



The Enemy Within: How Mattresses Act as a Hidden 5th Column Undermining Patient Safety in Health Care Facilities Toolkit

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I. Webinar Presentation

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The Enemy Within:

How Mattresses Act as a Hidden Fifth Column Undermining Patient Safety in Healthcare Facilities

Presented by Trinity Guardion
October 2024

TRINITY  GUARDION

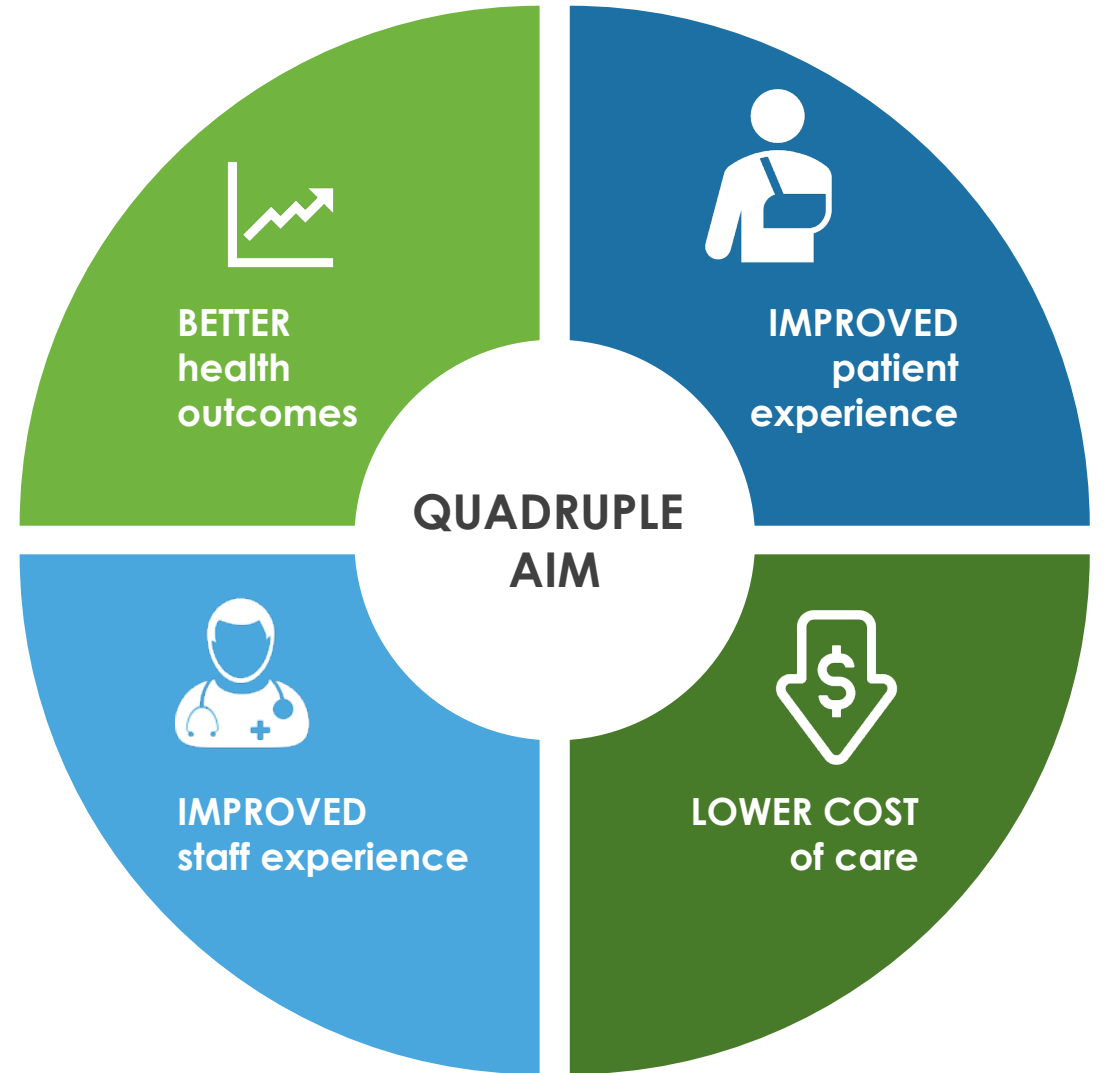
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Fifth Column:

A group of people who **undermine a larger group or nation from within**, usually in favor of an enemy group or another nation. The activities of a fifth column can be overt or clandestine.

Clandestine fifth column activities can involve acts of sabotage, disinformation, espionage, or terrorism executed within defense lines by secret sympathizers with an external force.



The Fifth Column

The average acute care bed supports 80 patients/year.

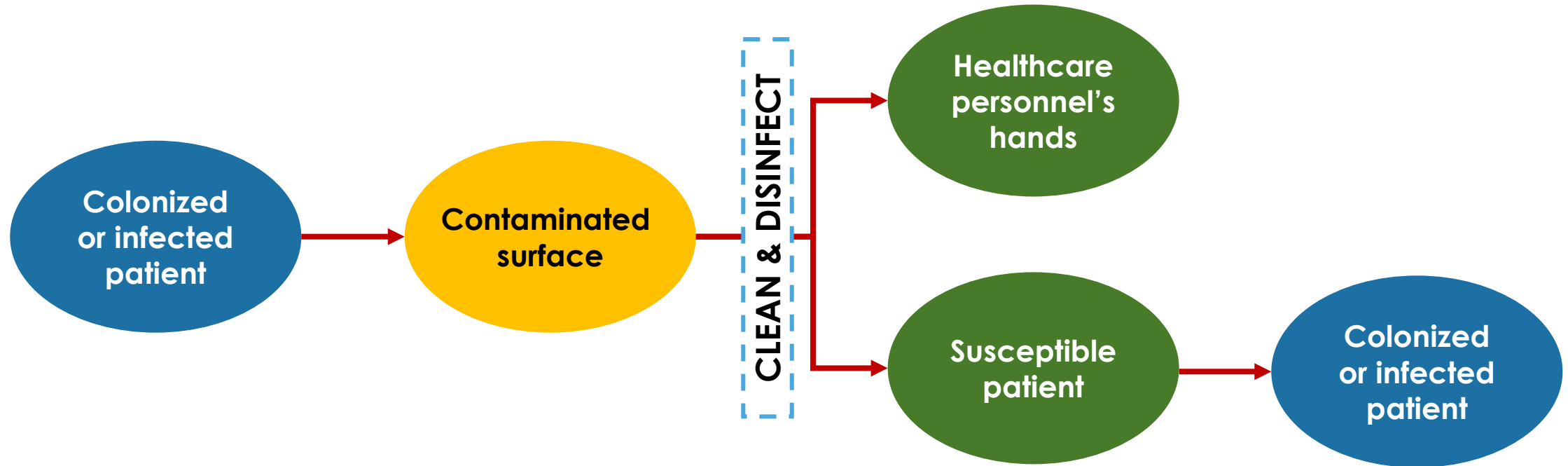
Each acute care bed moves approximately three times/month to different rooms and units.

Some 59% of mattresses red-tagged in Medline-sponsored poster.

Some 52% of IPs reported mattresses leaking previous patients' bodily fluids.

CDC 2020: Reduce Risk From Surfaces

It's not just about hand hygiene anymore



Research shows that the environment is another significant contributor to the spread of infection.

**Contaminated surfaces can serve as direct source for transmission to a second patient or as an indirect source via contaminated hands of healthcare personnel.*

It's complicated; lots of silos impacting each other.

EPA	FDA	Bed & Mattress Manufacturers	Hospitals	Other
<ul style="list-style-type: none">• Regulates disinfectants• No authority over medical devices• Disinfectant mfg cannot recommend disinfectants for medical devices• Surface disinfectant compatibility ≠ efficacy	<ul style="list-style-type: none">• Regulates medical devices including requirements for reprocessing• Device mfg can use disinfectants when validated in testing• Determined Device Intended Use	<ul style="list-style-type: none">• Own the MIFU and the choice of disinfectant(s) and validation for disinfection and reprocessing	<ul style="list-style-type: none">• CMS requires hospitals to follow Manufacturer's Instructions for Use --MIFU-- (including reprocessing) as a COP (Conditions of Participation)	<p>Consensus Documents and Evidence-based Practices can be Additive TO MIFU</p> <p>E.g., asymptomatic <i>c.diff</i> patients have resulted in more common daily use of sporicidal disinfectants*</p>

* Challenge: Consensus /evidence- based practices may not be consistent with device characteristics and may damage devices

Learning Objectives

The Size and Scope of the Hospital Bed/Mattress Problem.

Why We Should Care: The Patient Safety Issue.

Why the Beds Aren't Clean.

What Compliance Looks Like: MIFUs.

What Compliance Looks Like: Another Solution.

Today's Presenters



EDMOND HOOKER, MD, DrPH, Clinical Advisor

Professor, Health Services Administration, Xavier University (Cincinnati); program director, Xavier University MHA; practicing ER physician; Medical Director, Trinity Guardian.



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Most recently, Professor of Medicine in Internal Medicine and Infectious Diseases at UK Healthcare. Past president AMA. Board member, Trinity Guardian.



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BRUCE RIPPE

CEO, Trinity Guardian; past board member of Margaret Mary Health; former President, Romweber

The Size and Scope of the Bed Problem



The Down and Dirty on Beds

The Down & Dirty on Beds

Three real-world examples of mattresses found in use



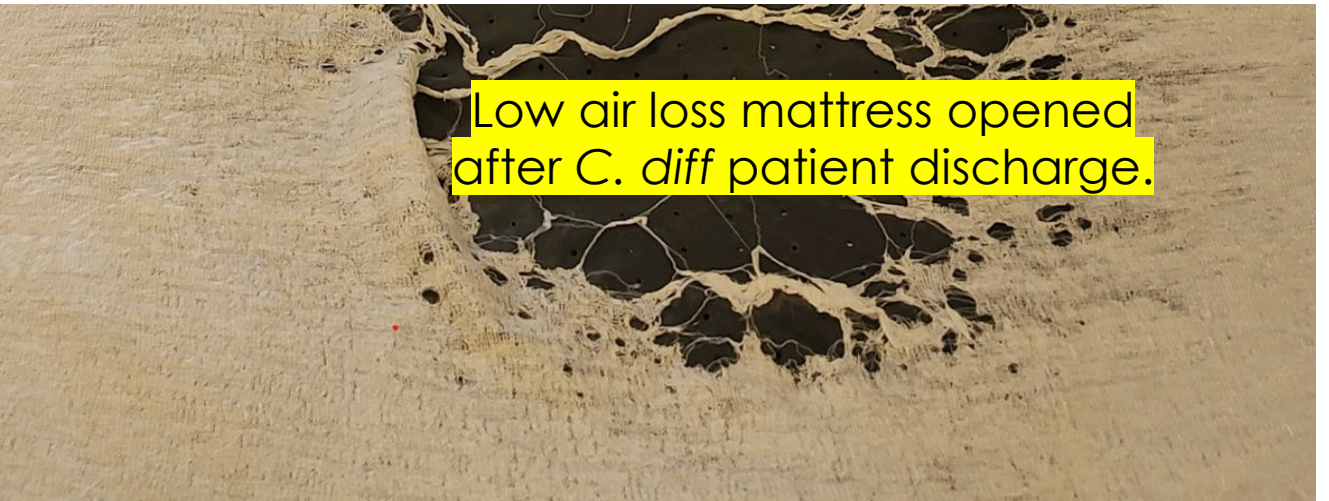
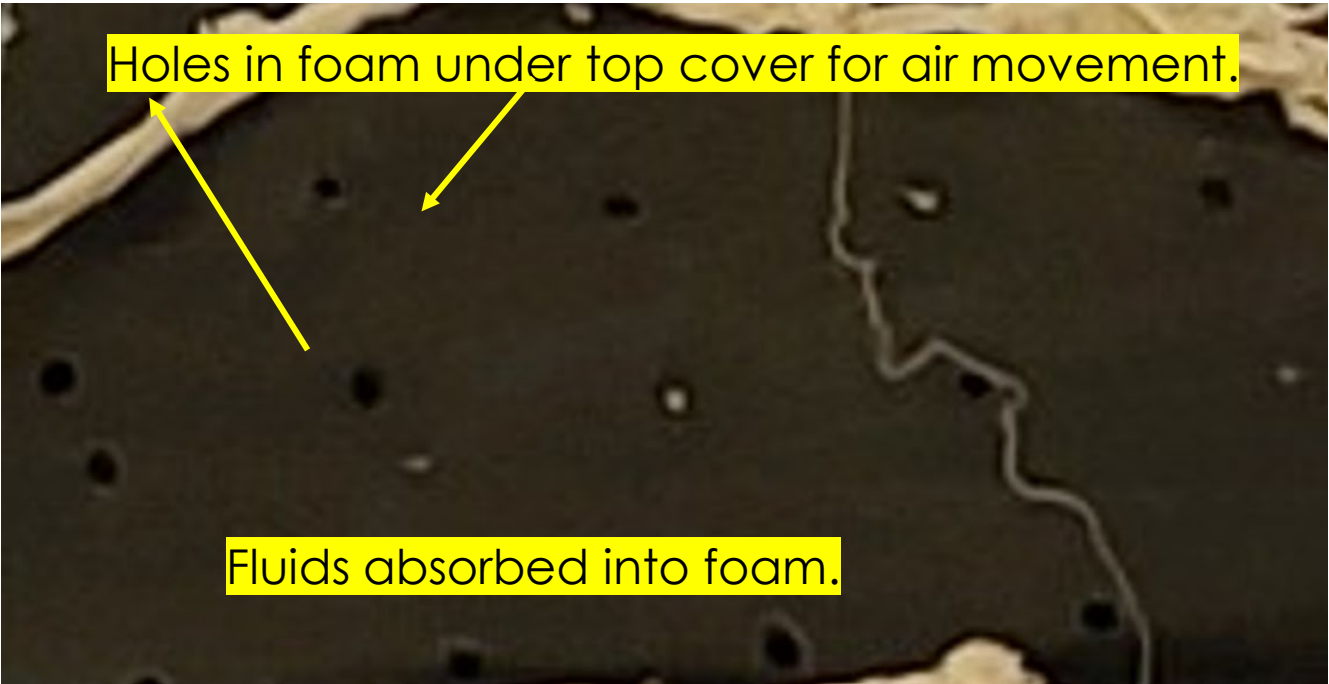
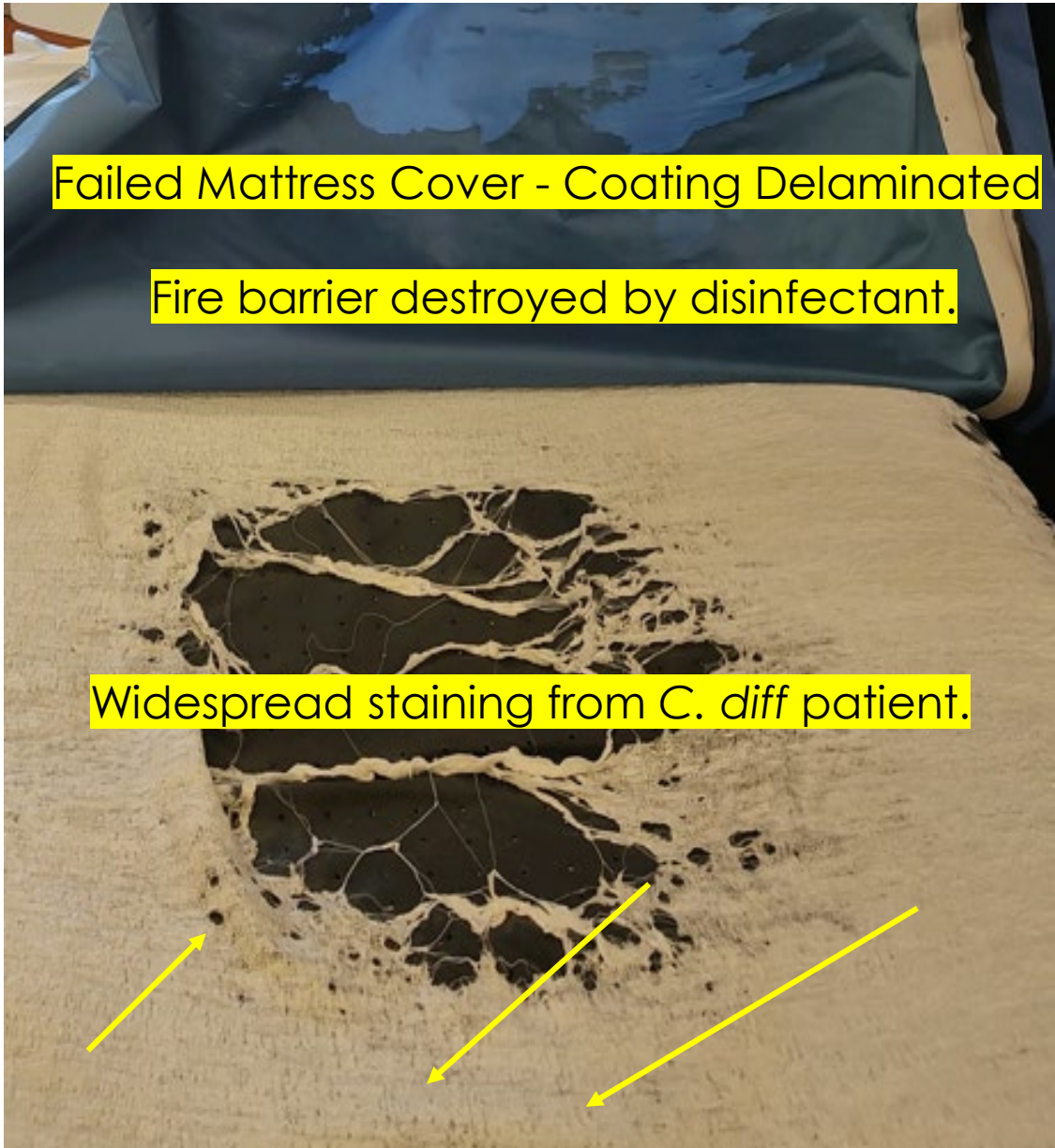
Soiling **EMBEDDED**
in fabric.



Fluid emersion **INSIDE** mattress,
staining on bottom of top
cover, fire barrier, & foam.



Inside of top mattress cover
is **DISINTEGRATED BY**
DISINFECTANT use as well
as fire barrier sock
protecting the patient.



It's Not a One-off Problem!

Medline evaluated 85 facilities with 5,121 support surfaces where patients lay.¹

Checked for:

- Holes or tears
- Poor response (rebound or exuding liquid) when compressed.
- Stains
- Internal damages
- Thinning areas
- Torn zippers

Red tags recommended mattress be replaced immediately.

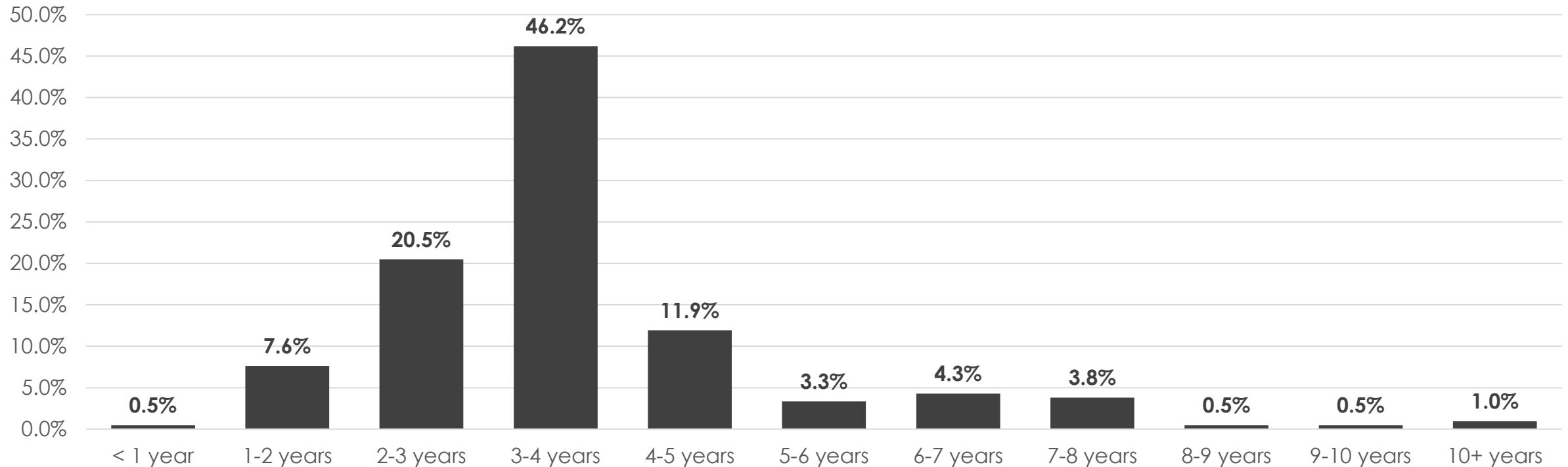
59% of surfaces had red tags

TAG COLOR	FREQUENCY	PERCENT
RED	3,023	59.03%
YELLOW	87	1.7%
GREEN	1,641	32.04%
INVALID*	370	7.23%

**Including both unidentified tags and missing values.*

2021 SHEA¹ 75% of Damaged Mattresses Were Less Than Four Years Old

STUDY OF FAILED MATTRESSES FROM DATE OF MANUFACTURE¹ (n=210)



- AHA depreciation table calls for asset life of 5 yrs on mattress and 12 yrs for bed.
- Failures at 2 years doubles per patient cost - no increase in reimbursement - wasting capital resources.

Multiple Validations Over Last Five Years

THIRD-PARTY VALIDATION



ECRIInstitute



"Clean" Mattresses Can Ooze
Body Fluids onto Patients



2019 Top 10
Health Technology Hazards
Executive Brief

A Report from Health Devices

REAL WORLD³

Washington State Nurses
Association alleges St. Joseph
Medical Center reusing mattresses
damaged by bodily fluids

The hospital is refuting claims from the Washington State Nursing Association that it didn't act quickly enough.



CLINICAL

Emory Peer-Reviewed Study

The role of the hospital bed on
hospital-onset *Clotridioides*
difficile infection: A retrospective
study with mediation analysis

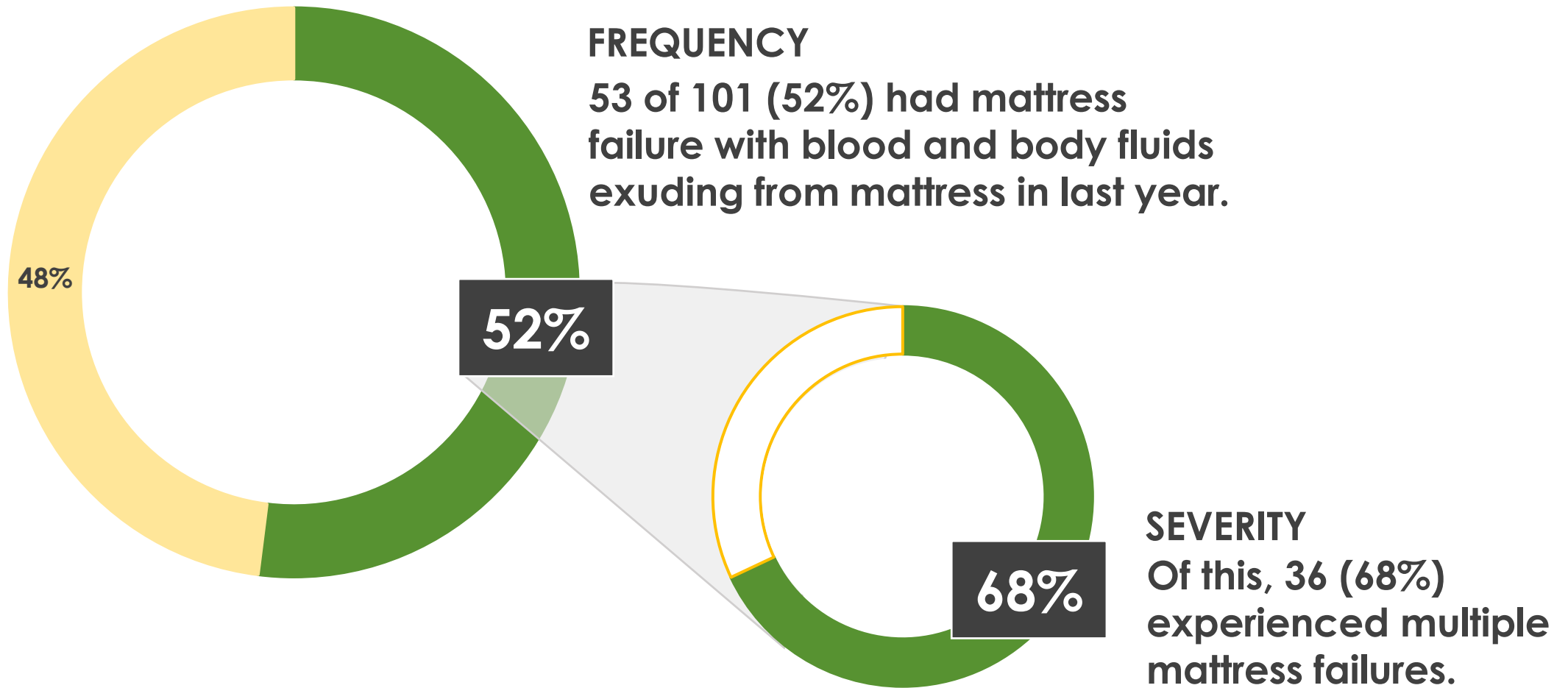
Lucy Witt; Jessica Howard-Anderson; Radhika
Prakash-Arani; Elizabeth Overton and Jesse
Jacob

*Infection Control &
Hospital Epidemiology* (2023) 1-5

<https://doi.org/10.1017/ice.2023.254>

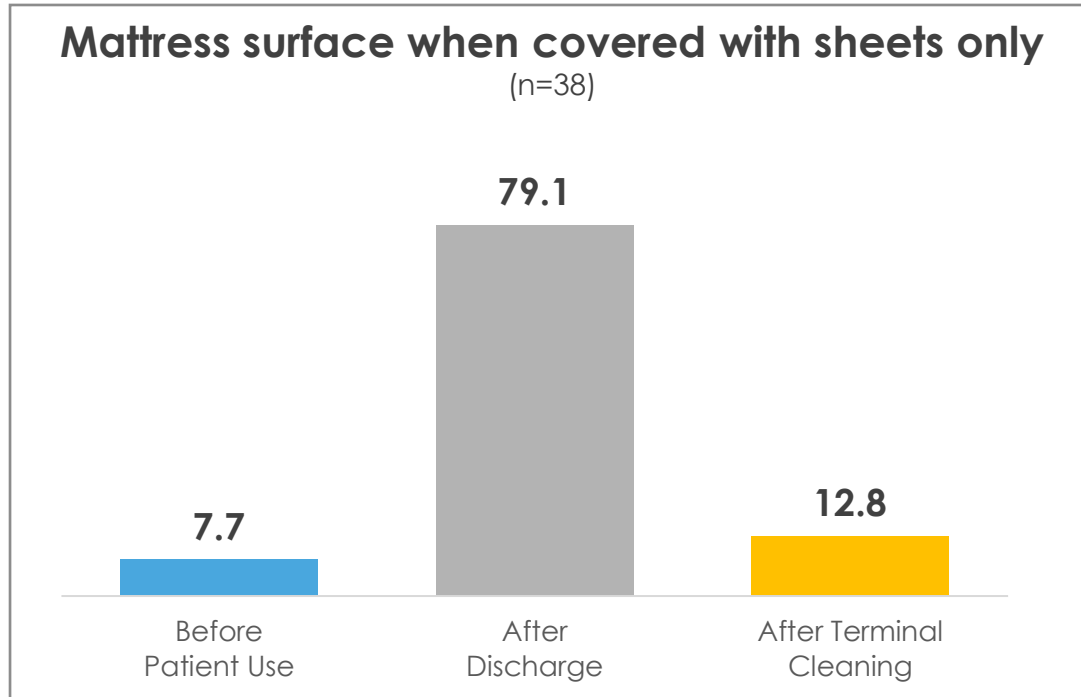
Even with all your efforts to do the right thing, mattresses still get contaminated and pose a risk to patients.

APIC 2019 Survey Identifies Widespread Mattress Failures (n=101)



Quats decrease bacteria but mattresses are still contaminated.

Cleaning Mattress with Quaternary Ammonium (Study limited to aerobic bacteria⁴)



- Reprocessing delivered ~1 log reduction (Only 90% microbial reduction vs 99.9999% requirement).
- Vegetative Bacteria on surfaces can quickly re-colonize to 42% of the pre-treatment level after the disinfection process within 6.5 hours.

AAMI TIR 2020

Non-critical devices that are soiled with blood or Other Potentially-Infectious Materials (OPIMs) and come in contact with the health care personnel or intended to have direct contact with the patient should be visibly clean and at a minimum, be intermediate-level disinfected.

FDA Classification for Disinfection (2015 Reprocessing Guidelines)

Based on Spaulding; Consistent with CDC

Soil	Disinfection Required	Objective	Required Impact
Contact Mucous Membranes or Non-Intact Skin	High-Level Disinfection	Free of all micro-organisms and only small # spores remain.	99.9999% vegetative bacteria and mycobacteria; spore reduction
Blood or Bodily Fluids	Intermediate-Level Disinfection	Kill viruses, mycobacteria, fungi, and vegetative bacteria; not effective on spores.	99.9999% veg bacteria; 99.9% mycobacteria
Normal Patient Flora	Low-Level Disinfection	Free of vegetative bacteria	99.9999% veg bacteria; some fungi and lipid viruses

6-LOG required for “disinfection”

LOG RATE	% KILL RATE	MICROBES LEFT FROM 1M
1-LOG	90%	100,000
2-LOG	99%	10,000
3-LOG	99.9%	1,000
4-LOG	99.99%	100
5-LOG	99.999%	10
6-LOG	99.9999%	1

Bacteria grown from “clean” mattress.



Bacteria Isolated on Mattress After Terminal Cleaning

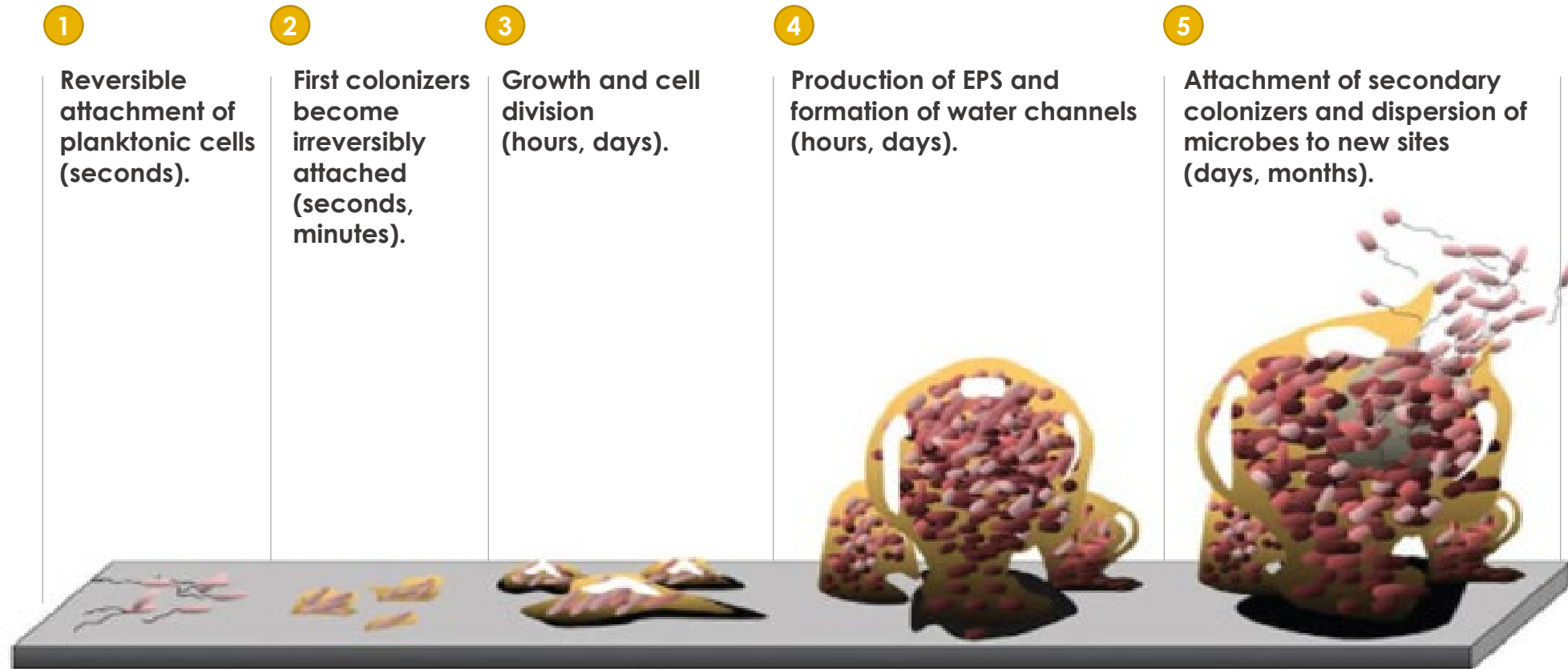
- **MRSA: Methicillin Resistant Staphylococcus aureus**
- **VRE: Vancomycin-resistant Enterococcus**
- Acinetobacter Iwoffii
- **Acinetobacter baumannii**
- **Klebsiella pneumonia**
- Enterobacter cloacea
- Pseudomonas fluorescens
- Streptococcus viridans
- **Pseudomonas aeruginosa**
- Stenotrophomonas maltophilia
- Rhizobium radiobacter
- Proteus mirabilis
- Bacillus species
- Micrococcus species
- **Coagulase negative Staphylococci**

*Bacteria identified in **bold** are leading contributors to HAIs according to NHSN/CDC*

Hooker et.al. A Randomized Trial to Evaluate a Launderable Bed Protection System for Hospital Beds
Antimicrobial Resistance and Infection Control.2012;1:27

The Role Biofilm Plays in Spreading HAIs

Biofilms form when a group of microbes sense a surface, adhere and colonize them produces and extra-cellular polysaccharide matrix-EPS.



Prinzi Andrea & Rohde R.E. The Role of Bacterial Biofilms in Antimicrobial Resistance. American Society of Microbiology, Bugs and Drugs article. March 6, 2023. <https://asm.org/Articles/2023/March/The-Role-of-Bacterial-Biofilmsin-Antimicrobial-Re>

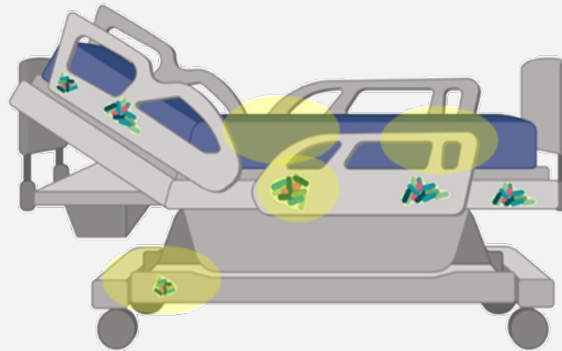
The Role Biofilm Plays in Spreading HAIs

DRAIN BIOFILMS



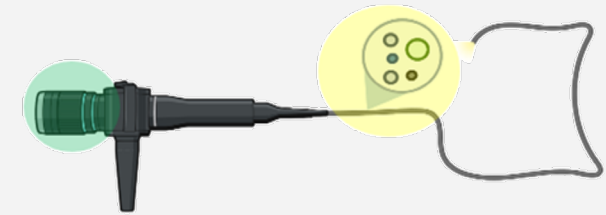
Each type of surface comes with its own challenges and considerations

DRY SURFACE BIOFILMS



Frequency of wet and dry cycles can affect the formation of biofilm

MEDICAL DEVICE BIOFILMS



Effect on medical devices:

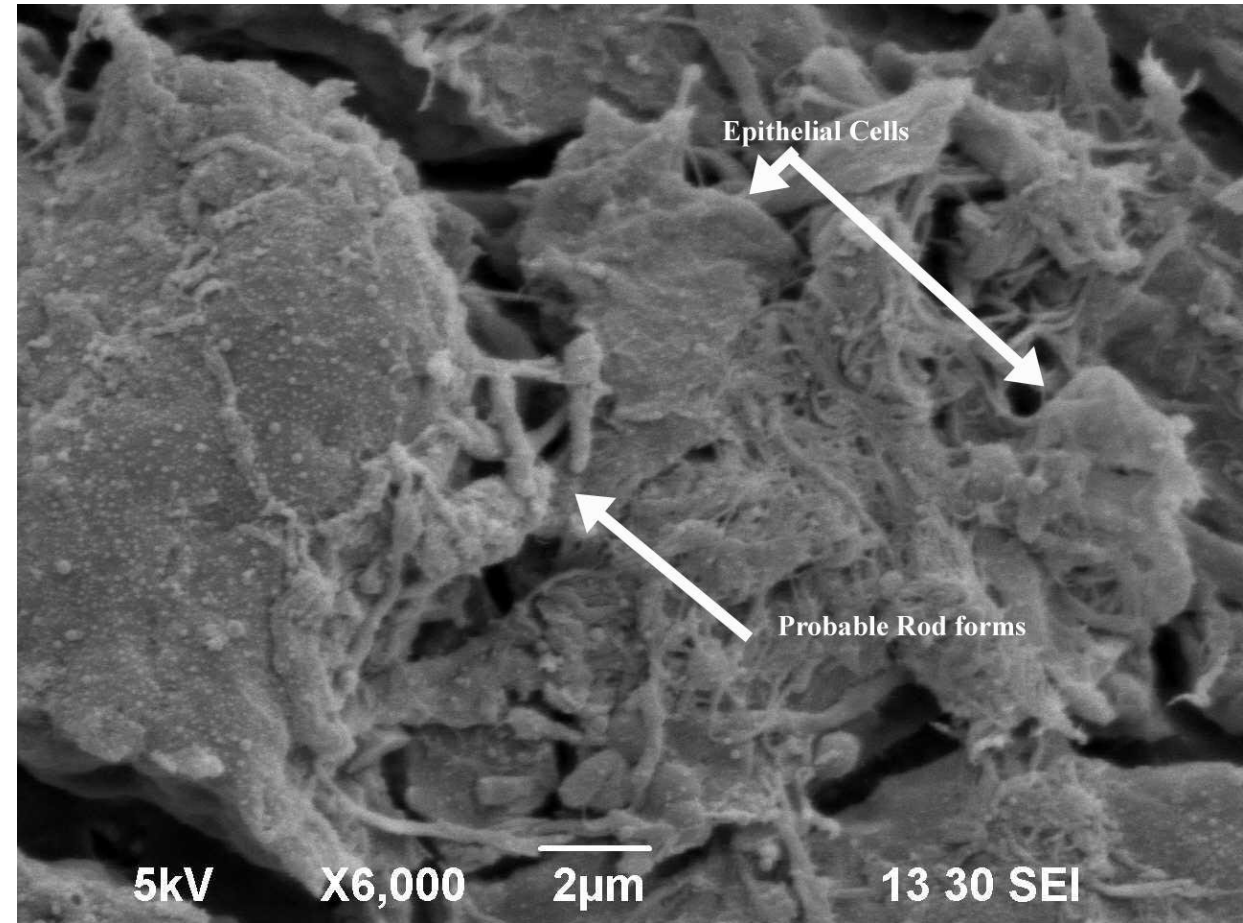
- Design
- MIFUs
- Damage
- Useful Life

Summary: “Cleaned” Beds Are Not Clean

Studies showing that beds/mattresses are still contaminated after terminal cleaning:

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

AAMI TIR 2020
Non-critical devices that are soiled with blood or Other Potentially-Infectious Materials (OPIMs) and come in contact with the health care personnel or intended to have direct contact with the patient should be visibly clean and at a minimum, be intermediate-level disinfected.



Sem image of mattress showing bacteria in failed areas of mattresses

Why We Should Care

The Patient Safety Issue

A photograph of a patient lying in a hospital bed, wearing a white hospital gown with a blue pattern. The patient's eyes are closed, and their hands are clasped together. In the background, there is a medical monitor with various colored lights and a screen. The scene is set in a hospital room with a green wall.

Mattresses and beds are the #1 patient touchpoints and are an under-appreciated patient safety issue.

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)



In Fact...

5.83X MORE LIKELY⁵:

Increased odds getting a healthcare-acquired infection (HAI) if previous bed occupant in room had an HAI.

2-3X MORE LIKELY⁵:

Patients are 2-3 times more likely to be infected with *C. diff* if previous bed occupant had *C. diff*.

The ESKAPE (*Enterococcus faecium*, *Staphylococcus aureus*, *Klebsiella pneumoniae*, *Acinetobacter baumannii*, *Pseudomonas aeruginosa*, and *Enterobacter* species) **pathogens** are nosocomial and associated with high levels of resistance and increased morbidity and mortality⁶.

Medical Device-Associated Healthcare Infections: Sterilization and the Potential of Novel Biological Approaches to Ensure Patient Safety

Infections Related to Mattresses

**CTX-M-15 producing
Enterobacter cloacae**

4 deaths
**18 infected
or colonized**

Bousquet, A., et al. (2017). Outbreak of CTX-M-15-producing Enterobacter cloacae associated with therapeutic beds and syphons in an intensive care unit. American journal of infection control, 45(10), 1160-1164.

**Multi-resistant enterobacter
cloacae**

**5 colonized
or infected in ICU**
**All mattresses
< 18 months old**

Van der Mee-Marquet, N., et al. (2006). Multiresistant Enterobacter cloacae outbreak in an intensive care unit associated with therapeutic beds. Critical Care, 10(1), 405.

Klebsiella

**19 ill
from single bed unit**

Cadot L., et al, Extended spectrum beta-lactamase producing Klebsiella pneumoniae outbreak reveals incubators as pathogen reservoir in neonatal care center. European Journal of Pediatrics (2019) 178:505-513.

Emory Bed Study published 2023

C. diff



The role of the hospital bed in hospital-onset *Clostridioides difficile*: A retrospective study with mediation analysis

Published online by Cambridge University Press: **13 December 2023**

Lucy S. Witt , Jessica Howard-Anderson , Radhika Prakash-Asrani ,
Elizabeth Overton  and Jesse T. Jacob 

Show author details 

Article Figures Supplementary materials Metrics

- 50% greater chance of getting *C. diff* from prior patients.
- **Contagion present even three months after initial *C. diff* patient.**
- Beds moved >7 x in study.
- UV light/Bleach/Oxycide did not break cycle.

VA Hospital Safety Alert



Alert ID: AL24-01

Alerts and Recalls ID: SR-46567

Date Issued: April 18, 2024

Item: **Undetected fluid ingress and egress from inpatient and outpatient mattresses can lead to hospital-associated infections, patient tissue degradation, and/or patient death**

Specific Incident: A facility reported the presence of blood inside hospital mattresses due to pinholes in the material (covering). The fluid infiltration was discovered in 37 mattresses when the covers were separated away from the foam insert during preventative maintenance inspections of beds and mattresses. The compromised mattresses were replaced.

The risk of this issue is that it can lead to hospital-associated infections, patient tissue degradation, serious illness of patient, or patient death.



VA Patient Safety Summary

The risk of this issue is that it can lead to hospital-associated infections, patient tissue degradation, serious illness of patient, or patient death.

Summary: Consistent Mattress Patient-Safety Warnings

The risk of this issue is that it can lead to hospital-associated infections, patient tissue degradation, serious illness of patient, or patient death.



ECRI Institute



Why the Beds Aren't Clean

Mattress Evolution

1) Mattresses have changed dramatically

- Over last 50 years, impetus to address pressure injuries.
- Mattresses have moved from vinyl to soft-porous surfaces, e.g., microclimate.
- Covers now 1/40-inch thick.
- Expected fabric life from 10+years to 1-2 years.

Pathogen Proliferation

2) *So have the pathogens we treat*

- Proliferation of Multi-Drug-Resistant-Organisms (MDRO).
- Attempting to clean and disinfect more aggressively... but not always effectively.
- Vinyl mattress was non-porous and Hard Surface Disinfectants Worked.
 - EPA: **No** Disinfectants Indicated for Soft Porous Surfaces.

Cleaning Confusion

3) Misperceptions about cleaning have proliferated as well



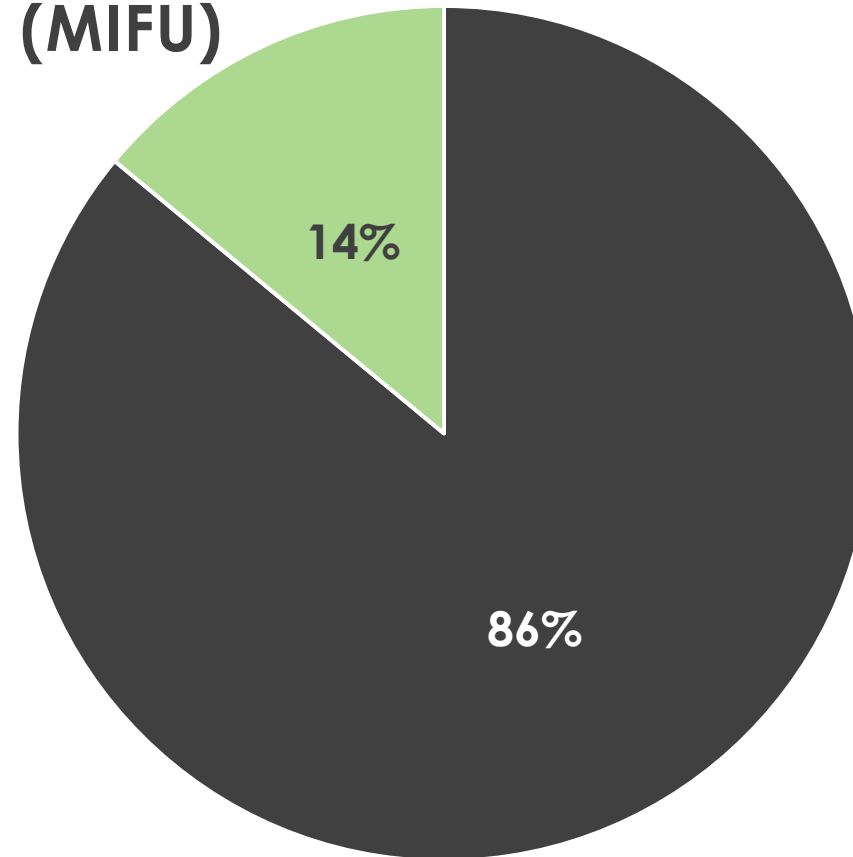
Is your facility following the manufacturer's IFU for beds and mattresses?

- **Yes; we are following the IFU from the manufacturer.**
- **No; we are following a facility-validated process.**
- **Unsure/Don't Know**

Which best describes the number of steps your facility uses for reprocessing a bed/mattress?

- 1 step (wipe with cleaner/disinfectant)
- 2 steps (wipe with cleaner/disinfectant, then use bleach)
- 3 steps (wipe with cleaner/disinfectant, then bleach, then UV light)
- 4 steps (pre-clean, clean, disinfect, rinse)
- 5 steps (pre-clean, rinse, clean, rinse, disinfect)
- 6 steps (pre-clean, rinse, clean, rinse, disinfect, rinse)
- Unsure/Don't Know

**Only 14% follow
the manufacturer's
instructions for use
(MIFU)**



**86% use a one-step
process to clean and
disinfect mattresses**

Source: 2019 APIC Survey, n=101

“Clean” Bed = *Function* of

1

Recognize the Type of Bed



2

Recognize type of bodily fluids/exudation

“Clean” Bed = *Function* of

1

Recognize the Type of Bed

Each manufacturer and type of bed has its own MIFU.
(Manufacturer's Instructions for Use, including Reprocessing)



2

Recognize type of bodily fluids/exudation

“Clean” Bed = *Function* of

1

Recognize the Type of Bed

Each manufacturer and type of bed has its own MIFU.
(Manufacturer's Instructions for Use, including Reprocessing)



2

Recognize type of bodily fluids/exudation

Normal ♦ Bodily Fluids ♦ Wound Exudate from Non-Intact Skin ♦
Worst-Case Scenario

Hospitals recognize this as Isolation vs Non-Isolation
Reprocessing

**ECRI suggests notifying EVS;
if not, default to Worst-Case Scenario.**

“Clean” Bed = *Function* of

1

Recognize the Type of Bed

Each manufacturer and type of bed has its own MIFU .
(*Manufacturer's Instructions for Use, including Reprocessing*)



2

Recognize type of bodily fluids/exudation

Normal ♦ Bodily Fluids ♦ Wound Exudate from Non-Intact Skin ♦
Worst-Case Scenario



3

Choice of Cleaner/Disinfectant

FDA recognizes there is a difference
between cleaning and disinfectant.

“Clean” Bed = *Function* of

- 1 Recognize the Type of Bed
- + 2 Recognize type of bodily fluids/exudation
- + 3 Choice of Cleaner/Disinfectant
- + 4 Human Elbow Grease
Soil must be removed first.
- + 5 Multi-Step Process
Must clean and disinfect and allow disinfectant dwell-time.

Common MIFU: When Cleaning and Disinfection Required



PRE-CLEAN
gross soil



CLEAN
non-visible soil



RINSE
(if bleach is used)



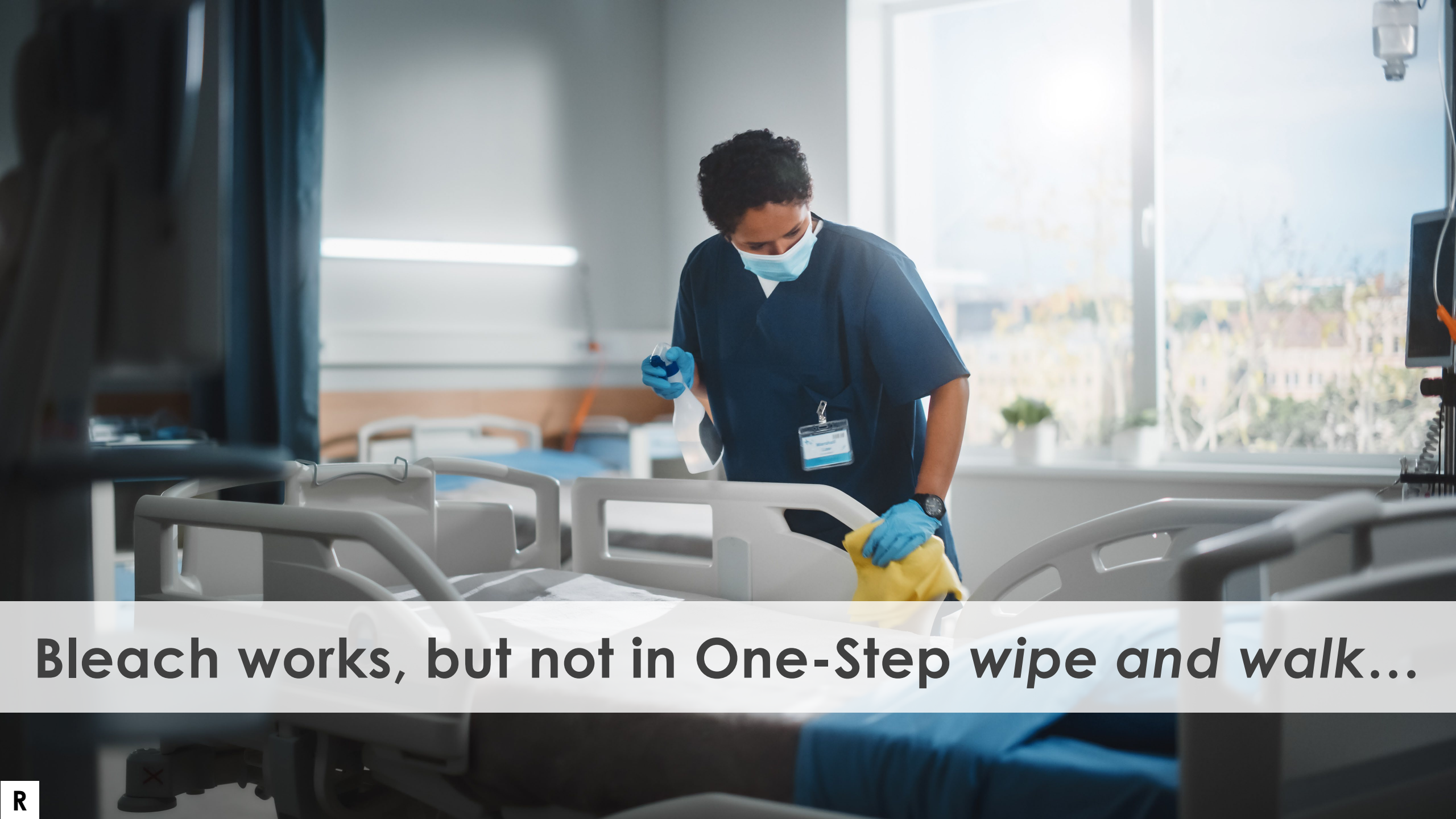
DISINFECT
2-3 re-wipes may
be required to meet
dwell time



RINSE

Does your facility use bleach as its disinfectant after each patient discharge for mattress reprocessing?

- **Yes**
- **No**
- **Unsure/Don't Know**



Bleach works, but not in *One-Step wipe and walk...*

For Bleach to Work Effectively as a Disinfectant...

- Any surface **must** be cleaned before you use bleach as a disinfectant.
 - This means you must remove the visible soil first.



PRE-CLEAN
gross soil



CLEAN
non-visible soil



RINSE
(if bleach is used)



DISINFECT
2-3 re-wipes may
be required to meet
dwell time.



RINSE

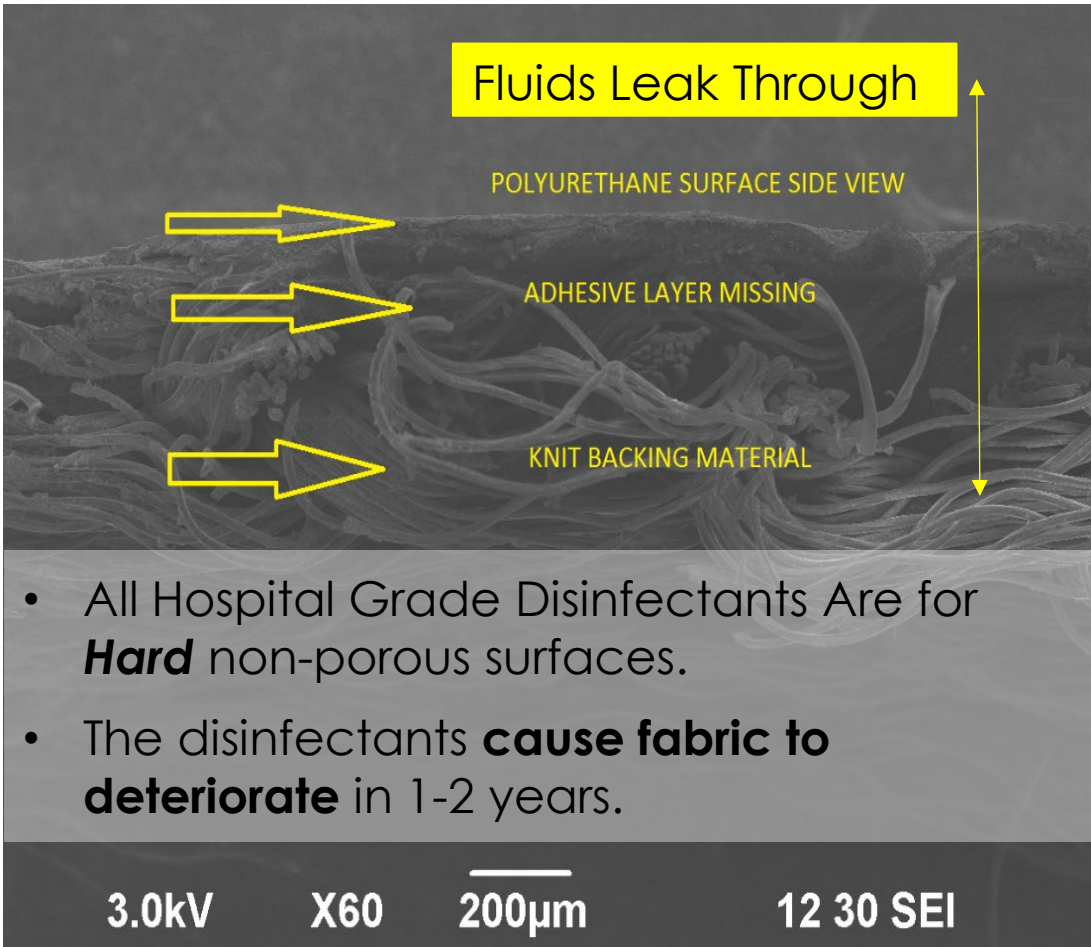
Even Repeated Cleaning with Bleach Can Fail to Disinfect

“...elimination of ABC and MRSA from hospital room surfaces is often challenging, with **approximately 1 of 4 rooms remaining contaminated** with either one of these organisms even after 4 rounds of cleaning and disinfection with bleach.”

Manian FA, Griesenauer S, Senkel D, et al. Isolation of Acinetobacter baumannii complex and methicillin-resistant Staphylococcus aureus from hospital rooms following terminal cleaning and disinfection: can we do better? Infect Control Hosp Epidemiol. 2011;32(7):667-672. doi:10.1086/660357

Major Mattress Manufacturer Reprocessing MIFU

Rinse after Disinfecting!



CAUTION:

Caution—Bleach may result in damage to the surface. Bleach can only be used for 6 applications for the life of the top cover (2 years). For more information, see “Expected Life” on page 95.

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

Hydrogen Peroxide Is Not a Panacea, Either

- Only gets a **log2-log3 reduction**, rather than log6 (99.9999%).
- **EPA** recognizes hydrogen peroxide + paracetic acid for *C. diff* but only on hard, non-porous surfaces BUT MIFU rules.
- Aerosolized (aHP) and accelerated (AHP) are sporicidals but not yet practical.

[EPA's Registered Antimicrobial Products Effective Against Clostridioides difficile \(C. diff\) Spores \[List K\] | US EPA](#)

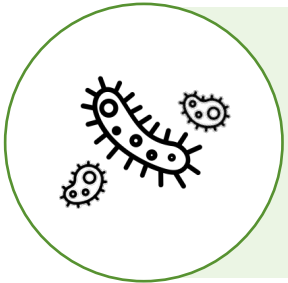
Some 28% Infection Preventionists Report Using UV Light

But UV light alone does not work on mattresses.

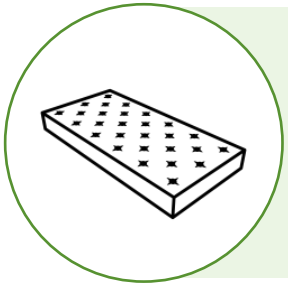
- FDA says UV Light is **not intended** for Soft, Porous Surface.
- **No** Bed Manufacturer Recommends UV Light to Disinfect a Mattress.
- UV light has failed in a randomized trial (Anderson, 2017⁷).

Summary: Why the Beds aren't Clean

The most prevalent re-processing is a one-step wipe and walk, which is ineffective in the presence of...



Growth of multi-drug-resistant organisms.



Softer, porous mattresses.



Need for disinfection at terminal cleaning.

What Does Clean Bed Compliance Look Like?

1) Follow the MIFUs

Regulatory Philosophy has Changed Significantly

In 2015, the FDA reprocessing guidance eliminated the option to follow “facility protocol.”

CMS and Joint Commission circumscribed reprocessing options to “follow the MIFUs only.”

Guidelines For The Environment: Standard Mattresses

FDA U.S. FOOD & DRUG
ADMINISTRATION

CENTER FOR DEVICES & RADIOLOGICAL HEALTH



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 manufacturers' 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.

CDC Infection Control Guidelines

E.1.C Follow manufacturer's instructions for cleaning & maintaining non-critical medical equipment.

E.1.D.3 Use barrier protective covering as appropriate for noncritical equipment surfaces that are: Touched frequently by gloved hands during the delivery of patient care. Likely to be contaminated with blood or body substances and difficult to clean.

NEW Joint Commission Assessment Standards Effective 7-1-24

Ensuring Alignment with CMS COPs

R³ Report | Requirement, Rationale, Reference

A complimentary publication of The Joint Commission

Issue 41, December 20, 2023

Joint Commission Requirements IC.06.01.01EP3

- 1) Follow the MIFUs for bed and mattress reprocessing.
- 2) Follow the MIFUs for disinfectant use; do not use them off-label.
- 3) Ensure you have a mattress management plan and are following it.

Joint commission statements on manufacturer's instructions for use recommendations for medical devices and CDC recommendations:

“It is important to understand that each patient care item has its own IFUs for cleaning and disinfection and the expectation is that the organization will follow those instructions. Failure to follow such instructions or misuse creates significant risk to safe, quality care.”

<https://www.jointcommission.org/standards/standard-faqs/office-based-surgery/infection-prevention-and-control-ic/000002250/?p=1>

Leading Mfg Cleaning & Disinfection MIFU

Now a 5-step process

SUMMARY OF STEPS

1. Pre-clean: gross soil
2. Clean: non-visible soil
3. Rinse (if bleach is used)
4. Disinfect: 2-3 re-wipes maybe required to meet dwell time.
5. Rinse

CLEANING AND DISINFECTING

NOTE:

The Cleaning and Disinfecting section of this manual only address pro+ mattress. Refer to the appropriate bed user manual for instruction on how to clean and disinfect the bed.



WARNING:

To help prevent injury and/or equipment damage, obey these warnings:

- **Warning**—The mattress must be cleaned and disinfected per the cleaning and disinfecting instructions.
- **Warning**—The potential for electrical shock exists with electrical equipment. Failure to follow facility protocol could cause death or serious injury.

Required to meet expected life of outer mattress skin

- **Warning**—Do not reuse wiping material for multiple steps or on multiple products.
- **Warning**—Harmful cleaning solutions may cause skin rash and/or irritation upon contact. Follow the manufacturer's instructions found on the product label and Safety Data Sheet (SDS).
- **Warning**—Lift and move items correctly. Do not twist, and seek assistance when necessary. Make sure the bed is at a correct height to lift items off the bed.
- **Warning**—Fluid spills on to the mattress electronics could cause a hazard. If such a spill occurs, unplug the bed and mattress and remove them from service. When fluid spills occur outside of what is seen in normal use, immediately do as follows:
 - a. Unplug the bed and mattress from its power source.
 - b. Remove the patient from the bed.
 - c. Clean the fluid spill from the bed system.
 - d. Have maintenance examine the system completely.
 - e. Do not put the mattress back into service until it is completely dry, tested, and found to be safe to operate.

Disinfectant concentration is a concern from mixing stations.

Mattress fabric takes 24 hours to normalize. Difficult to operationalize.

CLEANING AND DISINFECTING

Cleaning and disinfection are distinctly different processes. **Cleaning** is the physical removal of visible and non-visible soil and contaminants. **Disinfection** is intended 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		Maintain Wetness (Disinfection Contact Time)
	Cleaning and Disinfection	Disinfection	
	Routine	Clostridium Difficile (C.Diff)	
Virux® I			
OxyGid Disinfectant Cleaner			
Clorox HealthCare® Bleach Germicidal Cleaner ready-to-use	No*	Yes	3 minutes
Sani-Cloth® Bleach Germicidal Disposable Wipes	No*	Yes	4 minutes
Super Sani-Cloth® Germicidal Disposable Wipes	Yes	No	2 minutes
CaviWipes™	Yes	No	3 minutes
Oxivir® Tb	Yes	No	10 minutes
Peridox® ready-to-use	Yes	Yes	3 minutes

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

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

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

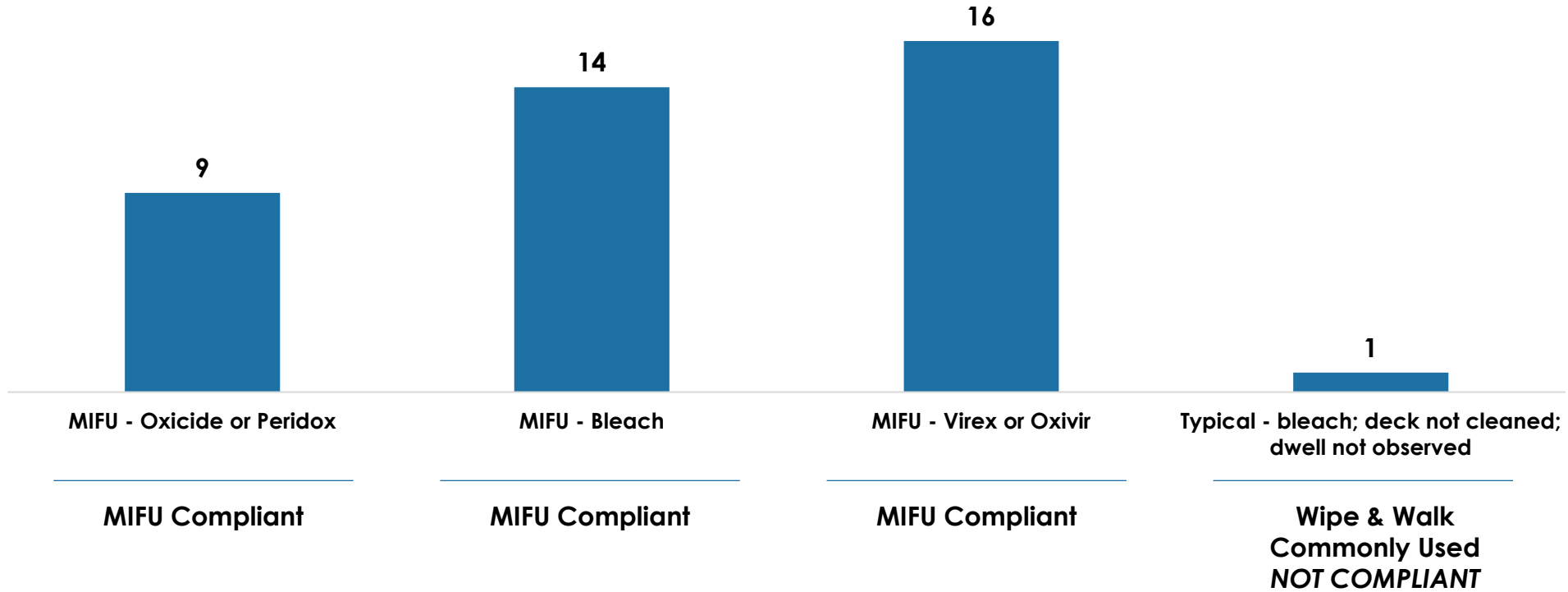
- A microfiber cloth or ready-to-use wipe is recommended as the wiping cloth.
- Always replace the wiping cloth when visibly soiled.
- Always replace the wiping cloth between steps (spot clean, clean, and disinfect).
- Always use Personal Protective Equipment (PPE).
- Adjust the bed position, siderails, headboard, and footboard as needed for ease of cleaning and disinfection.

Cleaning step is required regardless of visible soil.

Most hospitals use bleach for CDI rooms requiring additional step.

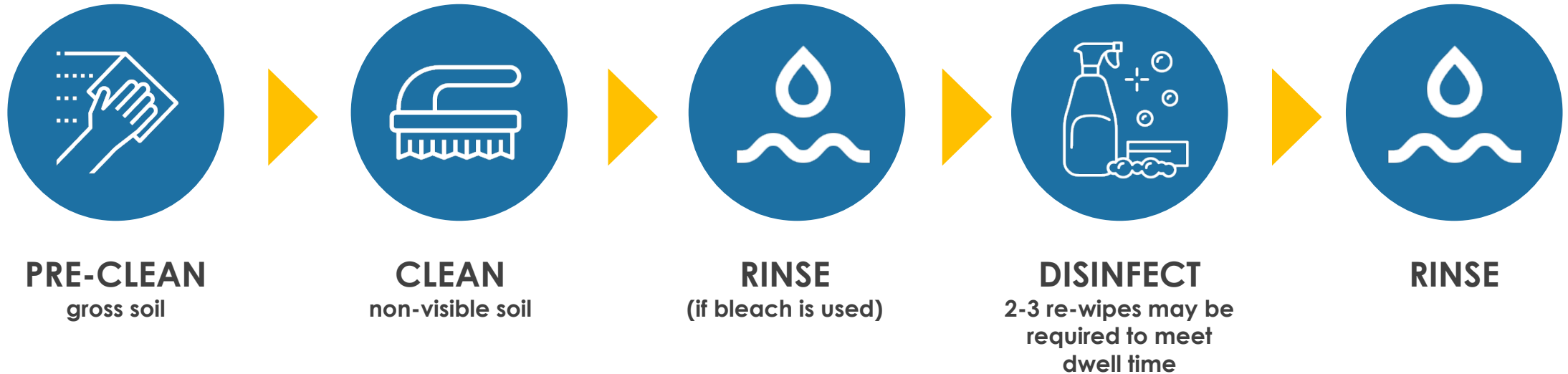
MIFU Reprocessing Time

Major manufacturer's top selling unit



MIFU compliance adds time to bed/mattress reprocessing

Following the MIFUs

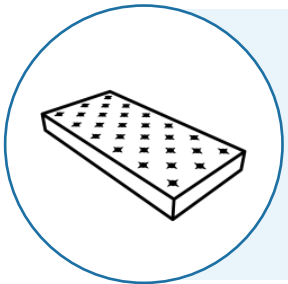


These are still dependent on human factors

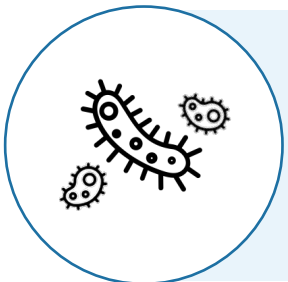
Compliance Summary



Following FDA, CDC, and CMS guidance, hospital beds exposed to patient non-intact skin must be cleaned with high level disinfection. With beds transferred between units, clean for the worst-case scenario.



Messaging is consistent in 2024: Follow the bed and mattress manufacturer's reprocessing MIFU to be in compliance.



Failure to follow the MIFUS degrades your mattresses, invalidates your mattress warranty, and jeopardizes patient safety.

What Does Compliance Look Like?

2) Use Soteria Bed Barrier

Another Compliance Option: Soteria® Bed Barrier



The Soteria Bed Barrier is the first of its kind **laundryable** and **reusable** healthcare bed barrier that **provides a physical barrier to protect** the bed and mattress from patient soiling, helping to reduce contamination during use.

- **FDA assigned unique product code (QTV).**
- Level 4 barrier per AAMI Standard PB70.

Simplifying the complication of reprocessing directives

EPA	FDA	Bed & Mattress Manufacturers	Hospitals	Other
<ul style="list-style-type: none"> Regulates disinfectants No authority over medical devices 	<ul style="list-style-type: none"> Regulates medical devices including requirements for reprocessing 	<ul style="list-style-type: none"> Own the MIFU and the choice of disinfectant(s) and validation for reprocessing 	<ul style="list-style-type: none"> CMS requires hospitals to follow Manufacturer's Instructions for Use --MIFU-- (including COP (Conditions of Participation)) 	<p>Consensus Documents and Evidence-based Practices can be Additive TO MIFU</p> <p><i>c.diff</i> patients have resulted in more common daily use of sporicidal disinfectants</p>

Soteria solves for all these silos



Soteria is an Engineered Solution To Deliver Repeatable Reprocessing and Minimize Human Factors Variability

- Proprietary surface formation allows laundering that meets AMMI TIR 12 acceptance criteria.
- Validated for 150 laundry cycles.



This reduces human factors variability in MIFU reprocessing.

Soteria® Bed Barrier Validated Laundry Process

*For either in-house or outsourced hospital laundries.
Uses same machines as launderable surgical materials.*

LAUNDRY



- 160°F Wash
- Chlorine Bleach
- Final Rinse – pH Neutral

LIGHT TABLE



Light table inspected for holes after laundering and before re-use.

RFID-CHIPPED



RFID-chipped to track for 150 laundry cycles.

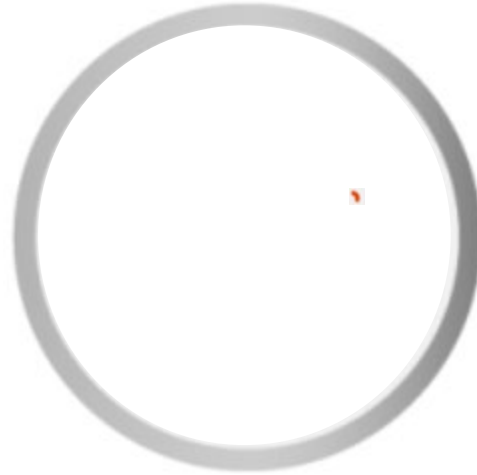
Impact of Soteria® Laundry Cycle

Laundering provides a 99.9999% reduction of colony forming units (CFUs).

BEFORE LAUNDERING
1,000,000 CFUs



AFTER LAUNDERING
Less than 1 CFU

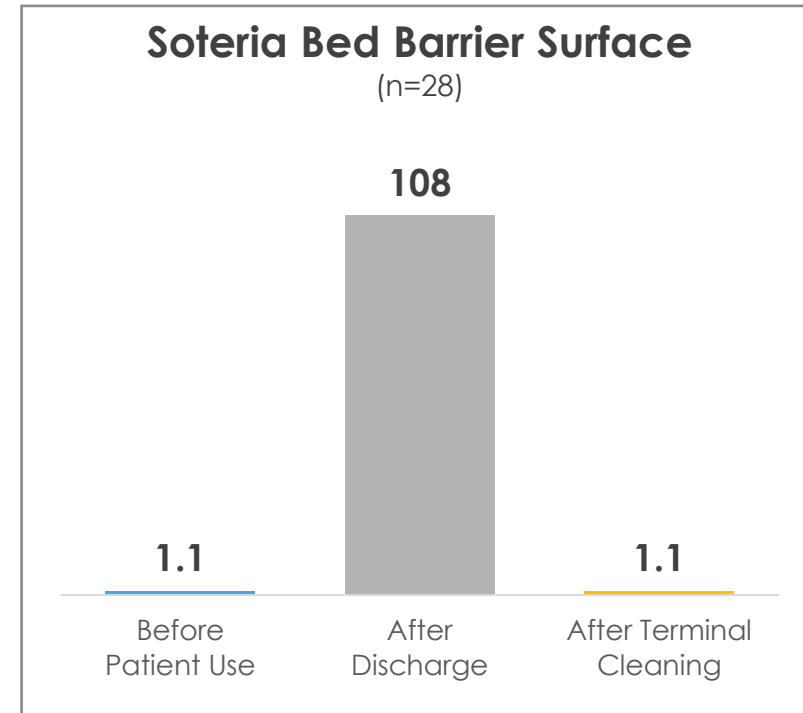
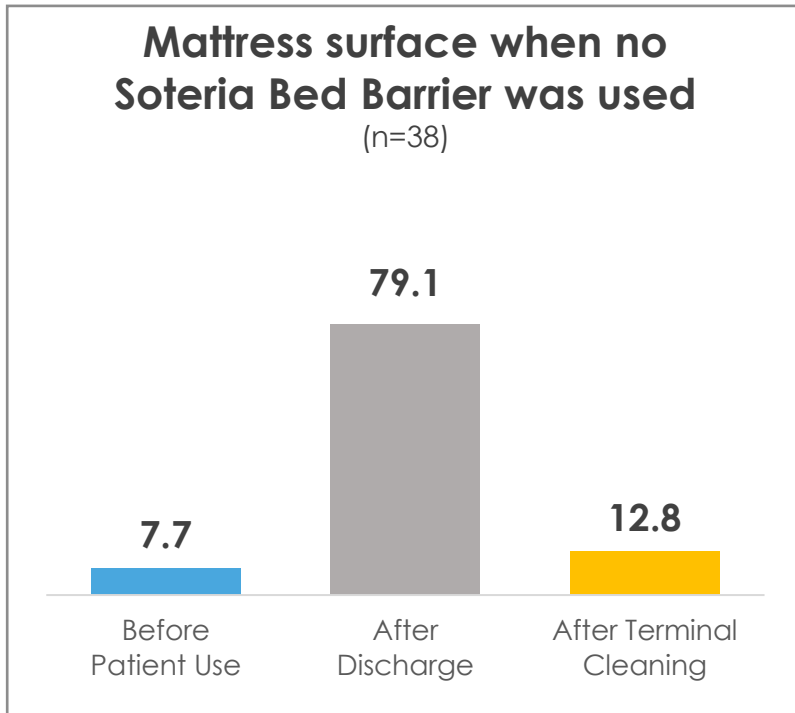


Organisms Tested

- Mixed suspension of
 - *Escherichia coli*
 - *Pseudomonas aeruginosa*
 - Methicillin Resistant *Staphylococcus aureus* (MRSA)
 - *Klebsiella pneumoniae*
- *Mycobacterium terrae*
- *Clostridium difficile* spores

This level of clean is difficult to achieve. It is equivalent to high-level disinfection.

A Randomized Trial to Evaluate a Launderable Bed Protection System for Hospital Beds⁸



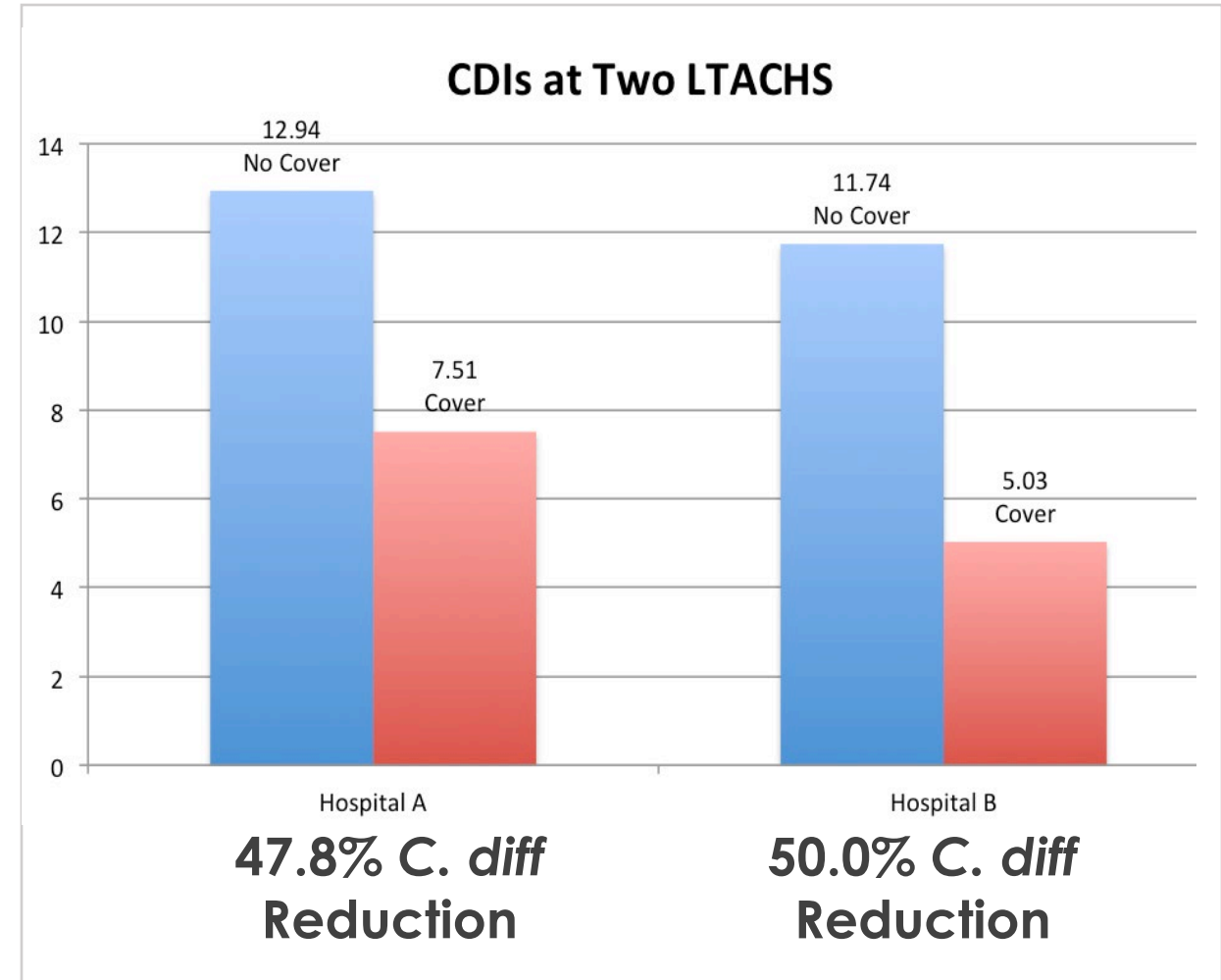
Soteria results in significant cleaning difference *and* mattress protection!

Patient Safety Study⁹ Shows Soteria Bed Barrier Reduced *C. diff*

Hospital-acquired *C. diff* reduced by barrier and disinfection intervention.

Hospital A cleaned rooms with quat disinfectant & CDI rooms cleaned with quat disinfectant, then bleach.

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

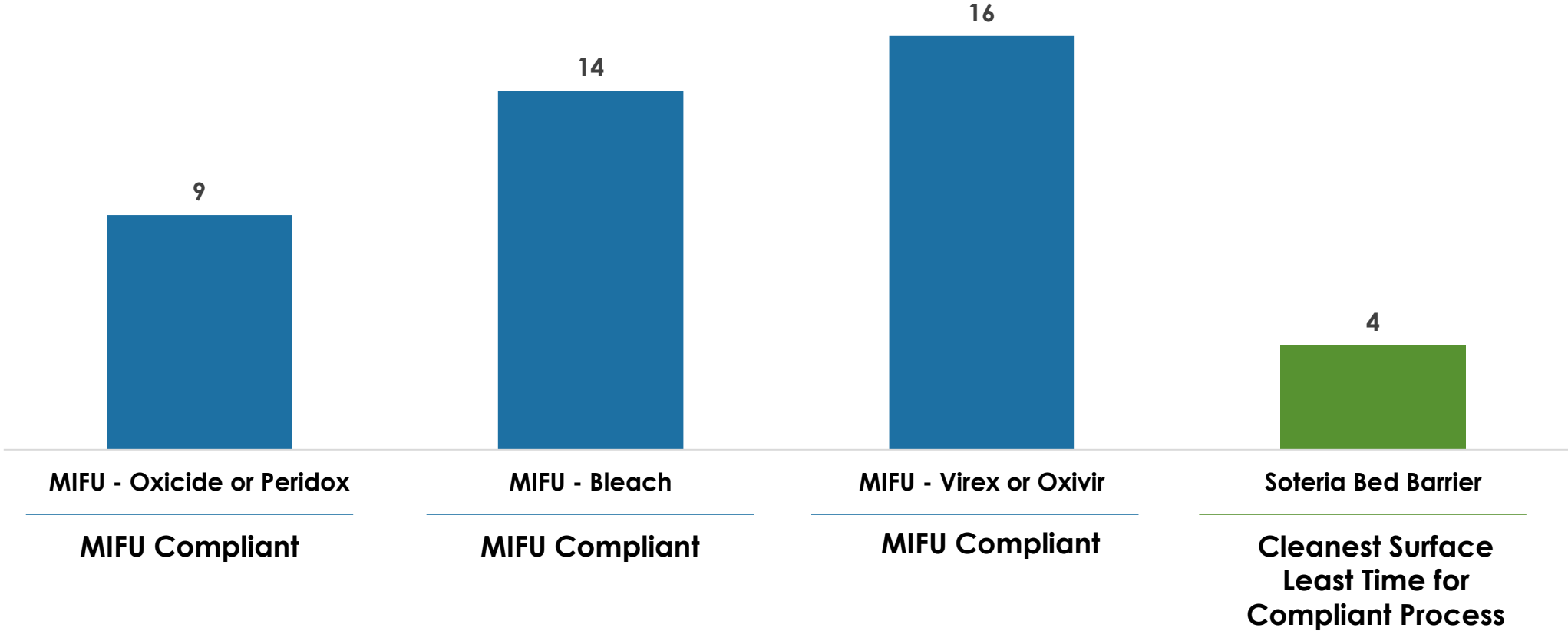


Soteria Designed to Promote Healthy Skin

- Breathable
- 4-way stretch fabric
- Free of forever chemicals
- Compatible with air loss and microclimate mattresses.
- Equivalency in HAPIs to underlying mattress.



Soteria Offers Significant Advantage on Reprocessing Time



New GE Healthcare Neonatal Mattress MIFUs Require High-level Disinfection

English


PRESSURE DIFFUSING MATTRESS

REF 2076066-001, PRESSURE DIFFUSING MATTRESS

Intended use
Pressure Diffusing Mattress (PDM) is used to position a neonate when used along with GE Incubators/Warmers. The Pressure Diffusing Mattress is reusable between patients after cleaning and disinfection.

Clinical Benefits
A patient support surface which enables a reduction in pressure and desired positioning in a warmer or incubator.

Part Number	Description	Product Compatibility
2076066-001	Pressure Diffusing Mattress (PDM)	Giraffe OmniBed, Giraffe Incubator, Giraffe OmniBed Carestation CS1, Giraffe Incubator Care Station CS1 and Giraffe iRes Warmer



PRESSURE DIFFUSING MATTRESS

Instructions for Use

1. Before putting a patient on the mattress, cover the mattress with a dry, clean sheet or blanket. Always replace wet sheets or blankets. For best performance, put the

NOTE: During weighing process:

- Do not put blankets below the scale platform.
- Make sure that blankets do not touch the bedside panels.
- Make sure that there are no objects below the mattress.

Soteria!



NOTE: It is recommended to use a commercially available microbiological barrier with appropriate decontamination level (reusable or single patient use barrier) on the mattress, if intended to contact mucous membranes or non-intact (immature skin) of the patient.

Soteria Provides Value

$$\text{VALUE} = \frac{\text{QUALITY}^*}{\text{COSTS}}$$

- Use our Cost Calculator for your own numbers, but in general, each bed barrier is <\$3.00 per patient day.
- Reduction in unreimbursed HAI infections (1 HOCIDI = \$34k).
- Avg HAI lawsuit settlement ~ \$1.5MM.
- Achieving mattress life expectancy goal saves too (vs 75% failure within 4 years).

**(outcomes, safety, services, etc.)*

Considerations: Address High-risk Conditions First

As a protocol for patients with seepy/draining wounds.

As a protocol for MRSA isolation patients.

As a protocol for *C. diff* or other immunocompromised patients.

VAs addressing patient safety alert.

Hospitals with JC citations.

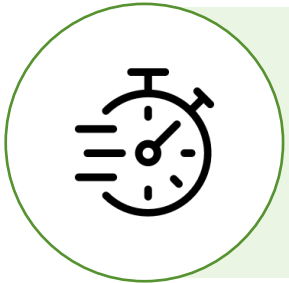
Children's hospitals/NICU units.

Summary: Soteria Bed Barrier Benefits



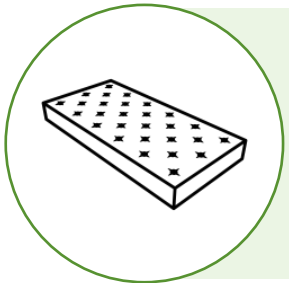
Patient Safety

Achieves log₆ clean of 99.9999%, equivalent to high level disinfection. Proven reduction of *C. diff* infections. No evidence of pressure ulcer issues.



Reprocessing Time Savings

Saves ~10 minutes reprocessing time versus MIFUs for mattresses without Bed Barriers. Requires same laundering process used for launderable surgical materials.



Mattress Investment Protection

Can help extend the useful of life of your mattress.

We Invite You To...



Confirm with eyes-on how your facility is reprocessing your beds and mattresses.



Ask Risk Management for perspective on the cost of your facility's HAIs.

Recommendations Depending on What You Learn

If you ARE NOT following the MIFU

- Follow it
- OR
- Give Trinity Guardion a call about how we might help.

If you ARE following the MIFU

If you have low HAIs:

- Do you have long ED patient hold-times while you open up a bed for admitted patients?
- Might a faster process using Soteria be helpful?

If you have units with problematic HAIs, give us a call.

For more on patient safety
and mattress reprocessing,
please contact us:

info@trinityguardion.com

812-932-2600

www.trinityguardion.com



SOTERIA®
BED BARRIER

TRINITY  GUARDION



Clinical Study Footnotes

1. Koshy, Thomas et al. *The State of Support Surface Integrity in Acute Healthcare Facilities*. For presentation NPIAP 2023, March 17-19.
2. Hooker, Edmond A, *Hospital mattress failures – A hidden patient danger*. Infection Control and Hospital Epidemiology 2021:doi 10.1017/ice2021.486
3. Wong, Nia. FOX13 Seattle. Published November 10, 2022 8:26pm PST
4. Hooker et al. *A randomized trial to evaluate a launderable bed protection system for hospital beds*. Antimicrobial Resistance and Infection Control 2012, 1:27.
5. Cohen B, Liu J, Cohen AR, Larson E. *Association between healthcare-associated infection and exposure to hospital roommates and previous bed occupants with the same organism*. Infect Control Hosp Epidemiol. 2018; 39(5):541-546. doi: 10.1017/ice.2018.22 <https://pubmed.ncbi.nlm.nih.gov/29486805/>
6. Garvey M. *Medical Device-Associated Healthcare Infections: Sterilization and the Potential of Novel Biological Approaches to Ensure Patient Safety*. Int J Mol Sci.2024 Jan; 25(1): 201. Published online 2023 Dec 22. doi: 10.3390/ijms25010201 PMID: 38203372
7. Anderson DJ, et al. *Enhanced terminal room disinfection and acquisition and infection caused by multidrug-resistant organisms and Clostridium difficile (the Benefits of Enhanced Terminal Room Disinfection study): a cluster-randomised, multicentre, crossover study*. Lancet. 2017 Feb 25;389(10071):805-814. doi: 10.1016/S0140-6736(16)31588-4. Epub 2017 Jan 17.PMID: 28104287
8. Hooker et al. *A Randomized Trial to Evaluate a Launderable Bed Protection System for Hospital Beds*. Antimicrobial Resistance and Infection Control. 2012 Jul 26; 1(1):27. doi: 10.1186/2047-2994-1-27.
9. Hooker et al. *Decreasing Clostridium difficile health care-associated infections through use of a launderable mattress cover*. AJIC 43; 12:1326-1330.December 2015. doi.org/10.1016/j.ajic.2015.07.002

Source Material Links

American Medical Association (AMA)

[2023 OMSS Annual Meeting policy proceedings | AMA \(ama-assn.org\)](#)

CDC

[Recommendations for Disinfection and Sterilization in Healthcare Facilities | Infection Control | CDC](#)

[A Rational Approach to Disinfection and Sterilization | Infection Control | CDC](#)

[Considerations for Reducing Risk: Surfaces in Healthcare Facilities | HAIs | CDC](#)

[Antimicrobial Resistance Threats in the United States, 2021-2022 | Antimicrobial Resistance | CDC](#)

ECRI

[2019 Top Ten Health Technology Hazards \(10/2019\) \(ecri.org\)](#)

EPA

[EPA's Registered Antimicrobial Products Effective Against Clostridioides difficile \(C. diff\) Spores \[List K\] | US EPA](#)

[Six Steps for Safe & Effective Disinfectant Use \(epa.gov\)](#)

FDA

[Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling - Guidance for Industry and Food and Drug Administration Staff \(fda.gov\): 2015 Reprocessing Guidelines](#)

[Covers for Hospital Bed Mattresses: Learn How to Keep Them Safe | FDA](#)

Healthcare Surfaces Institute

[How Inconsistent IFUs Can Lead to Regulatory Fines and Patient Safety Risks \(healthcaresurfacesinstitute.org\)](#)

Joint Commission

[R3 Report: New and Revised Requirements for Infection Prevention and Control for Critical Access Hospitals and Hospitals \(jointcommission.org\)](#)

[New and Revised Requirements for the "Infection Prevention and Control" \(IC\) Chapter | The Joint Commission](#)

Length-of-Stay

[Hospital average length of stay by state | Definitive Healthcare \(definitivehc.com\)](#)

Manufacturer Instructions for Use

[209196__8_.backup.book \(hillrom.com\)](#) p. 85...

[2972 Isolibrium Support Mattress \(stryker.com\)](#). P. 17...

Clinical Studies

Not directly referenced in slides but germane to the subject

Warnke P, Pappisch VR, Frickmann H, Podbielski A. *Influence of bed making on loads of airborne and surface-associated drug-resistant bacteria in patient rooms.* J Hosp Infect. 2023 Jun; 136:45-54. DOI:10.1016/j.jhin.2023.03.100

Hopman J, Donskey CJ, Boszczowski I, Alfa MJ. *Multisite evaluation of environmental cleanliness of high-touch surfaces in intensive care unit patient rooms.* Am J Infect Control. 2018 Oct;46(10):1198-1200. doi: 10.1016/j.ajic.2018.03.031. Epub 2018 May 24. PMID: 29803595

Hooker et al. *Use of a Launderable Bed Barrier and Antibiotic Stewardship to Decrease Hospital Onset Clostridioides difficile Infections in an Acute Care Hospital: A Retrospective Pre/Post Case Study.* JHEOR. 2019;6(3):196-202. doi:10.36469/001c.11149

Browne K et al. *Investigating the effect of enhanced cleaning and disinfection of shared medical equipment on health-care-associated infections in Australia (CLEEN): a stepped-wedge, cluster randomised, controlled trial.* Lancet Infect Dis 2024. Published Online Aug 13, 2024
[https://doi.org/10.1016/S1473-3099\(24\)00399-2](https://doi.org/10.1016/S1473-3099(24)00399-2)

Marks B, de Haas E, Abboud T, Lam I, Datta I. *Uncovering the rates of damaged patient bed and stretcher mattresses in Canadian acute care hospitals.* Canadian Journal of Infection Control. Fall 2018;33(3):171-175

Chin (2019): UV light added to bleach did not work for terminal cleaning. Patients became infected with MDROs that remained after cleaning.

Health Quality Ontario (2018): Systematic review that showed evidence for value of UV light is extremely poor and that the costs are huge.

Anderson (2017): UV failed to decrease C. diff or MRSA infections. No bed manufacturer recommends use of UV light for disinfection.

McMullen (2021): Showed that UV light use did not decrease C. diff at three hospitals.

Attia (2020): UV light failed to decrease CDIs, despite use in 87% of rooms.