection and Sterilization of Emerging Pathogens
Disinfection and Sterilization of Emerging Pathogens

- Hepatitis C virus
- Clostridium difficile
- Cryptosporidium
- Helicobacter pylori
- E.coli 0157:H7
- Antibiotic-resistant microbes (MDR-TB, VRE, MRSA)
- SARS Coronavirus, avian influenza, norovirus
- Bioterrorism agents (anthrax, plague, smallpox)

Standard disinfection and sterilization procedures for patient care equipment are adequate to sterilize or disinfect instruments or devices contaminated with blood and other body fluids from persons infected with emerging pathogens.
**Candida auris**

*Candida auris* is a globally emerging pathogen that is often resistant to multiple antifungal agents.

- In several reports, *C. auris* has been recovered from the hospital environment.
- CDC has recommended daily and post-discharge disinfection of surfaces in rooms of patients with *C. auris* infection.
- No hospital disinfectants are registered for use specifically against *C. auris*, and its susceptibility to germicides is not known.
Efficacy of Disinfectants and Antiseptics against *Candida auris*
Rutala, Kanamori, Gergen, Sickbert-Bennett, Weber, 2017

- **≥3 log$_{10}$** reduction (*C. auris*, 1m, 5% FCS, QCT)
  - 0.20% peracetic acid
  - 2.4% glutaraldehyde
  - 0.65% hydrogen peroxide, 0.14% peroxyacetic acid
  - 0.5% Quat, 55% isopropyl alcohol
  - Disinfecting spray (58% ethanol, 0.1% QUAT)
  - 28.7% isopropyl alcohol, 27.3% ethyl alcohol, 0.61% QAC
  - 0.07% o-phenylphenol, 0.06% p-tertiary amylphenol
  - 70% isopropyl alcohol
  - ~5,250 ppm chlorine
  - Ethanol hand rub (70% ethanol)
  - Accelerated hydrogen peroxide, 1.4%
  - Accelerated hydrogen peroxide, 2%

- **≤3 log$_{10}$** (most <2 log$_{10}$) reduction (*C. auris*, 1m, 5% FCS, QCT)
  - 0.55% OPA
  - 3% hydrogen peroxide
  - Quat, (0.085% QACs)
  - 10% povidone-iodine
  - ~1,050 ppm chlorine
  - 2% Chlorhexidine gluconate-CHG
  - 4% CHG
  - 0.5% triclosan
  - 1% CHG, 61% ethyl alcohol
  - 1% chloroxylenol
Effectiveness of Disinfectants Against *Candida auris* and Other *Candida* Species

Cadnum et al. ICHE 2017;38:1240-1243

In lab testing, sporicidal and IHP disinfectants were highly effective against *C. auris*, *C. glabrata* and *C. albicans*. Quats exhibited relatively poor activity against all of the *Candida* species.

Efficacy of Disinfectants and Antiseptics against Carbapenem-Resistant *Enterobacteriaceae*

Rutala, Kanamori, Gergen, Sickbert-Bennett, Weber, 2017

- ≥3 log<sub>10</sub> reduction (CRE, 1m, 5% FCS, QCT)
  - 0.20% peracetic acid
  - 2.4% glutaraldehyde
  - 0.5% Quat, 55% isopropyl alcohol
  - 58% ethanol, 0.1% QUAT
  - 28.7% isopropyl alcohol, 27.3% ethyl alcohol, 0.61% QAC
  - 0.07% o-phenylphenol, 0.06% p-tertiary amylphenol
  - ~5,250 ppm chlorine
  - 70% isopropyl alcohol
  - Ethanol hand rub (70% ethanol)
  - 0.65% hydrogen peroxide, 0.15% peroxyacetic acid
  - Accelerated hydrogen peroxide, 1.4% and 2.0%
  - Quat, (0.085% QACs; not *K. pneumoniae*)
Creutzfeldt Jakob Disease (CJD): Disinfection and Sterilization
Transmissible Spongiform Encephalopathies (TSEs) of Humans

- Kuru—now eradicated
- Gertsmann-Straussler-Scheinker (GSS)-1/40M
- Fatal Familial Insomnia (FFI)-<1/40M
- Creutzfeldt-Jakob Disease (CJD)-1/1M
- Variant CJD (vCJD), (221 cases, August 2011)
    Acquired from cattle with BSE. 1995: 172 UK, 25 France, 4 Ireland, 2 Italy, 3 USA, 2 Canada, 1 Saudi Arabia, 1 Japan, 3 Netherlands, 2 Portugal, 5 Spain, 1 Taiwan
Epidemiology of CJD in the US
Rutala, Weber. ICHE 2010;31:107-117

- Degenerative neurologic disorder
- CJD (a prion) incidence
  - One death/million population
  - No seasonal distribution, no geographic aggregation
  - Both genders equally affected
  - Age range 50-80+ years, average 67
- Long incubation, rapid disease progression after onset
- Prions resistant to conventional disinfection/sterilization

Prion Diseases
Rutala, Weber. ICHE 2010;31:107-117

- Etiology
  - Prions (proteinaceous infectious agent)
    - No agent-specific nucleic acid
    - Host protein (PrP<sup>c</sup>) converts to pathologic isoform (PrP<sup>sc</sup>); PrP gene resides on chromosome 20
    - Mutation in this gene may trigger transformation
    - Accumulates in neural cells, disrupts function, cell death
    - Resistant to conventional D/S procedures
Decreasing Order of Resistance of Microorganisms to Disinfectants/Sterilants

Most Resistant

Prions

Spores (C. difficile)

Mycobacteria

Non-Enveloped Viruses (norovirus, adeno)

Fungi

Bacteria (MRSA, VRE, Acinetobacter)

Most Susceptible

Enveloped Viruses

CJD: potential for secondary spread through contaminated surgical instruments
CJD and Medical Devices
Rutala, Weber. ICHE 2010;31:107-117

- Six cases of CJD associated with medical devices
  - 2 confirmed cases-depth electrodes; reprocessed by benzene, alcohol and formaldehyde vapor
  - 4 cases-CJD following brain surgery, index CJD identified-1, suspect neurosurgical instruments
- Cases occurred before 1980 in Europe
- No cases since 1980 and no known failure of steam sterilization

A New Practical Diagnostic Test for Creutzfeldt-Jakob Disease
Brown, Farrell. ICHE. 2015;36:849

- 14-3-3 protein in spinal fluid has proved to be an invaluable diagnostic aid for 2 decades but recognized as “marker protein” not causally related to CJD
- Two published independent studies of a newly modified prion protein amplification test named RT-QuIC (real-time quaking-induced conversion)
- Two studies yielded high sensitivity (85-96%) and specificity (99-100%)
- Tests results are available within 24 hours of specimen collection
Risk Assessment: Patient, Tissue, Device
Rutala, Weber. ICHE 2010;31:107-117

- Patient
  - Known or suspected CJD or other TSEs
  - Rapidly progressive dementia
  - Familial history of CJD, GSS, FFI
  - History of dura mater transplant, cadaver-derived pituitary hormone injection
- Tissue
  - High risk-brain, spinal cord, eyes
- Device
  - Critical or semicritical

CJD: Recommendations for Disinfection and Sterilization
Rutala, Weber. ICHE 2010;31:107-117

- High risk patient, high risk tissue, critical/semicritical device-special prion reprocessing
- High risk patient, low/no risk tissue, critical/semicritical device-conventional D/S or special prion reprocessing
- Low risk patient, high risk tissue, critical/semicritical device-conventional D/S
- High risk patient, high risk tissue, noncritical device-conventional disinfection
CJD: Disinfection and Sterilization
Conclusions
Rutala, Weber. ICHE 2010;31:107-117

- Critical/SC-cleaning with special prion reprocessing
  - 134°C for 18m (prevacuum)
  - 132°C for 60m (gravity)
  - NaOH and steam sterilization (e.g., 1N NaOH 1h, 121°C 30 m)
- No low temperature sterilization technology effective*
- Noncritical-four disinfectants (e.g., chlorine, Environ LpH) effective (4 log decrease in LD₅₀ within 1h)

*VHP reduced infectivity by 4.5 logs (Lancet 2004;364:521)

CJD: Disinfection and Sterilization
Conclusions
Rutala, Weber. ICHE 2010;31:107-117

- Epidemiologic evidence suggest nosocomial CJD transmission via medical devices is very rare
- Guidelines based on epidemiologic evidence, tissue infectivity, risk of disease via medical devices, and inactivation data
- Risk assessment based on patient, tissue and device
- Only critical/semicritical devices contaminated with high-risk tissue from high risk patients requires special treatment
Prevent Patient Exposure to CJD

**Question:** How do hospitals minimize patient exposure to neurosurgical instruments from a patient who is later given a diagnosis of CJD?

**Answer:** Consider using the reviewed sterilization guidelines for neurosurgical instruments used on patients undergoing brain biopsy when a specific lesion (e.g., tumor) has not been demonstrated. Alternatively, neurosurgical instruments used in such cases could be disposable.

Special Instrument Reprocessing Issues
In 2011, TJC recommended that laryngoscope blades be packaged in a way that prevent recontamination.

Examples of compliant storage include, but not limited to, a peel pouch or a closed plastic bag.

Examples of non-compliant storage would include unwrapped blades in an anesthesia drawer as well as unwrapped blades on top of or within a code cart.

Packaging not only prevents recontamination but also distinguishes a processed from non-processed semicritical item such as a specula, endoscope, etc.

The use of a tagging system that separates processed from non-processed items minimizes the use of a semicritical item that has not been reprocessed, and minimizes unnecessary patient exposures and risk of disease transmission.
Prostate Biopsy Probe
Rutala et al. ICHE 2007;28:916-919

- Evaluated effectiveness of HLD when assembled (needle biopsy holder in probe) and unassembled.
- Inoculated ($10^6$-$10^7$ *P. aeruginosa*): internal lumen/outside surface of needle biopsy holder; internal lumen of probe with and without needle biopsy holder in place
- Conclusion: HLD achieved when unassembled but not when assembled
Adenovirus 8
A Common Cause of Epidemic Keratoconjunctivitis
Adenovirus 8

- Adenovirus is extremely hardy when deposited on environmental surfaces and may be recovered from plastic and metal surfaces for more than 30 days
- Elimination of adenovirus from inanimate surfaces and ophthalmic instruments is essential in preventing outbreaks of epidemic keratoconjunctivitis
- Unfortunately, no reports that validate CDC recommendations for disinfecting tonometer tips. CDC. MMWR 1985; 34:533.

CDC, 1985

- Applanation tonometers-Soap and water cleaning and then disinfected by soaking them for 5 to 10 minutes in a solution containing either:
  - 5,000 chlorine (~1:10 household bleach)
  - 3% hydrogen peroxide
  - 70% ethyl alcohol
  - 70% isopropyl alcohol
Disinfectants and Antiseptics
Adeno 8 at 1 and 5 min, Rutala et al. AAC, April 2006

• Ineffective $<2 \log_{10}$ reduction
  ■ Bactoshield (4% CHG)
  ■ Vesphene (phenolic)
  ■ 70% isopropyl alcohol
  ■ 3% hydrogen peroxide
  ■ TBQ (0.06% QUAT)
  ■ Novaplus (10% povidone iodine)
  ■ Soft ‘N Sure (0.5% triclosan)
  ■ Acute-Kare (1% chloroxylenol)
  ■ Sterilox (218 and 695 ppm chlorine)
  ■ Dettol (4.8% chloroxylenol)
  ■ Accel TB (0.5% accelerated hydrogen peroxide)
  ■ Microcyn (~80 ppm chlorine)

• ~4 $\log_{10}$ reduction
  ■ Clorox, 1:10, ~6,000 ppm chlorine (but not 1:50)
  ■ Clorox Clean-up, ~1,910 ppm chlorine
  ■ Clorox disinfecting spray (65% ethanol, 0.6% Quat)
  ■ Steris 20 sterilant, 0.35% peracetic acid
  ■ Ethanol, 70%
  ■ Lysol disinfecting spray (79.6% ethanol, 0.1% Quat)
  ■ Cidex, 2.4% glutaraldehyde
  ■ Cidex-OPA, 0.55% OPA
  ■ Wavicide, 2.65% glutaraldehyde
CDC Guidelines

- CDC, 1985. Applanation tonometers-soap and water cleaning and then disinfect by soaking them for 5 to 10 minutes in a solution containing either:
  - 5,000 chlorine
  - 3% hydrogen peroxide
  - 70% ethyl alcohol
  - 70% isopropyl alcohol
- CDC, 2008. Wipe clean tonometer tips and then disinfect them by immersing for 5-10 minutes in either 5000 ppm chlorine or 70% ethyl alcohol. Category II.
- These results emphasize the proper selection of disinfectants for use in disinfecting semicritical items (e.g., applanation tonometers)

Failure to Follow Disinfection and Sterilization Principles
What Do You Do?

Scenario:

Hospital A discovered that for the past 3 days all surgical instruments were exposed to steam sterilization at 132°C for 0 minutes rather than the intended 4 minutes. A central processing technician turned the timer to 0 minutes in error.
Failure to Follow Disinfection and Sterilization Principles
Rutala, Weber. ICHE 2007;28:146-155

- What do you do?
  - Follow the 14 steps at website disinfectionandsterilization.org (confirm failure, embargo improperly D/S items, investigate the cause, etc)
  - The steps provide a general outline, but each event is unique and you must be flexible and adaptable
  - Communication among key stakeholders is very important
  - Ethical to notify patients if there is a risk-should be upfront and factual
  - Train staff and access processes/practices to minimize recurrence
  - These are stressful events (patients and staff) but the goal is to assess failure and protect patients rather than assessing blame
Recommendations
Quality Control

- Provide comprehensive and intensive training for all staff assigned to reprocess medical/surgical instruments
- To achieve and maintain competency, staff should:
  - hands-on training
  - all work supervised until competency is documented
  - competency testing should be conducted at commencement of employment and regularly
  - review written reprocessing instructions to ensure compliance

Disinfection, Sterilization and Antisepsis

- Provide overview of disinfection and sterilization principles
- Current Issues
  - Low-Level disinfection
    - Emerging pathogens
  - High-level disinfection
    - Endoscopes, endocavitary probes, etc
    - HPV
    - Failure to follow disinfection/sterilization principles and patient exposures
  - Antisepsis
Antisepsis

Antiseptic Agents
(used alone or in combination)

- Alcohols, 60-95%
- Chlorhexidine, 2% and 4% aqueous
- Iodophors
- PCMX
- Triclosan
Antiseptics

- Hand Hygiene-improvement and compliance monitoring
- Preoperative showers
- Preoperative skin preparation
- Surgical hand scrub
- Skin preparation prior to insertion of catheters
- Routine daily bathing of patients

Hand Hygiene

- No discussion of preoperative bathing
- No discussion of surgical site preparation
- No discussion of skin antisepsis before IV
- No preferential selection of antiseptics
Summary of Best Antiseptics


- **Preoperative showers**- CHG is preferred; significant impact on SSIs not proven
- **Preoperative skin preparation**- alcohol-containing products (with CHG or iodophor)
- **Surgical hand scrub**- alcohol-containing products reduce bacteria on hands best
- **Vascular access site preparation**- alcohol preparation containing >0.5% CHG
- **Routine daily bathing of patients**- CHG appear to be more effective than standard soap and water

Guideline for Hand Hygiene in Healthcare Settings

JM Boyce, D Pittet, HICPAC/SHEA/APIC/IDSA
Hand Hygiene Task Force
HEALTHCARE-ASSOCIATED INFECTIONS IN THE US: IMPACT

- 1.7 million infections per year
- 98,987 deaths due to HAI
  - Pneumonia 35,967
  - Bloodstream 30,665
  - Urinary tract 13,088
  - Surgical site infection 8,205
  - Other 11,062
- 6th leading cause of death (after heart disease, cancer, stroke, chronic lower respiratory diseases, and accidents)\(^1\)

\(^1\) National Center for Health Statistics, 2004

Sources of Healthcare-Associated Pathogens


- Endogenous flora (SSI, UTI, CLABSI): 40-60%
- Exogenous: 20-40% (e.g., cross-infection via contaminated hands [staff, visitors])
- Other (environment): 20%
  - Medical devices
  - Contact with environmental surfaces (direct and indirect contact)
Hand Hygiene

- Hand Hygiene—a general term that applies to either handwashing, antiseptic handwash, antiseptic handrub, or surgical hand antisepsis
- Main Results: alcohol-based handrubs reduce bacterial bacterial counts on hands more effectively than plain soaps, and in a majority of studies more effectively than antimicrobial soaps.

Hand Hygiene and Nosocomial Infections

- Healthcare-associated infections (HAIs)—2 million cases per year (U.S.); 80,000 deaths per year
- $5-10 billion per year (U.S.)
- Fraction of HAIs that are preventable with changes in hand hygiene practices not known
  - 38% due to cross-transmission
  - Increase in HW, reduction in HAIs
Evidence of Transmission of Pathogens on Hands

- Transmission from patient to patient via HCW hands requires four elements
  - Organisms on HCWs hands (via patient or environment)
  - Organisms must survive for several minutes on hands
  - Hand hygiene must be inadequate or agent inappropriate
  - Contaminated hands of HCW must come in contact with another patient (or an inanimate object that will contact patient)

TRANSMISSION MECHANISMS INVOLVING THE SURFACE ENVIRONMENT

Hand-borne Microorganisms

- Presence – bacterial counts on hands range from $10^4$ to $10^6$
  - resident microorganisms-attached to deeper layers of the skin and are more resistant to removal; less likely to be associated with HAIs.
  - transient microorganisms-colonize the superficial layers of skin and amenable to removable; acquired by direct contact with patients or contaminated environment surfaces; frequently associated with HAIs.
Hand Hygiene Practices in Healthcare

- Hand hygiene has been reported to average 40% (34 studies)
  - Inaccessibility of hand hygiene supplies
  - Skin irritation from hand hygiene agents
  - Inadequate time for hand hygiene
  - Interference with patient care
  - Lack of knowledge of the guidelines
  - Lack of information on the importance of hand hygiene

Hand Hygiene Practices in Healthcare

- Observational studies revealed that duration averages from 6.6 to 21 sec, and in 10/14 studies HW <15 sec, and in 8/14 studies HW < 10 sec
- HCWs also fail to wash all surfaces of their hands and fingers effectively
Hand Hygiene History

• Guidelines:
  ■ U.S. Public Health Service (1961)-soap and water, 1-2 min before and after patient contact
  ■ CDC (1975 and 1985)-non-antimicrobial handwashing between patient contacts, antimicrobial before invasive procedures
  ■ APIC (1988 and 1995)-similar to CDC, more discussion of alcohol-based handrubs
  ■ HICPAC (1996)-either antimicrobial soap or a waterless antiseptic agent be used for cleaning hands upon leaving MRSA/VRE patient rooms

Hand Hygiene

• Recommendations
  ■ IA-strongly recommended for implementation and strongly supported by experimental, clinical or epidemiological studies
  ■ IB- strongly recommended for implementation and supported by some experimental, clinical or epidemiological studies
  ■ IC-required for implementation, as mandated by federal and/or state regulation
  ■ II-suggested for implementation and supported by suggestive clinical or epidemiological studies or a theoretical rationale
Indications for Handwashing and Hand Antisepsis

- Hands are visibly dirty or soiled, wash with non-antimicrobial soap and water or antimicrobial soap and water. Category IA
- If hands are not visibly soiled, use an alcohol-based handrub for routinely decontaminating hands in all other clinical situations. IA. Alternatively, wash hands with antimicrobial soap and water. IB
  - Before having direct contact with patients. IB
  - Before donning sterile gloves when inserting a central intravascular catheter. IB

Indications for Handwashing and Hand Antisepsis

- Decontaminate hands not visibly soiled with handrub/antimicrobial (continued)
  - Before inserting urinary catheter, peripheral vascular catheter, or other invasive device. IB
  - After contact with a patient’s intact skin. IB
  - After contact with body fluids, mucous membrane, non-intact skin or wound dressings, as long as hands are not soiled. IA
  - If moving from a contaminated body site to clean site. II
  - After contact with inanimate objects in vicinity of patient. II
  - After removing gloves. IB
Indications for Handwashing and Hand Antisepsis

- Use non-antimicrobial/antimicrobial before eating and after using a restroom. IB
- Antimicrobial towelettes may be an alternative to washing hands with non-antimicrobial soap and water. IB
- No recommendation on routine use of non-alcohol-based handrubs. Unresolved issue

Simplify the Message: Clean In, Clean Out
Alcohol-Based Handrubs

- Minimize factors adversely affecting adherence to hand hygiene protocols
  - Reduce bacterial counts more effectively than washing hands with non-antimicrobial and antimicrobial soaps
  - Can be made much more accessible
  - Require less time to use
  - Produce less skin irritation and dryness
  - Improved adherence to hand hygiene policies and reduce NI rates
Hand Hygiene and “Clean Procedures”

- Personnel contaminate hands by performing “clean procedures”
- Nurses contaminate hands with 100-1000 CFU during such “clean” activities as lifting patients, taking the patient’s pulse, blood pressure, or oral temperature, or touching the patient’s hand, shoulder, or groin.

Studies Comparing Relative Efficacy of Plain Soap or Antimicrobial Soap vs Alcohol-Based Antiseptics in Reducing Counts on Hands

- Alcohol more effective than plain soap (17 studies)
- In all but two trials (15/17), alcohol-based solutions reduced bacterial counts on hands to a greater extent than washing with soaps or detergents containing povidone-iodine, 4% CHG, or triclosan
Hand Hygiene Technique

- Apply alcohol-based handrub to one hand and rub hands together, covering all surfaces. Follow manufacturer’s recommendation on volume. IB
- Soap and water-wet hands, apply amount of product recommended, rub hands together for 15 sec, covering all surfaces. Rinse with water and dry with disposable towel. IB

- Avoid using hot water, repeated exposure may increase risk of dermatitis. IB
- Liquid, bar, leaflet, or powdered forms of plain soap are acceptable when washing with a non-antimicrobial soap. II
- Multiple-use cloth towels of the hanging or roll type are not recommended for use in healthcare settings. II
Selection of Hand Hygiene Agents

- Provide personnel with efficacious hand hygiene products that have low irritancy potential. IB
- To maximize acceptance, solicit input from HCW regarding feel, fragrance, and skin tolerance. IB
- Prior to purchasing, evaluate dispenser systems to ensure function and delivery of appropriate volume. II

Selection of Hand Hygiene Agents

- Solicit information from manufacturers about known interactions between products used to clean hands, skin care products, and the types of gloves used in the institution. II
- Do not add soap to a partially empty soap dispenser. This practice of “topping off” dispensers may lead to bacterial contamination of soap. IA.
Skin Care

- Provide HCW with hand lotions or creams in order to minimize the occurrence of irritant contact dermatitis associated with hand antisepsis or handwashing. IA
- Solicit information from manufacturers regarding any effects that hand lotions, creams, or alcohol-based hand antisepsis may have on the persistent effects of antimicrobial soaps being used. IB

Other Aspects of Hand Hygiene

- Do not wear artificial fingernails or extenders when having direct contact with high-risk patients, such as those in intensive care units or operating rooms. IA
- Keep natural nail tips less than ¼ inch long. II
- Wear gloves when it can be reasonably anticipated that contact with blood or OPIM, mucous membranes, and non-intact skin will occur. IC
Other Aspects of Hand Hygiene

- Remove gloves after caring for a patient. Do not wear the same pair of gloves for the care of more than one patient, and do not wash gloves between patients. IB
- Change gloves during patient care if moving from a contaminated body site to a clean body site. II
- No recommendation on wearing rings in healthcare settings. Unresolved issue.

HCW Educational and Motivational Programs

- Educate staff regarding the types of patient care activities that can result in hand contamination and the adv/disadv of various methods used to clean their hands. II
- Monitor HCW adherence with recommended hand hygiene practices and provide personnel with information regarding their performance. IA
- Encourage patients and their families to remind HCW to decontaminate their hands. II
Administrative Measures

- Make improved hand hygiene adherence an institutional priority and provide appropriate administrative support and financial resources. IB
- Implement a multidisciplinary program (e.g., education, feedback, engineering controls, reminders in workplace, avoid understaffing) designed to improve adherence of health personnel to recommend hand hygiene practices. IB
- As part of the multidisciplinary program, provide HCW with a readily accessible alcohol-based handrub. IA

- In high workload and high intensity of patient care areas, make an alcohol-based handrub available at the entrance to the patient’s room or at the bedside, in other convenient locations, and in individual pocket-sized containers carried by HCW. IA
- Store supplies of alcohol-based hand rubs in cabinets or areas approved for flammable materials. IC
New CDC Hand Hygiene Guidelines

Major Difference

- Old CDC, APIC-non-antimicrobial between most patient contacts, antimicrobial before invasive procedures or caring for high-risk patients
- New CDC-if hands are not visibly soiled, use an alcohol-based handrub for decontaminating hands in all clinical situations; alternatively, wash hands with antimicrobial soap and water

RATIONALE FOR HAND HYGIENE

- Many infectious agents are acquired via hand contact with contaminated surfaces
  - Contact transmission: healthcare (MRSA, VRE), day care (MRSA), home (MRSA, “cold viruses”, herpes simplex)
  - Fecal-oral transmission: day care (Shigella, E. coli O157:H7), home (Salmonella, E. coli O157:H7, Cryptosporidium)
- Hand hygiene effective in reducing or eliminating transient flora
- Hand hygiene demonstrated to be effective in preventing illness (especially fecal-oral diarrheal illnesses) in healthcare facilities, child care centers/homes, and households
- ~40% of healthcare-associated infections due to cross-transmission
ASSOCIATION BETWEEN HAND HYGIENE COMPLIANCE AND HAI RATES

<table>
<thead>
<tr>
<th>Author, year</th>
<th>Setting</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Casewell, 1977</td>
<td>Adult ICU</td>
<td>Reduction HAI due to <em>Klebsiella</em></td>
</tr>
<tr>
<td>Maki, 1982</td>
<td>Adult ICU</td>
<td>Reduction HAI rates</td>
</tr>
<tr>
<td>Massanari, 1984</td>
<td>Adult ICU</td>
<td>Reduction HAI rates</td>
</tr>
<tr>
<td>Kohen, 1990</td>
<td>Adult ICU</td>
<td>Trend to improvement</td>
</tr>
<tr>
<td>Doebbeling, 1992</td>
<td>Adult ICU</td>
<td>Different rates of HAI between 2 agents</td>
</tr>
<tr>
<td>Webster, 1994</td>
<td>NICU</td>
<td>Elimination of MRSA*</td>
</tr>
<tr>
<td>Zafar, 1995</td>
<td>Newborn</td>
<td>Elimination of MRSA*</td>
</tr>
<tr>
<td>Larson, 2000</td>
<td>MICU/NICU</td>
<td>85% reduction VRE</td>
</tr>
<tr>
<td>Pittet, 2000</td>
<td>Hospitalwide</td>
<td>Reduction HAI &amp; MRSA cross-transmission</td>
</tr>
</tbody>
</table>

HAI, healthcare-associated infections *Other infection control measures also instituted

Boyce JM, Pitter D.  MMWR 2002;51(RR-16)

HAND HYGIENE ADHERENCE AN INSTITUTIONAL PRIORITY

- **Multidisciplinary Program**
  - Administrative support (IOC, Executive Staff, Dept Heads)
  - Monitor HCWs adherence to policy and provide staff with information about performance
  - Provide HCWs with accessible hand hygiene (HH) products to include alcohol based hand rubs
  - Education regarding types of activities that result in hand contamination and indications for hand hygiene
  - Reminders in the workplace (e.g., posters)
  - Considering ways to include HH in management standards (loss of hospital privileges, tickets for non-compliance, coffee coupons)
HAI Reductions and Associations with Hand Hygiene

- Over 17 months, we noted a significantly increased overall hand hygiene compliance rate ($p<0.001$) and significantly decreased overall HAI rate ($p=0.0066$) with 197 fewer infections.
- The association of hand hygiene compliance and HAIs adjusting for unit-level data was $p=0.086$ with a 10% improvement in HH associated with a 6% reduction in overall HAI.
- The association of hand hygiene compliance and *C. difficile* adjusting for unit-level data was $p=0.070$ with a 10% improvement in HH associated with a 14% reduction in *C. difficile* HAI.

Summary of Best Antiseptics

- **Preoperative showers**-CHG is preferred; significant impact on SSIs not proven
- **Preoperative skin preparation**-alcohol-containing products (with CHG or iodophor)
- **Surgical hand scrub**-alcohol-containing products reduce bacteria on hands best
- **Vascular access site preparation**-alcohol preparation containing >0.5% CHG
- **Routine daily bathing of patients**-CHG appear to be more effective than standard soap and water
Hand Hygiene Agents

- Non-antimicrobial
- Antimicrobial
  - Chlorhexidine gluconate (CHG)
  - Triclosan
  - Quaternary Ammonium Compounds (QAC)
  - Parachlorometaxylenol (PCMX)
  - Alcohols (ethyl, isopropanol, n-propanol)
  - Iodine and Iodophors

Relative Efficacy of Antimicrobial Hand Hygiene Agents

<table>
<thead>
<tr>
<th>Hand Hygiene Agents</th>
<th>Gram-positive bacteria</th>
<th>Gram-negative bacteria</th>
<th>Mycobacteria</th>
<th>Spores</th>
<th>Viruses</th>
<th>Fungi</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlorhexidine Gluconate</td>
<td>+++</td>
<td>++</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>++</td>
</tr>
<tr>
<td>Triclosan</td>
<td>+++</td>
<td>++</td>
<td>+</td>
<td>?</td>
<td>?</td>
<td>-</td>
</tr>
<tr>
<td>Quaternary Ammonium Compounds</td>
<td>+++</td>
<td>++</td>
<td>-</td>
<td>-</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td>Parachlorometaxylenol (PCMX)</td>
<td>+++</td>
<td>+</td>
<td>+</td>
<td>?</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Alcohol</td>
<td>+++</td>
<td>+++</td>
<td>+++</td>
<td>-</td>
<td>+</td>
<td>+++</td>
</tr>
<tr>
<td>Iodophors</td>
<td>+++</td>
<td>+++</td>
<td>++</td>
<td>+</td>
<td>++</td>
<td>++</td>
</tr>
</tbody>
</table>
THANK YOU!
www.disinfectionandsterilization.org