

Disclosure

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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
 - Steris System 1
 - SHEA Prion Guideline, February 2010
 - New Approaches to Room Decontamination
 - ◆ Ultraviolet
 - ◆ Hydrogen peroxide vapor
- Controversies
 - Laryngoscopes
 - Surface disinfection (high touch objects)
 - Contact time

disinfectionandsterilization.org

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**.

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Steris System 1



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

Steris System 1 (SS1)

- May 2008, FDA notified Steris that SS1 "adulterated and misbranded" and FDA has not determined it is safe and effective for label claims. Based on significant changes from 1988 to 2002.
- January 2009, Steris advised customers steps it was taking in response to FDA concerns (stopped selling SS1 in the US but support it for 2 years)
- December 2009, FDA not satisfied with transition of Steris customers to replacements for SS1 issued a notice to healthcare organizations recommending they transition to legally marketed devices; 3-6 months
- February 2010, reusable devices labeled for reprocessing by SS1 are misbranded. Revise labeling to identify legally-marketed devices.
- Steris submitted to FDA an updated SS1 in January 2009 but not FDA-cleared
- "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

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 (6mo initially → now 18mo [July 2011])

Steris System 1

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

- 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 Ultrasonics, Langford, Steris)
- If sterilization process, review FDA-cleared low temperature sterilization processes (i.e., ASP, Steris, TSO₃, ETO manufacturers [3M, Steris, HW Technology])

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“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

MEDICAL INSTRUMENTS AND EQUIPMENT - SHEA GUIDELINE

SHEA GUIDELINE

Guideline for Disinfection and Sterilization of Prion-Contaminated Medical Instruments

William A. Rutala, PhD, MPH (Lead); Thomas McD. MPH

**EPIDEMIOLOGY OF THE CROSS-COUNTRY
TRAVEL OF PRION**

Cross-country disease (CJD) is a degenerative neurodegenerative disorder of humans with its incubator in the United States. It is caused by a proteinaceous infectious agent, prion. CJD is related to other human neurodegenerative proteinopathies (TSEs) including bovine spongiform encephalitis (BSE), scrapie, and variant Creutzfeldt-Jakob disease (vCJD). The incubation period of prion disease ranges from months to decades, and is generally asymptomatic until the final months of the disease. Prion disease is an incurable neurodegenerative disease, and is caused by a proteinaceous infectious agent, prion. Prion disease is an incurable neurodegenerative disease, and is caused by a proteinaceous infectious agent, prion.

**TRANSMISSION OF CJD VIA MEDICAL
DEVICES**

CJD occurs as both a sporadic disease (~80% of cases) and as a result of acquired disease (~20% of cases). Travel that may cause CJD may include direct contact with contaminated instruments, the density of which is related to the type of contamination (e.g., prion), the type of CJD, the type of instrument, the type of patient, and the type of procedure. Prion disease is an incurable neurodegenerative disease, and is caused by a proteinaceous infectious agent, prion. Prion disease is an incurable neurodegenerative disease, and is caused by a proteinaceous infectious agent, prion.

Sterilization of Prion-Contaminated Instruments Rutala, Weber ICHE 2010:31:107-117

- 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
 - Provide the recommendations to prevent cross-transmission from medical devices contaminated with prions
 - Discuss future challenges

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

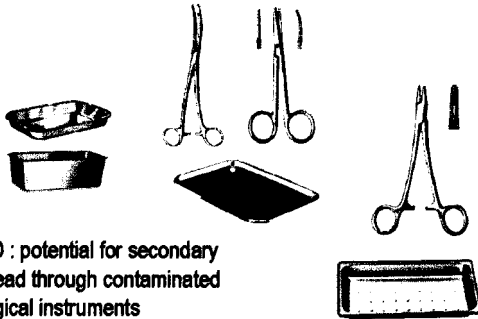
- Transmission
 - Not spread by contact (direct, indirect, droplet) or airborne
 - Not spread by the environment
 - Experimentally-all TSEs are transmissible to animals, including the inherited forms
 - Epidemiology of CJD: sporadic-90%; familial-10%; iatrogenic-1% (after implant of contaminated grafts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

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 Assessment for Special Prion Reprocessing: Patient, Tissue, Device

- High-Risk Patient
 - Known or suspected CJD or other TSEs
 - Rapidly progressive dementia consistent with possible prion disease
 - Familial history of CJD, GSS, FFI
 - History of dura mater transplant, cadaver-derived pituitary hormone injection; known mutation in the prion gene
 - Patients with EEG findings or laboratory evidence suggestive of CJD
- High-Risk Tissue
 - Brain, spinal cord, posterior eye (including retina or optic nerve)
- High-Risk Device
 - Critical or semicritical

Risk of CJD Transmission

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

High-transmission to inoc animals >50%, Low-transmission to inoc animals >10-20% but no epid evidence of human inf

CJD: Disinfection and Sterilization Conclusions

- 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)
- 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

*VHP and HP gas plasma (Sterrad NQ) reduced prion infectivity but not cleared by FDA

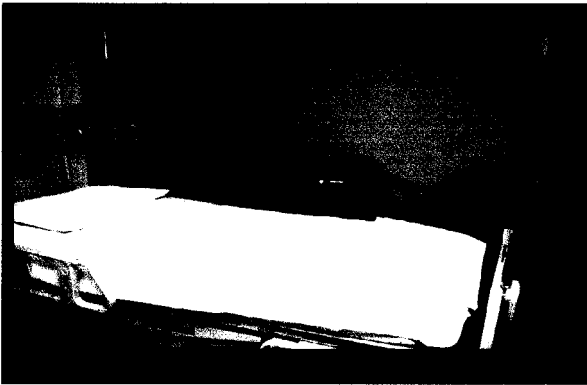
Prevent Patient Exposure to CJD Contaminated Instruments

How do you prevent patient exposure to neurosurgical instruments from a patient who is latter 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/Semical-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, then 121°C 1h)



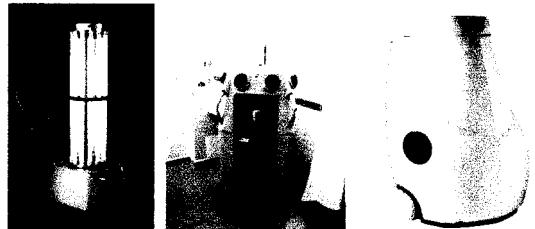
New Approaches to Room Decontamination

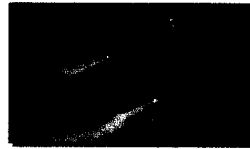
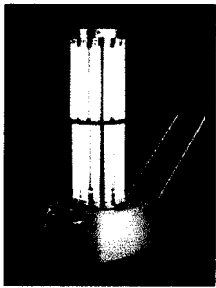
- Contaminated environmental surfaces can contribute to transmission of pathogens
- About 50% of 14 objects in patient room are cleaned at terminal disinfection
- Inadequate terminal cleaning of rooms occupied by patients with MDR pathogens places the next patients in these rooms at increased risk of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

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

Novel Methods of Room Disinfection





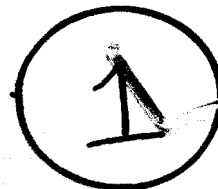
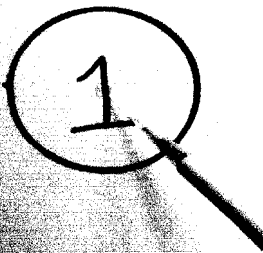
UV Room Decontamination

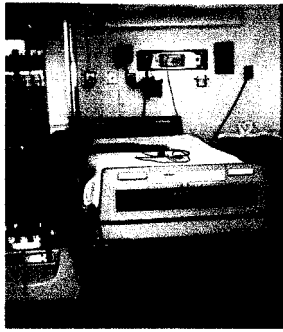
Rutala, Weber, Gergen, ICHE, In press, 2010

- 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 μ Ws/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 $\sim 10^{+6}$ 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.





Room Decontamination with UV

(Kutala, Gergen, Weber, ICHE, in press, 2010)

Organism	Direct (log ₁₀ reduction)	Indirect (log ₁₀ reduction)	Total (log ₁₀ reduction)
MRSA (~15m)	4.31	3.85	3.94 (n=50)
VRE (~15m)	3.90	3.29*	3.46 (n=47)
MDR- <i>Acinetobacter</i> (~15m)	4.21	3.79	3.88 (n=47)
<i>C. difficile</i> (~50m)	4.04	2.43*	2.79 (n=45)

Decontamination of Surfaces in Patient Rooms on Contact Precautions for MRSA

Overall Results	Before UV	After UV	Before UV	After UV
Mean Total CFU/5 Rodac	384	19		
Pos Rodacs/ Total Rodacs			81/400	2/400
Mean MRSA/ Rodac			37	2

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

Decontamination with UVC

- Disadvantages
 - Do not know if use decreases the incidence of HAIs
 - 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: ICHE 2008;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

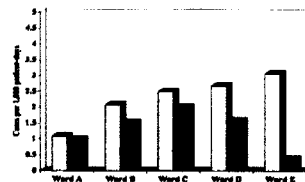


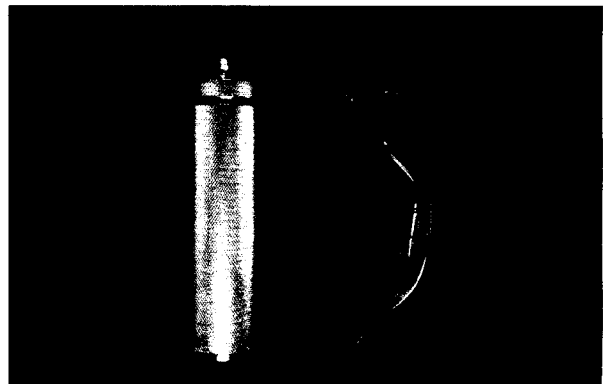
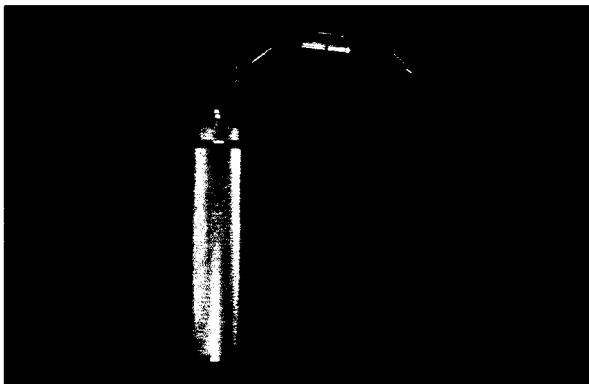
FIGURE 2. Incidence of nosocomial *Clostridium difficile*-associated disease on 5 wards (A-E) that underwent intensive hydrogen peroxide vapor decontamination, during the preintervention period (gray bars; June 2004 through March 2005) and the intervention period (black bars; June 2005 through March 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.

Current Issues and Controversies in Disinfection and Sterilization

- Disinfection and sterilization principles
- Current issues
 - Static System 1
 - SHEA Prion Guideline, February 2010
 - New Approaches to Room Decontamination
 - ◆ Ultraviolet
 - ◆ Hydrogen peroxide vapor
- Controversies
 - Laryngoscopes-clean then HLD/sterilize blades and handles
 - Surface disinfection
 - Contact time



Reprocessing of Rigid Laryngoscopes

JHI 2008, 66:101; ICHE 2007, 29:664; AJIC 2007, 36: 536

- 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/OPIM/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

- 55/64 (86%) of the handles deemed "ready for patient use" positive for *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.

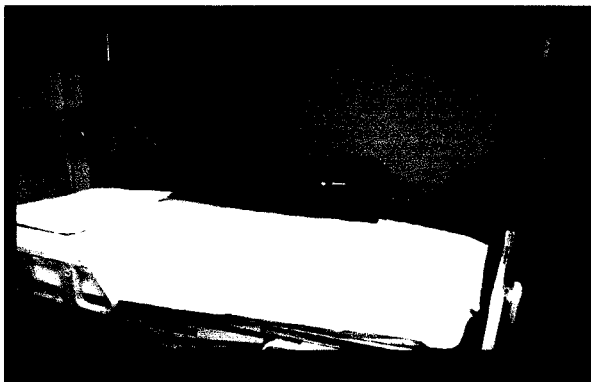
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 - Surface disinfection-suboptimal cleaning, high-touch objects
 - Contact time



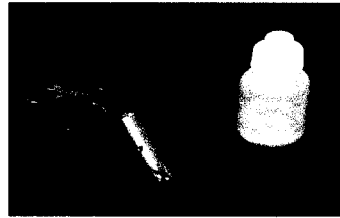
Patient Area Cleaning/Disinfecting

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: 20,648 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%

The Dazo Solution



Target Enhanced



TABLE. Rates of Cleaning for 14 Types of High-Risk Objects

Object	Percentage cleaned		95% CI
	Mean \pm SD	Range	
Sink	82 \pm 12	57-97	77-88
Toilet seat	76 \pm 18	40-98	68-84
Tray table	77 \pm 15	53-100	71-84
Bedside table	64 \pm 22	23-100	54-73
Toilet handle	60 \pm 22	23-89	50-69
Side rail	60 \pm 21	25-96	51-69
Call box	50 \pm 19	9-90	42-58
Telephone	49 \pm 16	18-86	42-56
Chair	48 \pm 28	11-100	35-61
Toilet door knobs	28 \pm 22	0-82	18-37
Toilet hand hold	28 \pm 23	0-90	18-38
Bedpan cleaner	25 \pm 18	0-79	17-33
Room door knobs	23 \pm 19	2-73	15-31
Bathroom light switch	20 \pm 21	0-81	11-30

NOTE. CI, confidence interval.

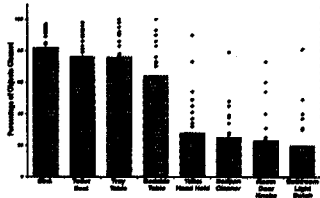


FIGURE 1. Rates of cleaning for the 14 types of object with the highest cleaning rates and the 4 types of object with the lowest rates. Shaded bar, mean value; filled diamond, value for a single hospital.

Practice* NOT Product

*surfaces not wiped

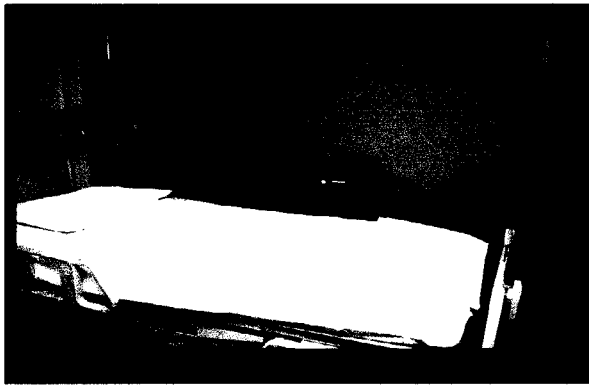
Patient Area Cleaning/Disinfecting

- Health care facilities may need to introduce other controls to ensure all surfaces are completely cleaned daily and terminally
 - Educating ES importance of work and feedback
 - Checklists (bed rail, call box, bedside table, phone, chair, etc)
 - Assignments of responsibility to ensure complete cleaning of all potentially contaminated surfaces. Ensure all surfaces are disinfected and all equipment is assigned (e.g., assign all equipment and environmental surfaces in a patient room to either ES, Nursing, etc)
 - Invisible fluorescent marker (mark high-touch objects and if not cleaned-educate, monitor process improvement, and feedback); ATP; dye

Patient Area Cleaning/Disinfecting

Carling et al. ICHE 2008;29:1 and ICHE 2008;29:1035

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Quantitative Approach to Defining High-Touch Surfaces

Huslage, Rutala, Sickbert-Bennett, Weber, ICHE, in press, 2010

- 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.

Quantitative Approach to Defining High-Touch Surfaces

Huslage, Rutala, Sickbert-Bennett, Weber, ICHE, in press

- 1490 surface contacts were recorded
 - ICU accounted for 1109 (74%)
 - Floor accounted for 381 (26%)
- 3 surfaces (bed rail, bed surface, supply cart) in the ICU setting that were considered high touch (> 3 contacts per interaction) and accounted for 40% of the touches
- 4 surfaces (bed rails, overbed tables, IV pumps, bed surface) in the floor setting were considered high touch (>1 contact per interaction) and accounted for 49% of the touches
- Highest contact item in both settings was the bed rails and bed surfaces

Quantitative Approach to Defining High-Touch Surfaces

Huslage, Rutala, Sickbert-Bennett, Weber, ICHE, in press

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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- Controversies
 - Laryngoscopes
 - Surface disinfection
 - Contact time \geq 1 minute

Surface Disinfection

- Exposure Time
 - CMS surveyors (CA) have been paying closer attention to cleaning the environment, including assurance that hospitals are following manufacturer's directions for disinfectant contact time
 - Hospital cited for using a shorter contact time than manufacturer's directions and appealed based upon published peer-reviewed literature supporting shorter exposure times
 - Appeal denied

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"

Surface Disinfection

- Exposure Time
 - Multiple scientific studies have demonstrated the efficacy of hospital disinfectants against pathogens causing HAIs with a contact time of 1 minute
 - HCFs can achieve a contact time of 10 minutes by reapplying the disinfectant 5-6 times to the surface as the typical dry time is 1.5-2 minutes
 - Equally important as contact time is the application of the disinfectant to the surface or equipment to ensure all contaminated surfaces are wiped
 - No data that demonstrate improved infection prevention by a 10 minute contact time versus a 1 minute contact time

Current Issues and Controversies Summary

- "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
- 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, 121°C 30 m)
- 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
 - Steris System 1
 - SHEA Prion Guideline, February 2010
 - New Approaches to Room Decontamination
 - Ultraviolet
 - Hydrogen peroxide vapor
- Controversies
 - Laryngoscopes
 - Surface disinfection
 - Contact time

Thank you

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- Rutala and Weber. Guideline for disinfection and sterilization of prion-contaminated medical instruments. 2010;31:107-117