Current Issues and Controversies in Disinfection and Sterilization

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Current Issues and Controversies in Disinfection and Sterilization

- Disinfection and sterilization principles
- Current issues
  - Sterile System 1
  - SHEA Prior Guidelines, February 2010
  - New Approaches to Room Decontamination
    - Ultraviolet
    - Hydrogen peroxide vapor
- Controversies
  - Laryngoscopes
  - Surface disinfection (high touch objects)
  - Contact time

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.

Disclosure

This educational activity is brought to you, in part, by Advanced Sterilization Products (ASP) and Ethicon. The speaker receives an honorarium from ASP and Ethicon and must present information in compliance with FDA requirements applicable to ASP.

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**Steris System 1 (SS1)**

- SS1 processor is a tabletop liquid peracetic acid system promoted to sterilize instruments such as endoscopes and other medical devices between patient use.
- 30,000 pieces of equipment run through SS1 daily.
- Typically used in surgical and endoscope suites.
- No confirmed cases of infections when used as directed.

**Recommendations for Identifying Replacement Devices**

- Identifying which devices our hospitals are reprocessing using SS1.
- For each device being reprocessed, identify type of reprocessing needed.
  - Review CDC and professional organization guidance.
  - Review manufacturer’s instructions for each device.
  - Consider Spaulding classification scheme.
  - Select a reprocessing device that will provide reprocessing needed.
  - Consult the endoscope or reusable device manufacturer’s written instructions for use or contact device manufacturer for reprocessing procedures.

**Steris System 1**

- Healthcare organizations have little choice but to plan for the replacement of SS1.
- May mean significant and unexpected costs to health care facilities (capital equipment, staff time and/or inventory).
- Three options:
  - Transition immediately from SS1 to other methods or equipment.
  - Continue using SS1 until Steris terminates support.
  - Orderly transition to other methods (9mo initially → now 18mo [July 2011]).

- If HLD is desired, review FDA-cleared list of CS and HLD.
- If HLD via automated endoscope reprocessor (AER), review FDA-cleared AERs (i.e., ASP, Medivators, Custom Ultrasone, Langford, Steris).
- If sterilization process, review FDA-cleared low temperature sterilization processes (i.e., ASP, Steris, TSO₂, ETO manufacturers [3M, Steris, HW Technology]).
“Hospitals using SS1 should be figuring out what their next sterilizer will be and how quickly they can switch over” Steven Silverman, Office of Compliance, FDA

Current issues and Controversies in Disinfection and Sterilization

- Disinfection and sterilization principles
- Current issues
  - Sterile System 1-switch to legally marketed device
  - SHEA Prion Guidelines, February 2015
  - New Approaches to Room Decontamination
    - Ultraviolet
    - Hydrogen peroxide vapor
- Controversies
  - Laryngoscopes
  - Surface disinfection
  - Contact time

Epidemiology of CJD in the US

- Degenerative neurologic disorder
- Incidence
  - One death/million population
  - No seasonal distribution, no geographic aggregation
  - Both genders equally affected
  - Age range 50-80+ years, average 67
- Long incubation disease (months-years)
- Rapid disease progression after onset (death within 6 mo)
- Relatively resistant to conventional disinfection/sterilization

Transmissibility of Prions

- Transmission
  - Not spread by contact (direct, indirect, droplet) or airborne
  - Not spread by the environment
  - Experimentally-all TSEs are transmissible to animals, including the inherited forms
  - Epidemiology of CJD: sporadic-90%; familial-10%; iatrogenic-1% (after implant of contaminated grafts [dura mater] or receive hormone therapy, ~400 cases worldwide)

Sterilization of Prion-Contaminated Instruments

- SHEA Guideline
  - Define the etiology, epidemiology, and clinical features of prion transmission
  - Review iatrogenic transmission of prion diseases
  - Examine the infectivity of human tissues
  - Review the prion inactivation studies
  - Review the recommendations to prevent cross-transmission from medical devices contaminated with prions
  - Discuss future challenges
Iatrogenic Transmission of CJD

- Contaminated medical instruments
  - Electrodes in brain (2)
  - Neurosurgical instruments in brain (4 suspected cases)
- Implantation of contaminated grafts
  - Dura mater grafts (>190)
  - Corneal grafts (3)
- After patients received hormone therapy
  - Use of human growth hormone and gonadotropin (>190 cases)

CJD and Medical Devices

- Six cases of CJD associated with medical devices
  - 2 confirmed cases—depth electrodes, reprocessed by benzene, 70% alcohol and formaldehyde vapor
  - 4 unconfirmed cases—CJD following brain surgery, suspect neurosurgical instruments, index CJD identified 1
- Cases occurred from 1953-1980 in UK, France and Switzerland
- No cases since 1980 and no known failure of steam sterilization

Risk of CJD Transmission

<table>
<thead>
<tr>
<th>Risk of Infection</th>
<th>Tissue</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>Brain (including dura mater), spinal cord, pituitary tissue and posterior eye</td>
</tr>
<tr>
<td>Low</td>
<td>CSF, liver, lymph node, kidney, lung, spleen, placenta, olfactory epithelium</td>
</tr>
<tr>
<td>No</td>
<td>Peripheral nerve, intestine, bone marrow, whole blood, leukocytes, serum, thyroid gland, adrenal gland, heart, skeletal muscle, adipose tissue, gingiva, prostate, testes, tears, nasal mucus, saliva, sputum, urine, feces, semen, vaginal secretions, sweat and milk</td>
</tr>
</tbody>
</table>

High transmission to inoc animals >50%, Low transmission to inoc animals >0.001% but no overt evidence in human primates

CJD: Disinfection and Sterilization

Conclusions

- Critical/Semisricritical devices contaminated with high-risk tissue from high-risk patients requires special prion reprocessing
  - 134°C for 18m (prevacuum)
  - 132°C for 60m (gravity)
  - NaOH and steam sterilization (e.g., 1N NaOH 1h, then 121°C 1h)
- Discard instruments that are impossible to clean
- No low temperature sterilization technology recommended*
- Noncritical disinfectants (e.g., chlorine, Environ LpH+) effective (4 log decrease in LD50 within 1h) and some detergents

*VP and HP gas plasma (Sterrad N01) reduced prion infectivity but not cleared by FDA
Prevent Patient Exposure to CJD Contaminated Instruments

How do you prevent patient exposure to neurosurgical instruments from a patient who is later given a diagnosis of CJD?

Hospitals should use the special prion reprocessing precautions for instruments from patients undergoing brain biopsy when a specific lesion has not been demonstrated (e.g., CT, MRI). Alternatively, neurosurgical instruments used in such cases could be disposable.

Conclusions

- Epidemiologic evidence suggests 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
- Critical/Semicritical-devices contaminated with high-risk tissue from high-risk patients requires special prion reprocessing
  - 134°C for 18m (prevacuum)
  - 132°C for 60m (gravity)
  - NaOH and steam sterilization (e.g., 1N NaOH 1h, then 121°C 1h)

Current Issues and Controversies in Disinfection and Sterilization

- Disinfection and sterilization principles
- Current issues
  - Sterile System 1
  - SHEA Prion Guideline, February 2010
  - New Approaches to Room Decontamination (after discharge)-both effective
    - Ultraviolet
    - Hydrogen peroxide vapor
- Controversies
  - Laryngoscopes
  - Surface disinfection (high touch objects)
  - Contact time

New Approaches to Room Decontamination

- Contaminated environmental surfaces can contribute to transmission of pathogens
- About 50% of 14 objects in patient room are cleaned at terminal disinfection
- Inadequate terminal cleaning of rooms occupied by patients with MDR pathogens places the next patients in these rooms at increased risk of acquiring these organisms

Novel Methods of Room Disinfection

- See images for novel methods and equipment.
UV Room Decontamination

- Fully automated, self-calibrates, activated by hand-held remote
- Room ventilation does not need to be modified
- Uses UVC (254 nm range) to decontaminate surfaces
- Measures UV reflected from walls, ceilings, floors or other treated areas and calculates the operation time to deliver the programmed lethal dose for pathogens.
- UV sensors determines and targets highly-shadowed areas to deliver measured dose of UV energy
- After UV dose delivered (e.g., 36,000 µWs/cm² RD), will power-down and audibly notify the operator
- Reduces colony counts of pathogens by >99.9% within 15 minutes

UV Room Decontamination

- Phase 1 - 3x3” formica sheets contaminated with ~10^4 organisms (MRSA, VRE, MDR-Acinetobacter, C. difficile spores) were placed in a room, both in direct line-of-sight of the UV device and behind objects (indirect line-of-sight using a laser pointer). Following timed exposure, the growth of the microbes was assessed.
- Phase 2 - rooms that housed patients with MRSA or VRE had specified sites sampled before and after UV-C irradiation. Following timed exposure, the growth of MRSA, VRE and total colony counts was assessed.
Decontamination of Surfaces in Patient Rooms on Contact Precautions for MRSA

<table>
<thead>
<tr>
<th>Overall Results</th>
<th>Before UV</th>
<th>After UV</th>
<th>Before UV</th>
<th>After UV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Total CFU/5 Rodac</td>
<td>384</td>
<td>19</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pos Rodacs/ Total Rodacs</td>
<td>81/400</td>
<td>2/400</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean MRSA/ Rodac</td>
<td>37</td>
<td>2</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Decontamination with UVC

<table>
<thead>
<tr>
<th>Organism</th>
<th>Direct (log₁₀ reduction)</th>
<th>Indirect (log₁₀ reduction)</th>
<th>Total (log₁₀ reduction)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MRSA (-15m)</td>
<td>4.31</td>
<td>3.85</td>
<td>3.94 (n=50)</td>
</tr>
<tr>
<td>VRE (-15m)</td>
<td>3.90</td>
<td>3.29*</td>
<td>3.46 (n=47)</td>
</tr>
<tr>
<td>MDR-Enterobacter (-15m)</td>
<td>4.21</td>
<td>3.79</td>
<td>3.88 (n=47)</td>
</tr>
<tr>
<td>C difficile (-50m)</td>
<td>4.04</td>
<td>2.43*</td>
<td>2.79 (n=45)</td>
</tr>
</tbody>
</table>

Summary

- UVC radiation was found to reduce >99.9% of vegetative bacteria within 15 minutes and 99.84% for C. difficile spores with 50 minutes.
- UVC was more effective when there was a direct line-of-sight to the contaminant but meaningful reduction (3.3-3.9 log₁₀ reduction for bacteria) occurred when the contaminant was not directly exposed to the UVC.
- In MRSA patient rooms, there was a significant reduction in total average CFU per Rodac (384 CFU pre and 19 CFU post); samples positive for MRSA (81/400 pre and 2/400 post); and the average MRSA per Rodac (37 pre and 2 post-treatment).

Decontamination with UVC

- Advantages
  - Reliable biocidal activity against a wide range of pathogens
  - Surfaces and equipment decontaminated
  - Room decontamination is rapid (~15 minutes) for vegetative bacteria
  - HVAC system does not need to be disabled and the room does not need to be sealed
  - It is residual free and does not give rise to health and safety concerns
  - No consumable products so costs are capital equipment and staff time
  - Good distribution in the room of UV energy via an automated monitoring system

- Disadvantages
  - Do not know if use decreases the incidence of HAs
  - Only done at terminal disinfection (i.e., not daily cleaning)
  - All patients and staff must be removed from the room/area
  - Capital equipment costs are substantial
  - Does not remove dust and stains which are important to patient/visitors
  - Sensitive use parameters (e.g., UV dose delivered)
Decontamination with Hydrogen Peroxide Vapor
Boyce et al: ICH 2006;29:723

- 5 wards with a high incidence of C. difficile
- HPV was injected into sealed wards and individual patient rooms using generators until approx 1 micron film of HP was achieved on the surface
- 11/43 (25.6%) surface samples yielded C. difficile compared to 0/27 (0%) after HPV decontamination
- The incidence of nosocomial CDAD was significantly lower during the intervention period
- Conclusion: HPV was efficacious in eradicating C. difficile from contaminated surfaces and reducing infections

\[ \text{Figure 1. Incidence of nosocomial C. difficile-associated disease on 5 wards (A-E) that underwent intensive hydrogen peroxide vapor decontamination, during the pretreatment period (gray bars), from June 2004 through March 2005 and the intervention period (black bars, June 2005 through March 2006).} \]

Novel Methods of Room Disinfection
Summary

- UV and HPV are effective and significantly reduced the contamination with C. difficile, MRSA, VRE, MDROs and other pathogens
- Offer an option for room decontamination at patient discharge (daily cleaning still suboptimal)
- HPV studies have shown benefits in controlling outbreaks and reducing infections
- Since contamination of surfaces is common, even after surface disinfection, this technology should be considered in selected patient rooms and care areas when the environmental mode of transmission is significant.

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- Disinfection and sterilization principles
- Current issues
  - SARA Pathogen Guidelines, February 2009
  - New Approaches to Room Decontamination
    - Ultraviolet
    - Hydrogen peroxide vapor
- Controversies
  - Laryngoscopes - clean or hi-level disinfect blades and handles
  - Surface disinfection
  - Contact time
Reprocessing of Rigid Laryngoscopes

- No guideline for reprocessing laryngoscope's blades and handles
- 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 blood/OPIMI pathogens suggest its potential and blade and handle function together
- Ideally, clean then HLD/sterilize blades and handles (UNCHC-blades-Steris, handle (without batteries)-Sterrad; blade/handle with batteries-Sterrad

Contamination of Laryngoscope Handles

- J Hosp Infect 2010;74:123
- 5584 (86%) of the handles deemed “ready for patient use” positive for S. aureus, enterococci, Klebsiella, and Acinetobacter
- 3040 (75%) samples from handles positive (CONS, Bacillus, Staphylococcus, S. aureus, Enterococcus) after cleaning
- AANA J 1997;65:241
- 2665 (40%) of the handles and 1365 (20%) of the blades were positive for occult blood. These blades and handles were identified as ready for patient use.

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- Disinfection and sterilization principles
- Current issues
  - Sterile Systems 1
  - SHEA Patient Guidelines, February 2010
  - New Approaches to Room Decontamination
    - Ultrasound
    - Hydrogen peroxide vapor
- Controversies
  - Laryngoscopes
  - Surface disinfection-suboptimal cleaning, high-touch objects
  - Contact lines

Patient Area Cleaning/Disinfecting

- Carling et al. ICHE 2008;29:1 and ICHE 2008;29:1035
- Monitor cleaning performance using an invisible fluorescent targeting method. Rooms (14 high-risk objects) were marked and evaluated after terminal cleaning.
- Results: 20,846 environmental surfaces (14 types of objects) were evaluated in 36 hospitals. Mean proportion of objects cleaned was 48%. Following education and process improvement feedback, cleaning improved to 77%.
- Conclusion: Substantial opportunity for improving terminal cleaning/disinfecting activities.
Mean proportion of surfaces disinfected at terminal cleaning is ~50%.

**Table. Rates of Cleaning for 14 Types of High-Risk Objects**

<table>
<thead>
<tr>
<th>Object</th>
<th>Percentage cleaned</th>
<th>95% Cl</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sink</td>
<td>82 ± 12</td>
<td>77-88</td>
</tr>
<tr>
<td>Toilet seat</td>
<td>76 ± 18</td>
<td>68-84</td>
</tr>
<tr>
<td>Tray table</td>
<td>77 ± 15</td>
<td>71-84</td>
</tr>
<tr>
<td>Bedside table</td>
<td>64 ± 22</td>
<td>54-73</td>
</tr>
<tr>
<td>Toilet handle</td>
<td>60 ± 22</td>
<td>50-69</td>
</tr>
<tr>
<td>Side rail</td>
<td>60 ± 21</td>
<td>51-69</td>
</tr>
<tr>
<td>Call box</td>
<td>50 ± 19</td>
<td>42-58</td>
</tr>
<tr>
<td>Telephone</td>
<td>49 ± 16</td>
<td>42-56</td>
</tr>
<tr>
<td>Chair</td>
<td>48 ± 28</td>
<td>35-61</td>
</tr>
<tr>
<td>Toilet door knobs</td>
<td>28 ± 22</td>
<td>18-37</td>
</tr>
<tr>
<td>Toilet hand hold</td>
<td>28 ± 23</td>
<td>18-38</td>
</tr>
<tr>
<td>Bedpan cleaner</td>
<td>23 ± 18</td>
<td>17-33</td>
</tr>
<tr>
<td>Room door knobs</td>
<td>23 ± 19</td>
<td>15-31</td>
</tr>
<tr>
<td>Bathroom light switch</td>
<td>20 ± 21</td>
<td>11-30</td>
</tr>
</tbody>
</table>

*Note:* CI = confidence interval.

**Target Enhanced**

**Practice* NOT Product**

*surfaces not wiped*
Quantitative Approach to Defining High-Touch Surfaces

- CDC/EIC guideline makes a Category II recommendation to clean and disinfect high-touch surfaces (e.g., doorknobs, bed rails, light switches, and surfaces in and around toilet in patients' rooms) on a more frequent schedule than minimal-touch surfaces.
- No one has quantitatively assessed frequency of HCW contact with different room surfaces.
- Over 18 months, HCW were observed while providing routine care to a patient to ascertain the frequency of contact with surfaces on the immediate environment of the patient.
- 50 interactions were observed in 5 ICUs and 7 general medical/surgical floors at UNC Health Care.

Summary
- Data demonstrated that in the ICU and floor, high and medium touch surfaces occurred in the immediate vicinity of the patient.
- While it is desirable that all environmental surfaces be routinely disinfected, surfaces that are not likely contaminated or frequently touched such as thermostats may not warrant as much concern.
- All surfaces should be disinfected at terminal cleaning.
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  - Sterile System 1
  - SHEA Policy Guideline, February 2010
  - New Approaches to Room Decontamination
    - Ultraviolet
    - Hydrogen peroxide vapor
- Controversies
  - Laryngoscopes
  - Surface disinfection
  - Contact time < 1 minute

Surface Disinfection

- Exposure Time
  - CDC guideline recommends a contact time of at least 1 minute
  - In order to get EPA clearance of the CDC Guideline it was necessary to insert two sentences. "By law, all applicable label instructions on EPA-registered products must be followed. If the user selects exposure conditions that differ from those on the EPA-registered product label, the user assumes liability from any injuries resulting from off-label use and is potentially subject to enforcement action under FIFRA."

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- Critical/Semi-critical devices contaminated with high-risk tissue from high-risk patients requires special prion reprocessing
  - 134°C for 18m (prevacuum)
  - 132°C for 60m (gravity)
  - NaOH and steam sterilization (e.g., 1N NaOH 1h, 121°C 30m)
- UV and HPV are effective and offer an option for room decontamination

Current Issues and Controversies Summary

- Reprocessing rigid laryngoscopes, clean then HLD/sterilize blades and handles
- Significant improvements in surface disinfection are needed to eliminate the risk associated with contaminated surfaces
- 3 surfaces (bed rail, bed surface, supply cart) in the ICU and 4 surfaces (bed rails, overbed tables, IV pumps, bed surface) in the floor setting were considered high touch and accounted for 40-49% of the touches
- While it is desirable that all environmental surfaces be routinely disinfected, surfaces that are not likely contaminated or frequently touched such as thermostats may not warrant as much concern.
- All surfaces should be disinfected at terminal cleaning
Current Issues and Controversies in Disinfection and Sterilization

- Disinfection and sterilization principles
- Current issues
  - Sterile System I
  - SBIA Prion Guidelines, February 2008
  - New Approaches to Room Decontamination
  - Ultraviolet
  - Hydrogen peroxide vapor
- Controversies
  - Laryngoscopes
  - Surface distribution
  - Contact time

References


Thank you