



Hospital Mattresses as a Source of Healthcare Acquired Infections: Current Recommendations for Disinfection and Future Directions



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Conflict of Interest

- Dr. Hooker is the medical advisor to Trinity Guardion, the manufacturer of the Soteria® launderable mattress cover.



Why are we here?

People are dying of Hospital-Acquired Infections (HAIs)



ARNIE STONE

LOCATION: CONNECTICUT

AGE: 87

GENDER: F

LENGTH: 2 MONTHS

SOURCE: HOSPITAL ACQUIRED



JOSEPHINE

LOCATION: NEW YORK

AGE: 79

GENDER: F

LENGTH: THREE MONTHS

SOURCE: HOSPITAL ACQUIRED



THERESA M.

LOCATION: KANSAS

AGE: 57

GENDER: F

LENGTH: 18 MONTHS

SOURCE: HOSPITAL ACQUIRED



JUDY DEXTER

LOCATION: MARYLAND

AGE: 70

GENDER: F

LENGTH: 6 MONTHS

SOURCE: HOSPITAL ACQUIRED



JOSEPH V. TARDIBUONO

LOCATION: NEW YORK

AGE: 51

GENDER: M

LENGTH: ONE MONTH

SOURCE: HOSPITAL ACQUIRED



JOAN

LOCATION: GEORGIA

AGE: 91

GENDER: F

LENGTH:

SOURCE: HOSPITAL ACQUIRED



REGINA MULLIGAN

LOCATION: NEW YORK

AGE: N/A

GENDER: F

LENGTH:

SOURCE: HOSPITAL ACQUIRED



Clostridium difficile

- Doubling of Cases between 2001 and 2010¹
- Estimated 600,000 CDI cases in 2014²
- 29,000 dead
- Cost of Hospital onset \$34,000 in additional medical cost per case³
- Total CDI-attributable cost \$6.3 billion
- Total CDI-related cost \$12.4 billion³

1. Reveles 2014; 2. Desia (2016); 3. Zhang (2016)



Causes of CDIs

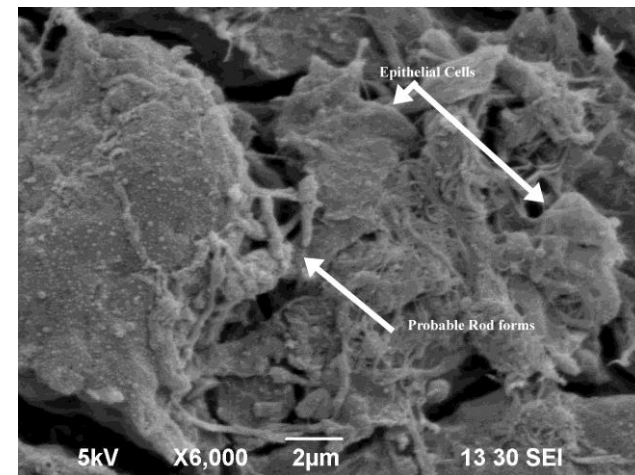
- Antibiotics overuse
- Proton-Pump Inhibitors
- Increased occupancy rate
- Poor Handwashing compliance
- **MATTRESSES**



“Cleaned” Beds Are Not Clean

Studies showing that beds are still contaminated after terminal cleaning

- Andrade (2000)
- Bayat (2003)
- Blythe (1998)
- Boyce (2017)
- Byers (1998)
- Carling (2008)
- Corbella (1998)
- Creamer (2014)
- Dancer (2006)
- Dancer (2008)
- Dancer (2009)
- Das (2003)
- Hooker (2012)
- Hu (2015)
- Fernando (2013)
- French (2004)
- Fujita (1981)
- Griffith (2000)
- Hardy (2006)
- Manian (2011)
- Moore (1991)
- Mundim (2003)
- Pantel (2016)
- Sexton (2006)
- Siegel (2010)
- Tsay (2017)
- van der Mee-Marquet (2006)
- Viani (2016)
- Vickery (2012)



SEM IMAGE OF MATTRESS SHOWING BACTERIA IN FAILED AREAS OF MATTRESS



Damaged Mattresses Are Common

- Bradbury (2014)
- Heudorf (2009)
- Marks (2016)
- Moore (1991)
- Ndawula (1991)
- O'Donoghue (1992)
- Peto (1996)
- Rahman (1993)
- Russell (2001)
- Sherburn (2004)
- Sherertz (1985)
- US Food and Drug Administration (2014)

Infections and Deaths Linked to Mattresses

- Aygün (2002)
- Bayat (2003)
- Bousquet (2017)
- Freeman (1994)
- Hammami (1991)
- Lilly (1982)
- Moore (1991)
- Ndawula (1991)
- O'Donoghue (1992)
- Oie (2005)
- Pantel (2016)
- Rahman (1993)
- Van den Broek (2006)
- Viani (2016)





Brief Report

Outbreak of CTX-M-15-producing *Enterobacter cloacae* associated with therapeutic beds and syphons in an intensive care unit

A. Bousquet PharmD ^{a,*}, N. van der Mee-Marquet PharmD, PhD ^b, C. Dubost MD ^c,
C. Bigaillon MD ^a, S. Larréché MD ^a, S. Bugier MD ^a, C. Surcouf PharmD ^a, S. Mérat MD ^c,
H. Blanchard MD ^d, A. Mérens MD ^{a,e}

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^c Service d'anesthésie et de réanimation, HIA Régis, Saint Mandé, France

^d Centre de coordination de la lutte contre les infections associées aux soins Paris-Nord, Paris, France

^e Equipe opérationnelle d'hygiène, HIA Régis, Saint Mandé, France

MATTRESS DISINFECTION: A PUBLIC HEALTH CONCERN

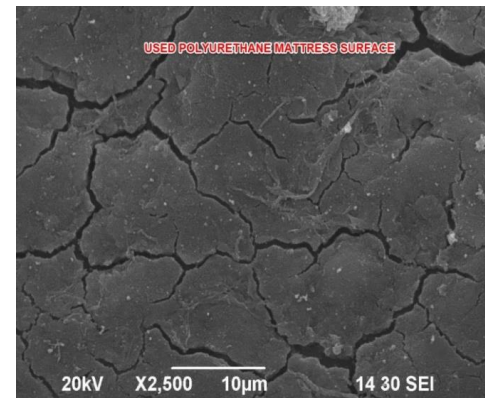
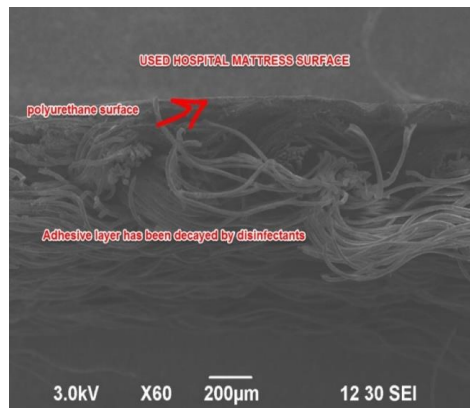
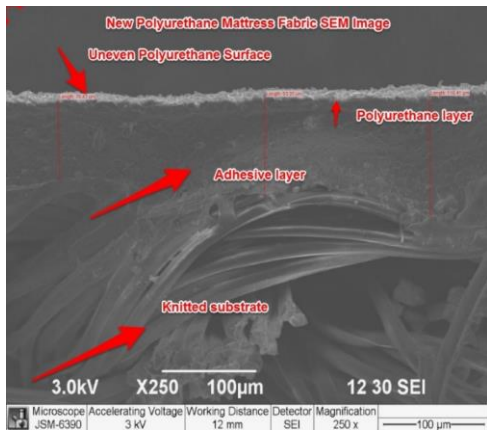


- Mattresses are difficult to disinfect
- Mattresses are a significant source of HAI's
- Mattress covers are failing at an alarming rate due to harsher chemicals
- Action needed

THERAPY MATTRESSES CONTRIBUTED TO OUTBREAK- 4 DIED



DEGRADATION OF FABRIC



Side – view SEM of polyurethane out coated fabric-woven nylon or polyester backing

Used polyurethane Out Fabric Top polyurethane layer abraded by disinfectant. Adhesive layer disintegrated by disinfectant

Used polyurethane out fabric layer-plasticizer dried out by disinfectants. Not seen by the naked eye



HOW BAD COULD THE PROBLEM BE?

- 2016 Study presented at APIC (Uncovering the Rate of Damaged Mattress Cover) (Marks, Abboud)
- 711 mattress study
- FINDINGS:
- Mattresses - Damage rates 35% (2014 U Mass Study found 26%)
- Stretchers 46%

Most Common Damages

- Cuts and tears 34%
- Cracked surfaces 34%
- Punctures 15%
- Ripped seam 9%
- Abrasions 2%
- Fluid emersion 4%





Why Inspect Mattresses?



MATTRESS DOES NOT DRY AFTER TERMINAL CLEANING

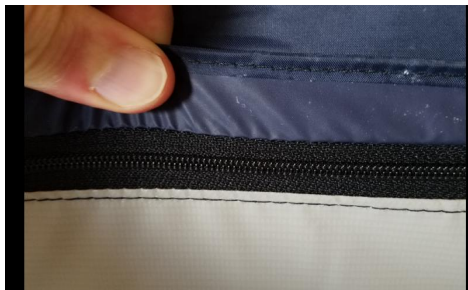


STAINED MATTRESSES NEED TO BE REPLACED
SOME DISINFECTANTS BIND SOIL TO SURFACE

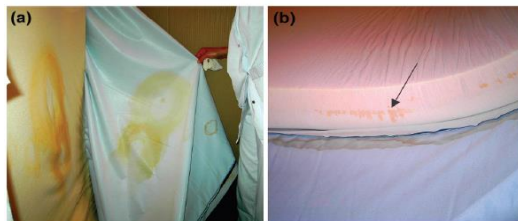
What lies beneath



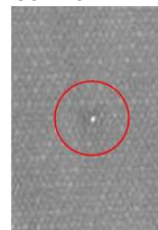
STAINED MATTRESS CORE AND/OR COVER
INTERIOR MUST BE REMOVED



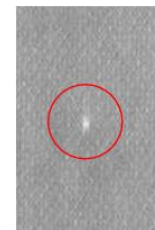
SEWN ZIPPER SEAMS CAN FAIL DUE TO EXPOSURE TO DISINFECTANT



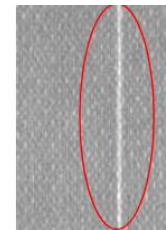
Photographs of a 6-month-old therapeutic bed. (a) Stained mattress foam where the patient was situated. (b) Stained mattress foam where the seams of the cover were situated.



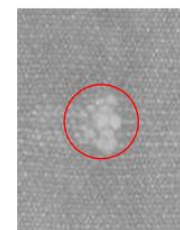
Needle stick



Gouged hole



Scratched hole



Puncture hole



PROBLEMS YOU CAN SEE





CHALLENGES WITH MATTRESS DESIGN





Mattresses Have Changed



1970's
Mattress
Covers were
Vinyl
Non-porous



Bed sores
and skin
breakdown



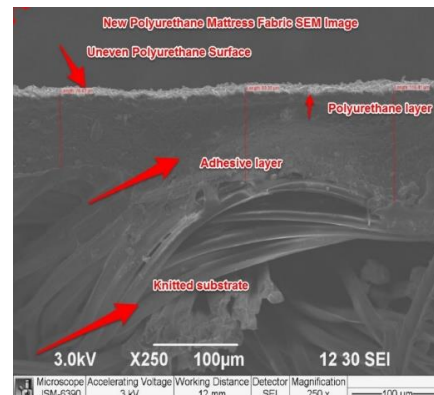
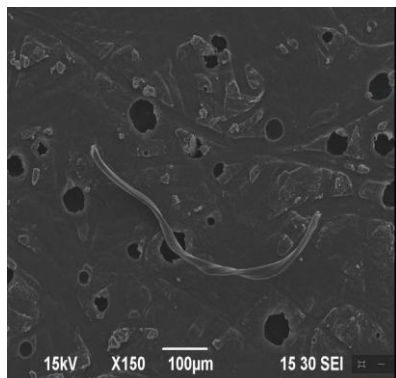
2000's
Microclimate
High MVT
porous
surface



HOSPITAL MATTRESS FABRICS

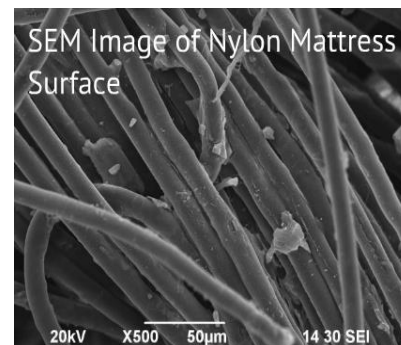
The Challenges You Don't See

New polyurethane out coated fabric surface SEM



SEM Side View of PU Fabric

Knit Nylon/Polyester



Breathable



Why are we failing?

- Current processes fail to reduce bacterial counts
- Current processes fail are using chemicals that are not intended for use of soft surfaces (mattresses are soft surfaces)



Lots of C. diff in stool

- There are 3.8 million ($\log_{10} 6.58$) cfu of C. diff. in 1 gram of stool^{1,2}
- Patients with diarrhea have 200 gm per stool event and 3+ stools a day.



Performance of Quaternary Ammonia in the real world:

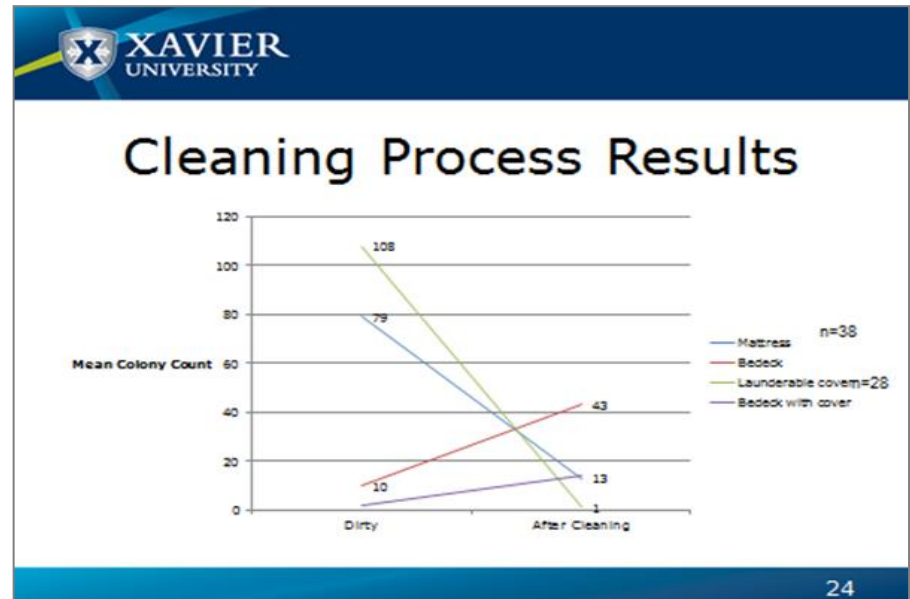
- Only a Log 1 reduction after terminal cleaning (bed, countertop, monitor) with Quats.¹
 - 60% of surfaces still contaminated after terminal cleaning
- Most surfaces still contaminated after daily cleaning with Quats.²
- Hooker (2012) showed less than a log 1 reduction when mattresses cleaned with Quats

1-Manian 2013; 2-Sigler 2013; Hooker 2012



RESULTS OF OFF LABEL USE OF DISINFECTANT

Less than 1 log reduction
in real world study using
disinfectants



Study limited to aerobic bacteria



Performance of Bleach Real World

- Anderson (2017) showed no reduction in *C. diff* counts with the use of bleach or bleach plus UV. No reduction in all infections with bleach or bleach plus UV.
- Catalano (1999) showed that the use of bleach on mattresses eliminated *Acinetobacter baumannii*.
- Rutala (2012) showed in a lab study that 5000ppm of bleach had a log 3-4 reduction in *C. diff*.



Performance of hydrogen peroxide/peracetic acid in the real world

- Doan (2012)- Log 2-3 reduction in *C. diff.* in hospitals rooms that were purposely contaminated with *C. diff.*
- Alfa (2015) failed to show a reduction in *C. diff* HAIs under normal cleaning conditions
- Looking at lab based studies
 - Deshpande (2014)- hard plates log 3-5 reduction *C. diff*
 - log 4-6 reduction for MRSA and VRE
 - Rutala (2012)- Log 5 reduction in *C. diff.*



Performance of UV light in the real world

- Anderson (2017) (BETR disinfection trial). No decrease in *C. diff* infections by adding UV light. NO reduction in *C. diff* counts (less than log 1). They did get a log 1-3 reduction in MRSA and VRE. But no decreased infections of MRSA, only VRE
- Anderson (2013) only a log 1 reduction in *C. diff*.
- Havill (2012) showed a log 1-3 reduction in *C. diff*.
- Korchinski (2016) showed only a log 1 reduction in bacteria in a pragmatic trial. Much worse when EVS not being observed.
- Randive (2017) showed only a log 1 reduction in *C. diff*.



Performance of Hydrogen Peroxide Vapor in the real world

- Boyce (2008) showed a 50% decrease in HAIs with *C. diff.* by using HPV
- Havill (2012) found HP vapor showed a log 6 reduction in *C. diff* on hard non-porous surfaces
- Ali (2016) showed a log 5 reduction in *C. diff.* on hard non-porous surfaces



“Normal” Cleaning

- One step process using a quaternary ammonia cleaner.¹
- Typically do not pre-clean or rinse
- Total time to clean room is 20 minutes and only 3 minutes on the bed
- This will not kill C. diff.

1. Hooker 2011

Current Practices in USA (AHE survey)

- 41% Respondents had blood or bodily fluids come through a mattress
 - More than half had 2-5 experiences per year
- 63% of respondents are not inspecting mattresses
- 40% Use quats, 40% use peroxyacetic acid
- 50% were not aware of FDA guidance to inspect mattresses
- 90% don't rinse
- 80% use one step process
- 70% are having problems with damaged mattress surfaces
- 2.5% of respondents take an hour to clean a room



Must assume every bed infected with CDI

- Many patients are asymptomatic yet expose next patient to *C. diff.* because it is on the bed.¹
- If previous patient did have *C. diff.*, then the next patient has 2-3 times greater risk of getting *C. diff.*¹⁻⁶

1. Blixt (2017); 2. Datta (2011); 3. Hamel (2010)
4. Scheidt (1983); 5. Sexton (2006); 6. Shaughnessy (2011)



FDA

- “Non-critical devices also include devices that do not directly contact the patient but may become contaminated with microorganisms and organic soil during patient care...FDA recommends thorough cleaning, then intermediate or low level disinfection.”
- “Semi-critical devices are devices that contact intact mucous membranes or non-intact skin.these devices should be reprocessed to be free from all microorganisms.”



FDA ACKNOWLEDGEMENT OF MATTRESS PROBLEM

700 REPORTED INCIDENTS OF MATTRESS FAILURE

ADVISORY ELEMENTS

- DEVELOP INSPECTION PLAN
- INSPECT
- REMOVE AND REPLACE
- MAINTAIN



1 FAILED MATTRESS COULD EXPOSE 50 PATIENTS A YEAR TO ???

RELEASED 11/17

Keeping Patients Safe from Contaminated Mattresses

Hospital bed mattress covers provide outer protection to mattresses used on hospital beds. Worn or damaged covers can let fluids inside the mattress, posing a risk of infection to patients who may come into contact with a contaminated mattress. Follow the tips below to help keep covers in good condition and to identify and handle covers that are worn or damaged.

Develop an Inspection Plan

- Create an inspection plan for all hospital bed mattresses and mattress covers in your facility.
- Check the manufacturer's guidelines for an expected life time on the hospital bed mattress and mattress covers and follow any additional recommendations listed there.
- Contact the mattress cover manufacturer for any additional questions not covered here.

Inspect

- Regularly check each hospital bed mattress cover for any visible signs of damage or wear such as cuts, tears, cracks, pinholes, snags, or stains.
- Routinely remove the hospital bed mattress cover and check its inside surface. Once the mattress cover is removed, inspect the mattress for wet spots, staining, or signs of damage or wear. Check all sides and the bottom of the mattress.
- Be aware that it may be difficult to identify damaged or soiled mattresses without removing the mattress covers first. Mattress covers tend to be dark in color, making it hard to see what lies underneath.

Remove and Replace

- Remove any damaged, worn, or visibly stained hospital bed mattress according to the healthcare facility's procedures and manufacturer's instructions.
- Immediately replace any hospital bed mattress cover with visible signs of stains, damage or wear to reduce the risk of infection to patients.

Maintain

- Clean and disinfect undamaged hospital bed mattress covers according to the manufacturer's guidelines.
- DO NOT stick needles into a hospital bed mattress through the mattress cover.

FDA U.S. FOOD & DRUG ADMINISTRATION



ECRI



The ECRI Institute has unveiled its [Top 10 Health Technology Hazards for 2018](#),

ECRI is a nonprofit organization dedicated to bringing the discipline of applied scientific research to discover which medical procedures, devices, drugs, and processes are best, all to enable 5000 member Healthcare organizations to improve patient care.

2018



Cleaning a hospital bed. Credit: YouTube

3. Bed and stretcher mattress contamination

This can occur even after cleaning, creating the risk of exposure to body fluids or microbiological contaminants. Examples of reported incidents included patients on an apparently clean bed or stretcher when blood from a previous patient oozed out of the support surface onto the patient. Regular inspections of mattresses and covers are suggested to identify damage or contamination.

2019

The List for 2019

1. Hackers Can Exploit Remote Access to Systems, Disrupting Healthcare Operations
2. "Clean" Mattresses Can Ooze Body Fluids onto Patients
3. Retained Sponges Persist as a Surgical Complication Despite Manual Counts

FDA COMPLIANT CLEAN /DISINFECTION IFU

FIVE STEP CLEANING/DISINFECTION PROCESS - MEETS NEW FDA RE-PROCESSING GUIDELINES

Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling
Guidance for Industry and Food and Drug Administration Staff

Document issued on: March 17, 2015

Appendix E of this guidance was updated on June 9, 2017.

This document supersedes: "Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance" issued April 1996.

The draft of this document was issued on May 2, 2011.

Cleaning and Disinfecting

Cleaning and disinfection is a 3-step process as outlined below.

For effective cleaning and disinfection, **all** 3 steps must be performed.

Step 1: **Spot clean** with an approved cleaner/disinfectant when the bed or mattress becomes soiled. This includes the prompt, initial cleaning steps to prevent the drying of and removal of soil and contaminants.

Step 2: **Clean** the entire bed and mattress.

Step 3: **Disinfect** the entire bed and mattress to kill microorganisms.

Table 1 below summarizes the approved cleaners/disinfectants for use with the associated contact time for disinfection.

Table 1: Approved Cleaners/Disinfectants

Cleaner/Disinfectant	Recommended for Routine Cleaning and Disinfection	Recommended for Disinfection against Clostridium Difficile (C.Diff)	Maintain Wetness (Disinfection Contact Time)
Wex-Cide™ Germicidal Detergent ready-to-use	Yes	No	10 minutes
Virex® II 256	Yes	No	10 minutes
OxyCide® Daily Disinfectant Cleaner	Yes	Yes	3 minutes
Clorox HealthCare® Bleach Germicidal Cleaner ready-to-use	No*	Yes	5 minutes
Clorox HealthCare® Bleach Germicidal Wipes	No*	Yes	3 minutes

*Bleach is not recommended as the primary cleaner/disinfectant.

Remove any disinfectant residue prior to and after the use of bleach with a new microfiber cloth soaked in tap water.

When you perform the detailed cleaning steps, please note the following:

- A microfiber cloth or the Clorox HealthCare® Bleach Wipe is recommended as the wiping cloth.
- Always replace the wiping cloth when visibly soiled.
- Always replace the wiping cloth between steps (spot clean, clean, and disinfect).
- Always use Personal Protective Equipment (PPE).
- Adjust the bed position, siderails, headboard, and footboard as needed for ease of cleaning and disinfection.
- For rental beds, Hill-Rom Service personnel will follow all applicable infection control policies and procedures including Infection Control Procedures (BS00936) and Disinfectants for Infection Control and their Application (BS00937).

Hill-Rom Centrella Bed Manual

CHALLENGES- THROUGHPUT/TRAINING. END OF LIFE OF THIS MATTRESS = 2 YRS: COST: > \$12,000; FAILURE TO FOLLOW IFU VOIDS WARRANTY



Steps per IFU

1. Spot clean with cleaner /disinfectant
2. Clean - top, bottom and sides
3. Disinfect - must re-wet to meet dwell time
4. If bleach – then
5. Rinse must be added before and after use

Clean and Disinfect Entire Bed= 55 Minutes for 6 Steps

Cleaning and Disinfecting

Prepare the Bed for Cleaning and Disinfecting

- Fully extend the foot section.
- Unplug the bed.

STEP 1: Spot Clean

- Remove visible soil from the bed and the mattress using a wiping cloth soaked with an approved cleaner/disinfectant (see "Table 1: Approved Cleaners/Disinfectants" on page 76).
 - Give special attention to seams and other areas where soil may accumulate.
 - A soft bristle brush may be used to loosen hardened soil.
 - Use as many wiping cloths as needed to remove the soil.

NOTE:

If the Centrella™ MAX mattress cover is stained, remove the cover, launder it, and then continue to Step 2—Clean the Bed. See "Laundry Guidelines" on page 79.

STEP 2: Clean the Bed

- With a new wiping cloth soaked in an approved cleaner/disinfectant, use firm pressure to wipe all surfaces of the bed and mattress. Use a new wiping cloth as often as necessary. Make sure the following items are cleaned:
 - Siderails
 - Headboard and footboard
 - Areas between the footboard and mattress, headboard and mattress, and siderails and mattress
 - Upper frame
 - Base frame
 - Power cord
 - Patient pendant (handheld remote) and pendant cord
 - Accessories (See "Accessories" on page 68.)
 - Mattress - top and bottom
 - To raise the mattress to clean underneath, find the mattress retention knobs on the underside of the mattress, and slide the knobs to the center of bed.
 - Clean the "bladder fold" area indicated in the picture below (Centrella™ MAX mattress).



Centrella™ Bed User Manual (193587 REV 2)



1/9/17 RELEASE: EC.02.04.01 EP 5

The [ORGANIZATION]'s activities and frequencies for inspecting, testing, and maintaining the following items must be in accordance with manufacturers' recommendations:

- Equipment subject to federal or state law or Medicare Conditions of Participation in which inspecting, testing, and maintaining must be in accordance with the manufacturers' recommendations, or otherwise establishes more stringent maintenance requirements

INSTRUCTIONS FOR USE MUST BE FOLLOWED PER CMS



The Bleach Disconnect

- Bed manufacturers recommend 1000 ppm
- CDC recommends 5000 ppm to kill C. diff.



Concentrations of Bleach in different products

Disinfectant	Active Ingredient	Contact Time	Hard surface cleaner
Fuzion Cleaner Disinfectant Spray	Sodium Hypochlorite 0.39% (3900 ppm)	2 minutes	"to clean and disinfect hard, nonporous non-food contact surfaces"
Clorox Bleach Germicidal Wipes	Sodium Hypochlorite 0.55% (5500 ppm)	3 minutes	"to clean and disinfect and deodorize hard, nonporous surfaces"

BOTH PRODUCTS REQUIRE PRECLEANING



Clorox Surface Compatibility

Surface	Examples	 Clorox Healthcare® Bleach Germicidal Wipes	 Dispatch® Hospital Cleaner Disinfectant Towels with Bleach	 Clorox Healthcare® Hydrogen Peroxide Cleaner Disinfectant Wipes	 Clorox Healthcare® Multi-Surface Quat Alcohol Cleaner Disinfectant Wipes
Polyurethane (PU)	Upholstery, lights, tubing, mattress covers	★	★	★	★
Polyvinylchloride (PVC)	Furniture, mattress covers, tubing, floors	★★★	★★★	★★★	★★★

3-star system	
★★★	No visible surface damage or effect on the material is likely to occur when used according to label directions. No change to the integrity of the material is expected.
★★	Some visible surface damage such as tarnishing or clouding may be seen with long-term exposure. Little to no effect on material integrity is expected. Periodic wiping of surfaces with a clean damp cloth to remove residue can help to minimize damage.
★	Visible damage to the surface is likely to occur with long-term exposure and some effect on material integrity is possible. Surfaces should be wiped with a clean damp cloth immediately after the contact time has been reached to reduce the risk of



Laundryable Mattress Cover



- Laundryable, reusable cover made of knit polyester fabric with a polyurethane coating on the patient side
- Prevents penetration of fluids and microorganisms
- Fits securely over items such as healthcare mattresses, chairs, pillows, and cushions



Cover works in tandem with bed so that the bed can fully function through all positions.



Soteria bed barrier on Stryker Secure II Bed



Attaches around mattress stops



90 second installation

HOW DOES THE SOTERIA BED BARRIER WORK?

Soteria is a registered trademark of Trinity Guardian.- Patent Protected



Fitted Sheets work with bed barrier

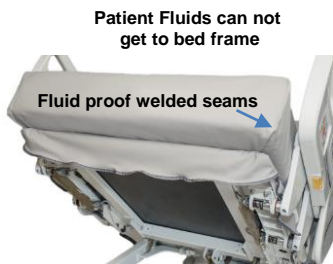
Bed barrier encapsulates mattress and bed deck



Barrier does not interfere with bed operation-features: guard rails, CPU release, mattress stops turn assist...



IV poles accessible through barrier



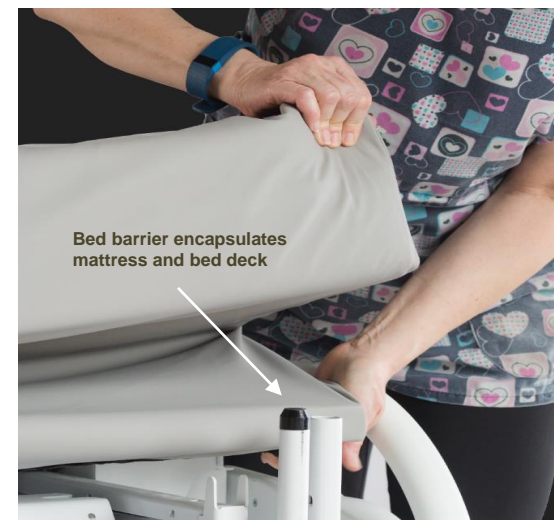
Patient Fluids can not get to bed frame

Fluid proof welded seams

Photo showing head end of bed with bed barrier



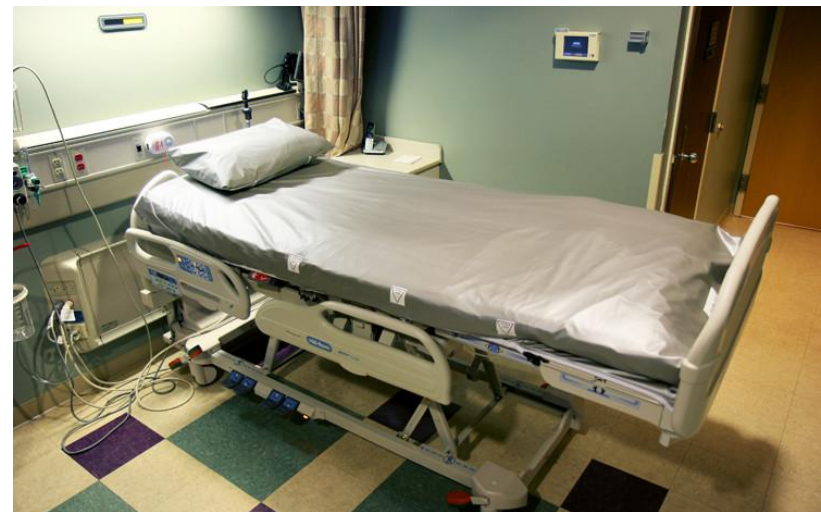
Hooks attach to the frame



Bed barrier encapsulates mattress and bed deck



XAVIER
UNIVERSITY



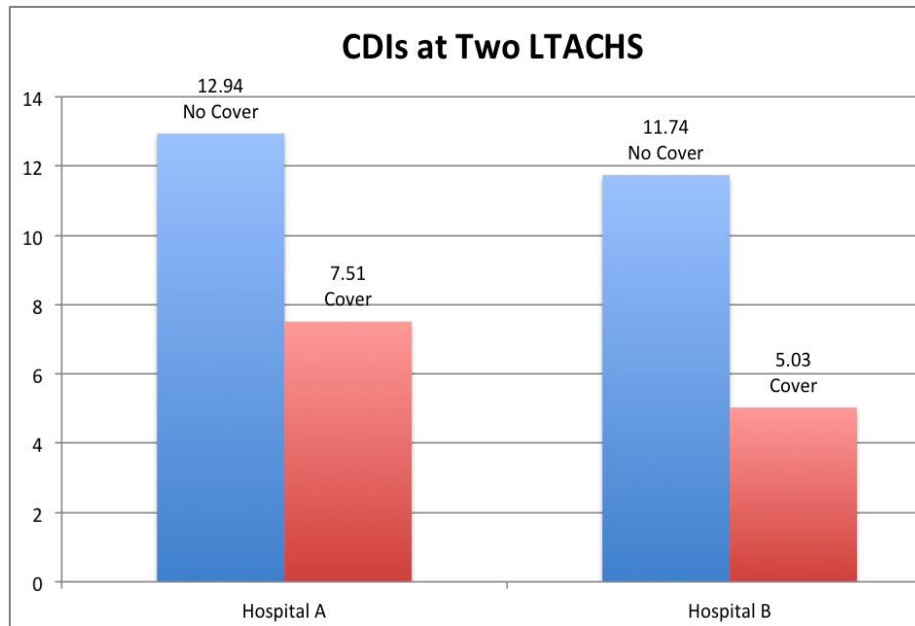
<https://www.youtube.com/watch?v=bntp3qMeHUK>



HOSPITAL ACQUIRED C.diff REDUCED BY DISINFECTION INTERVENTION

Hospital A cleaned rooms with quat disinfectant and CDI rooms cleaned with quat disinfectant then bleach

Hospital B cleaned rooms with phenol disinfectant and CDI rooms cleaned with bleach



Xavier University Published
Research Results - AJIC December
2015



How it works

- Launderable cover is removed after every patient and sent out of the hospital to be laundered.
- Use bleach, detergent, hot water, multiple rinses, then dry with heat.
- Inspect cover for damage and repair immediately prior to use.
- The bed works normally with the cover in place



Summary

- Hospital Mattresses are not being cleaned
- Hospital Mattresses are making people sick and killing them
- Many Mattresses have failed but are still being used
- Current practices for cleaning mattresses is unacceptable
- All mattresses should be considered semi-critical and appropriately disinfected every time!
- Launderable mattress cover is a potential solution



XAVIER
UNIVERSITY