Enhancing Patient Safety through Strategic Placement of Copper Surfaces

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INTRODUCTION:

The implementation of Medicare's Never Events policy and the passage of the Affordable Care Act have heightened the value of practices that increase patient safety. Healthcare Associated Infections (HAIs) continue to be one of the most common and significant complications associated with hospitalization across the globe. Microbes have an intrinsic ability to survive and ultimately colonize common touch surfaces where acquisition and transport from surfaces to humans is common.[1,2] Healthcare workers have the potential to transfer microbiological contaminants not only from patient to patient, but amongst themselves and back to surfaces.[3] This adds to the complexity of the microbial reservoir involved in transmission and the acquisition of infection.

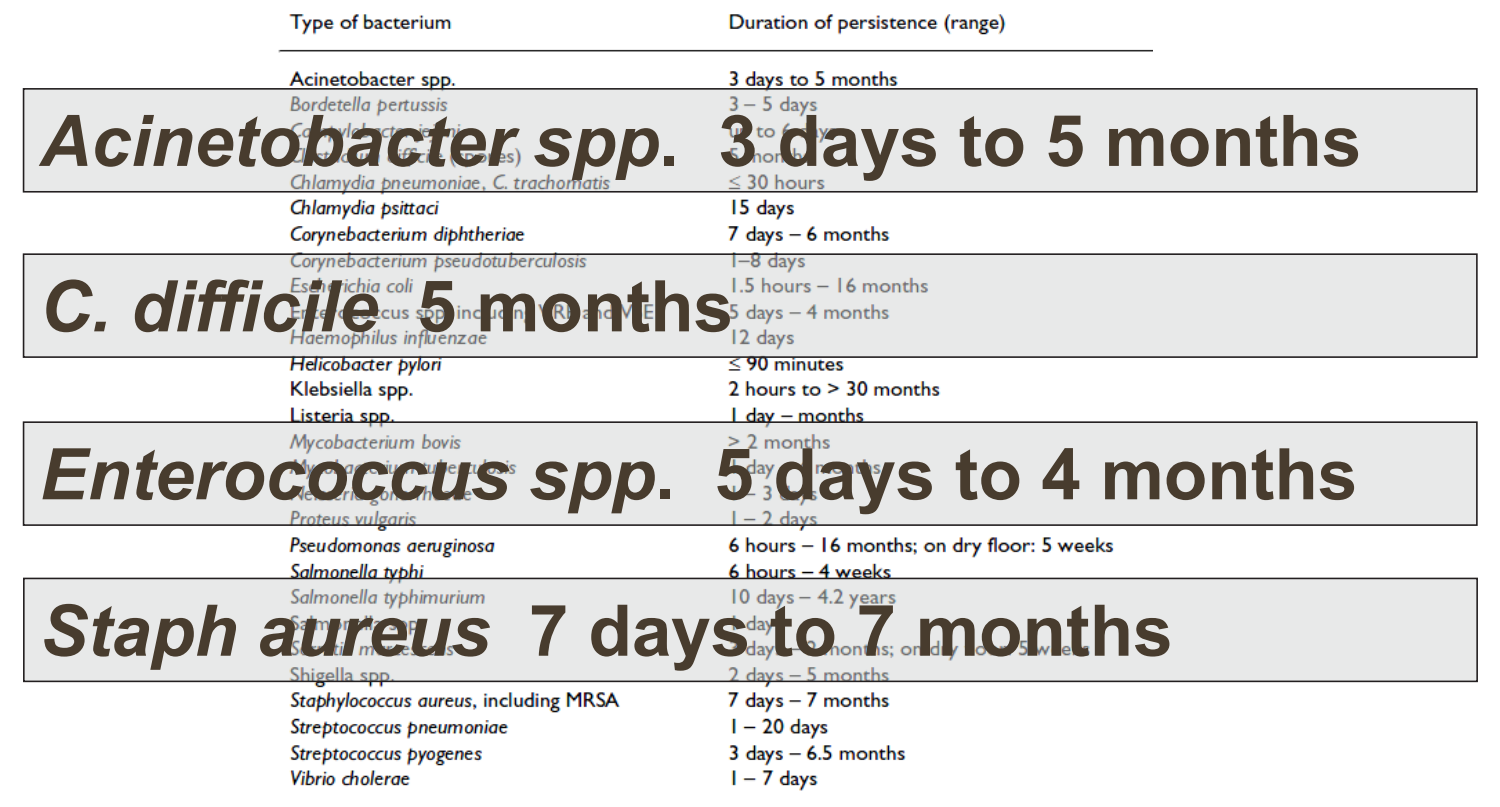
Hand washing, cleaning, and disinfecting surfaces within the built environment are critical to mitigating transmission of microbes.[4,5] However, these solutions have not stemmed the growing tide of HAIs.[6] Each year, two million patients will develop infections during their hospital stay; 100,000 individuals will die, costing the healthcare system approximately $45B.[7] For millennia humans have indirectly appreciated the antimicrobial activity of metallic copper. The inherent antimicrobial activity of metallic copper surfaces and its alloys containing greater than 60% copper offer an advantage to infection control as its action is continuous rather than episodic.[8] Significant interest has been generated in learning how to manage and provide best practice applications for hospitals to improve infection control as a consequence of recent publications demonstrating the ability of continuously active antimicrobial copper surfaces to improve patient safety.[9,10]

Recently we have shown that a limited application of EPA-registered antimicrobial copper surfaces within the built clinical environment resulted in an average 83%[11] reduction to the bacterial burden resulting in a 58% percent decrease in the incidence of HAI in the intensive care units at three US hospitals[12].

Healthcare Associated Infections

- *Remains 4th leading cause of death in the US behind Heart Disease, Cancer & Stroke*
- *Accounts for an additional $47 Billion in added health care costs in the US*
- *2004 CDC published study estimates HAI add 208% to hospital bill*
- *2008-CMS prevents reimbursement for certain preventable conditions, mistakes & HAI*
- *2014-CMS penalizes hospitals with poor quality care and gives additional money to hospitals with high quality care measures, metrics include HAIs*

Persistence of Bacteria on Dry Surfaces[2]

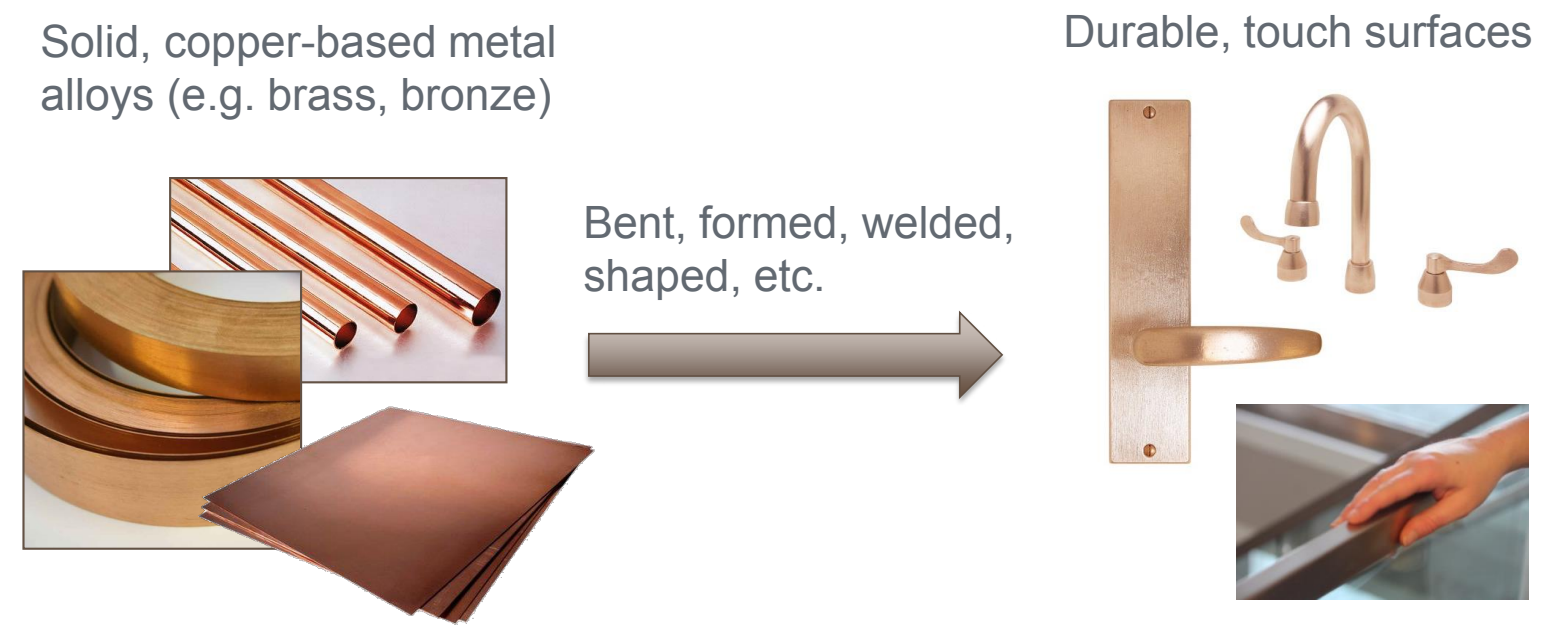


Type of bacterium	Duration of persistence (range)
Acinetobacter spp.	3 days to 5 months
Bordetella pertussis	3 – 5 days
[illegible]	[illegible]
[illegible]	[illegible]
Chlamydia pneumoniae, C. trachomatis	≤ 30 hours
Chlamydia psittaci	15 days
Corynebacterium diphtheriae	7 days – 6 months
Corynebacterium pseudotuberculosis	1–8 days
Escherichia coli	1.5 hours – 16 months
[illegible]	5 days – 4 months
Haemophilus influenzae	12 days
Helicobacter pylori	≤ 90 minutes
Klebsiella spp.	2 hours to > 30 months
Listeria spp.	1 day – months
Mycobacterium bovis	> 2 months
[illegible]	[illegible]
[illegible]	[illegible]
Proteus vulgaris	1 – 2 days
Pseudomonas aeruginosa	6 hours – 16 months; on dry floor: 5 weeks
Salmonella typhi	6 hours – 4 weeks
Salmonella typhimurium	10 days – 4.2 years
[illegible]	[illegible]
[illegible]	[illegible]
Shigella spp.	2 days – 5 months
Staphylococcus aureus, including MRSA	7 days – 7 months
Streptococcus pneumoniae	1 – 20 days
Streptococcus pyogenes	3 days – 6.5 months
Vibrio cholerae	1 – 7 days

The Challenges of Controlling HAI from the Environment[6,14]

1. Ubiquity of microbes in the environment
2. Resilience of bacteria on surfaces
3. Persistence of contamination
4. Approximately 50% of the items are cleaned properly at the time of terminal cleaning
5. No universally recognized standard for environmental cleanliness
    - Aerobic colony count from hand contact surface should be < 2.5 cfu/cm²
    - MRSA, C. diff, VRE should be <1cfu/cm²
6. Contribution of surface contamination to HAIs has not been well defined

What is Antimicrobial Copper?

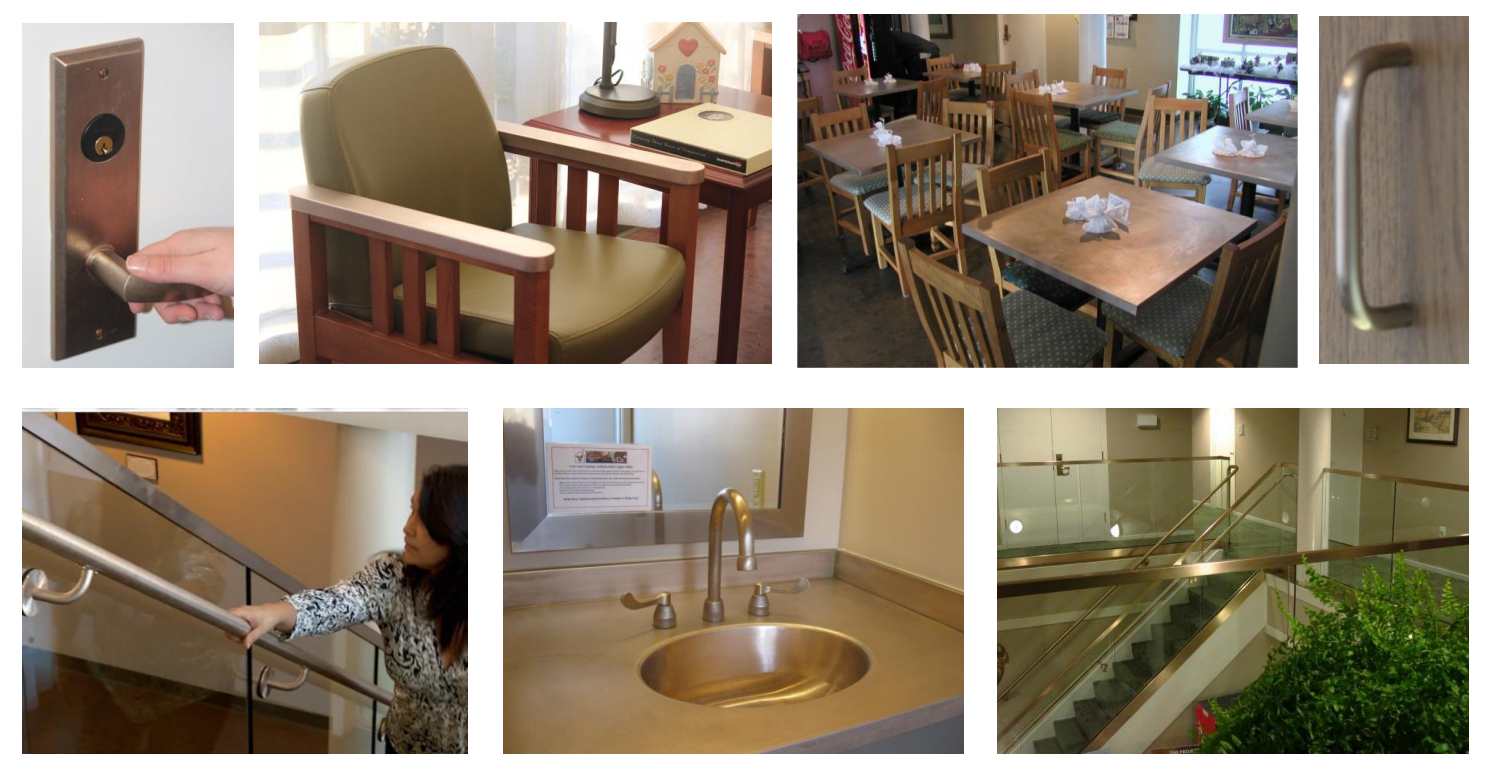


Not a coating, surface treatment, or embedded particles!"

EPA Registration of Copper Alloys[8]

- First solid materials registered with EPA to kill disease-causing bacteria*
    - Brass, bronze, copper nickel, nickel silver
- 6 disease causing bacteria:
    - Methicillin-Resistant *Staphylococcus aureus* (MRSA)
    - *E. coli* 0157:H7
    - *Enterobacter aerogenes*
    - *Pseudomonas aeruginosa*
    - *Vancomycin Resistant Enterococcus (VRE)*
    - *Staphylococcus aureus*
- Rigorous, independent and EPA audited performance testing
- Surfaces kill more than 99.9% of bacteria within 2 hours
- Materials offer continuous antimicrobial activity

Example Antimicrobial Copper Surfaces



OBJECTIVES:

The randomized, intention to treat based clinical trial was designed with the following objectives:

1) Quantify the inherent microbial burden found on common surfaces within the Intensive Care Units
2) Prioritize critical objects within the ICU based on average microbial burdens.
3) Investigate the antimicrobial properties of uncoated, metallic, copper-alloy surfaces strategically placed within the ICU.
4) Assess whether or not a lower environmental microbial burden on critical touch surfaces within an Intensive Care Unit results in a lower incidence of infection and/or colonization during hospitalization.

PROJECT OVERVIEW

In 2006, the U.S. Department of Defense funded a multi-center randomized, intention to treat based clinical trial to assess the ability of copper alloy materials to reduce microbial burden and the acquisition of infection during hospitalization. The study took place from 2007 to 2011 in the Medical Intensive Care Units (MICU) of three hospitals: The Ralph H. Johnson Veterans Affairs Medical Center and The Medical University of South Carolina (both in Charleston SC), and Memorial Sloan-Kettering Cancer Center (New York, NY).

The study was divided into three phases to assess the impact of copper surfaces at reducing microbial burden and HAI:

Clinical Trials Funded by US Dept. of Defense

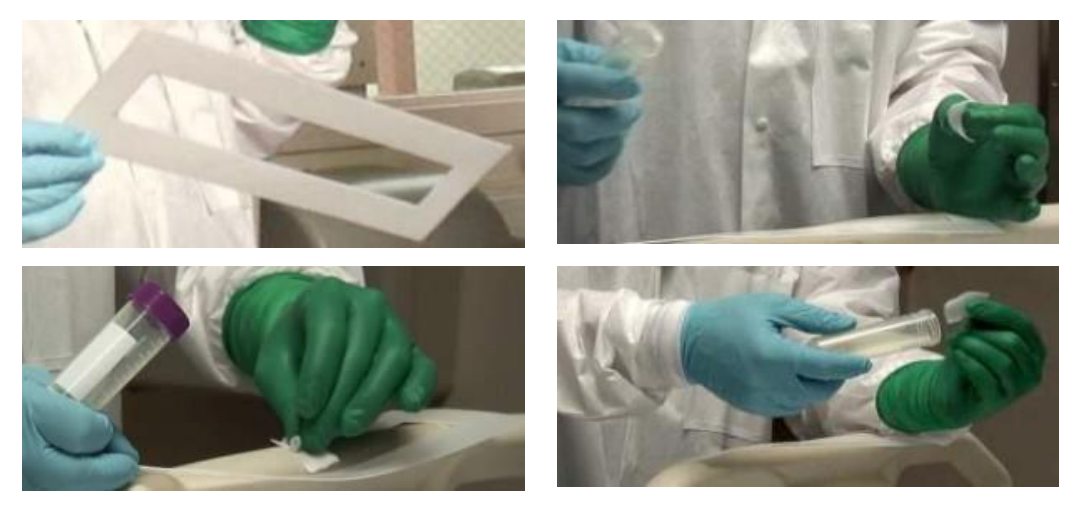
- Medical Intensive Care Units of three hospitals:
    - Memorial Sloan-Kettering Cancer Center (New York, NY)
    - Medical University of South Carolina (Charleston, SC)
    - Ralph H. Johnson VA Medical Center (Charleston, SC)

PHASE 1:

The inherent Microbial Burden (MB) on common objects throughout the ICUs of the three hospitals was quantified using an established method described below. Surfaces were cultured once each week for a collective total of 119 weeks for which baseline data were collected from approximately 6,500 surfaces. MB levels from Phase 1 were used to prioritize objects for conversion to copper alloy equivalents in Phase 2.

Phase 1: Sampling the built environment

- What surfaces are the most contaminated in the ICU?
- 11 surfaces in 16 rooms
- 100 cm² sterile templates placed over tested surfaces



PHASE 2:

Six items were selected to be replaced with copper items based on Phase 1 findings: bedrails, IV pole, over-bed tray table, visitor chair arms, nurse call device, and the data input device. Half of the study rooms in each facility were outfitted with these copper items for evaluation. The MB was monitored as before in control rooms as well as copper-outfitted rooms for an additional 83 weeks.[9-13]

Hospital Room with Antimicrobial Copper

PHASE 3:

Outcomes of patients treated in both copper and non-copper study rooms were measured to assess impact on acquisition of HAI and colonization during hospital stay. Environmental microbial burden data captured in Phase 2 was correlated against collected outcome data to assess risk. Statistical analysis and patient data collection methods are described in the following section.

What are the appropriate metrics needed to investigate HAI reduction from copper?

1. Numbers of HAI contracted during hospitalization in the ICU
2. Average Length of Stay
3. Acquisition of colonization by MRSA, VRE
4. APACHE-2 Score (Acute Physiology And Chronic Health Evaluation)
5. Number of re-admissions for any reason
6. Number of re-admissions for infection or complication

SAMPLING METHODS:

Six copper and equivalent non-copper objects (bed rails, overbed tray tables, chairs, call buttons, data devices, & IV poles) were sampled weekly from December 2007 to June 2011 and the associated microbial burden of each object was quantitatively assessed. Non-copper objects were made of plastic, metal (non-copper based), wood, or a composite material. The concentration of bacteria on each object was assessed by vigorously wiping a 10cm x 10cm area (side to side using 5 strokes) with a pre-moistened rayon/polyester sterile wipe. The wipe was placed in a sterile tube with 3ml of sterile PBS/LT. Bacteria were liberated from the wipe and were plated onto appropriate growth media.

CALCULATIONS AND STATISTICAL ANALYSIS:

The microbial burden (MB) was determined as Colony Forming Units (CFU) per 100cm². The MB of each room was calculated as the sum of the MB of the objects within that room. The median overall MB of a room was calculated as well as that of each object sampled. The MB due to total bacteria, Staphylococcus, MRSA, VRE, and gram negative organisms was calculated for each room and for each object. The efficacy of copper was calculated as the difference in median MB between the copper and non-copper objects and rooms.

PATIENT DATA COLLECTION:

The study was evaluated and approved by the respective Institutional Review Board of each institution as well as the Office of Risk Protection of the United States Army. De-identified patient data were collected from randomized patients assigned to either arm of the study. The principal outcome measured was whether or not they acquired an infection and/or were colonized with MRSA or VRE. The CDC/NHSN definition of an HAI was rigorously applied in assessing each outcome.

RESULTS AND LESSONS LEARNED

The limited application of EPA-registered antimicrobial copper surfaces within the built clinical environment resulted in an average 83% reduction to the bacterial burden on the following critical objects in the intensive care units at all three participating hospitals: bedrail, I.V. pole, over-bed tray table, visitor chair arms, nurse call device, and the data input device.[11]

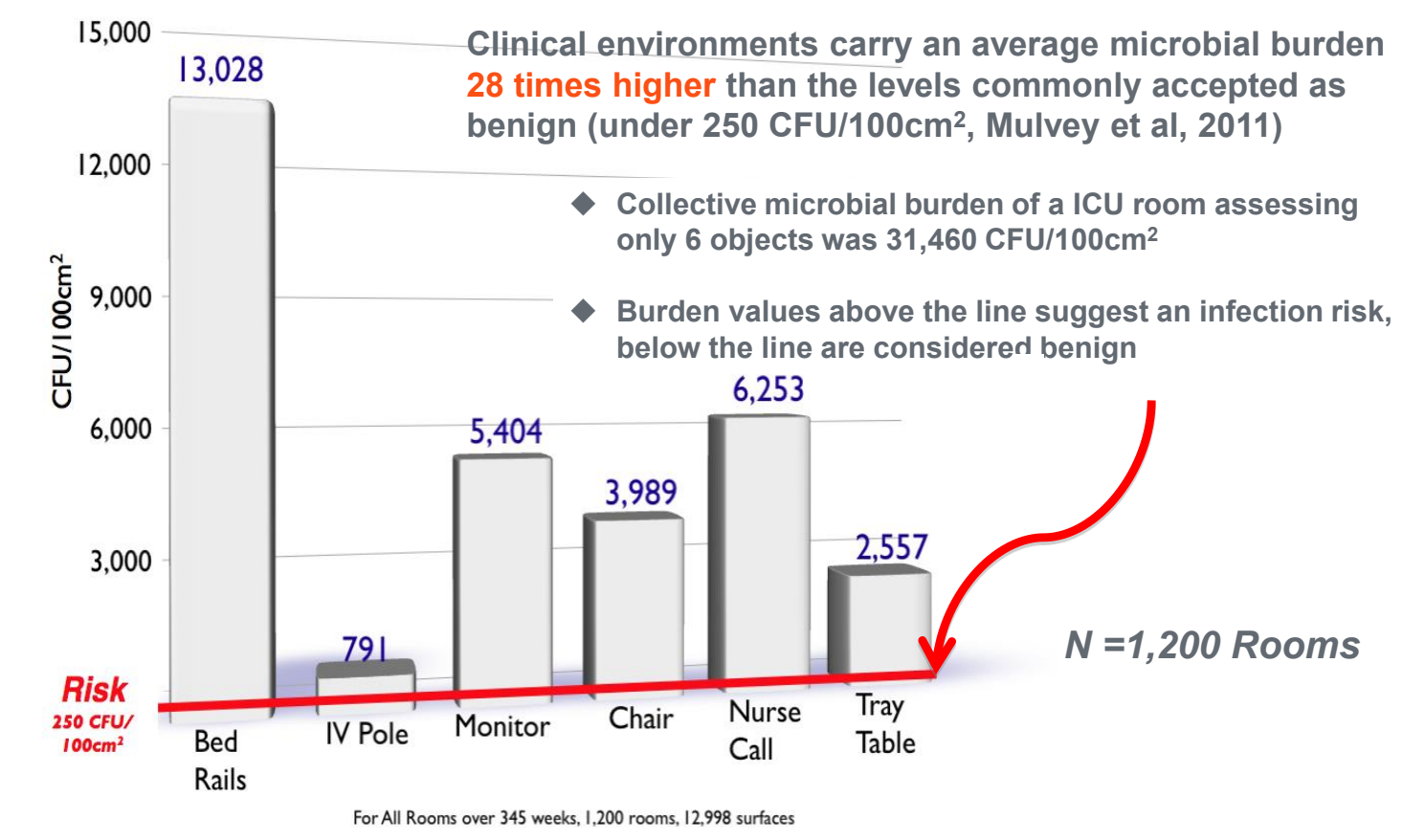
Installed copper surfaces consistently achieved the generally accepted terminal cleaning standard of 2.5 Aerobic Colony Forming Units/cm² during clinical care.[14]

MRSA was only isolated once from 3,384 copper surfaces. This translates to a 99.9% reduction vs. ICU control surfaces. (30 CFU/100 cm² vs. 29,029 CFU/100 cm²)

The lower microbial burden on these copper objects resulted in a 42 percent decrease in the incidence of HAI/or colonization by MRSA or VRE (p=.020). The decrease in the rate of HAIs only was 58 percent (p=.013).[12]

These findings suggest that the environment plays a substantial role in the contraction of HAI. Through the introduction of a continuously active antimicrobial solution, like metallic copper, it is possible to substantially lower the infection rate in the ICU. Nationally, the average HAI results in an additional 19 days of hospitalization and an additional $43,000 in costs.[15] Further investigation is warranted in order to fully realize the true potential of antimicrobial copper surfaces to enhance quality of care and improve patient outcomes in the ICU.

Phase 1 Results: Ubiquity of risk[11]



Clinical environments carry an average microbial burden **28 times higher** than the levels commonly accepted as benign (under 250 CFU/100cm², Mulvey et al, 2011)

◆ Collective microbial burden of a ICU room assessing only 6 objects was 31,460 CFU/100cm²

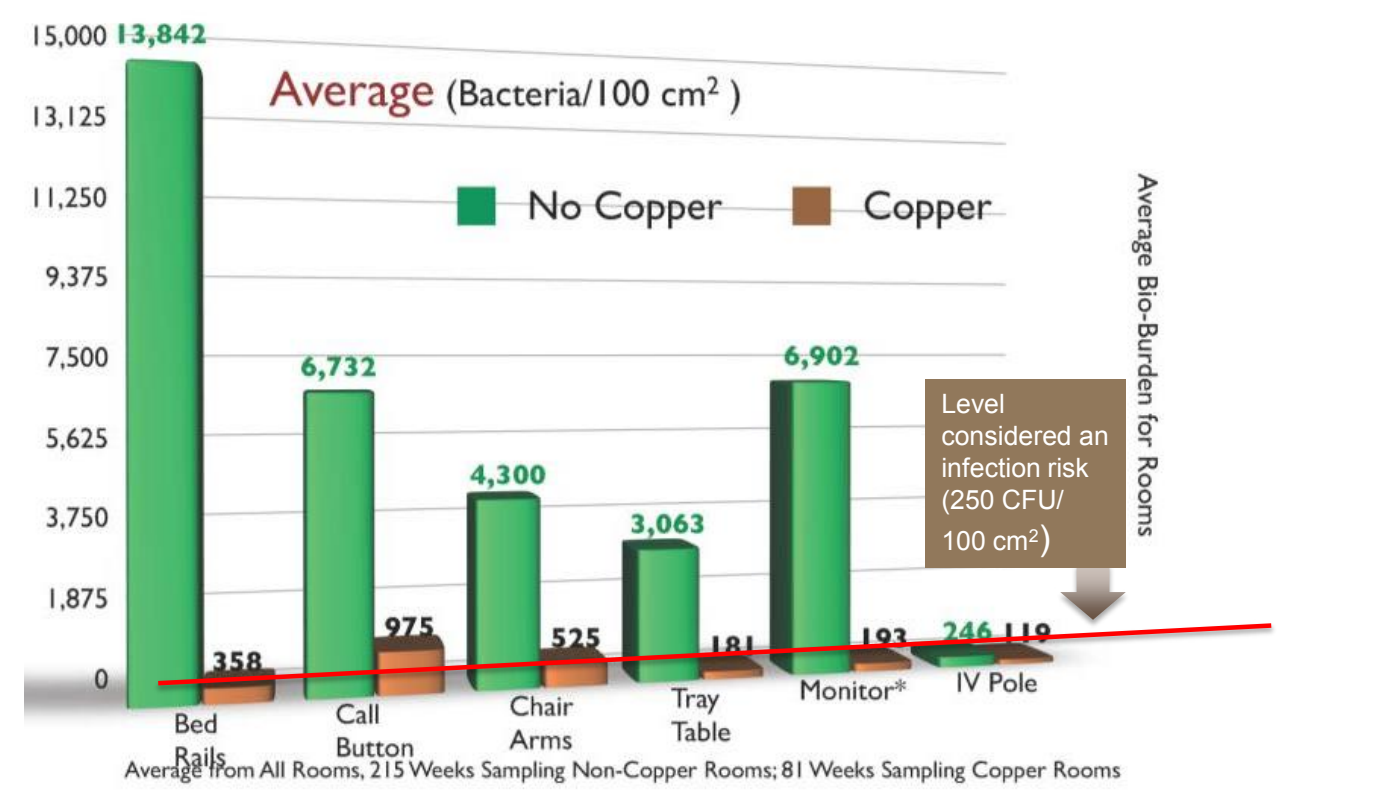
◆ Burden values above the line suggest an infection risk, below the line are considered benign

For All Rooms over 345 weeks, 1,200 rooms, 12,998 surfaces

Phase 1 Results: Principal observations

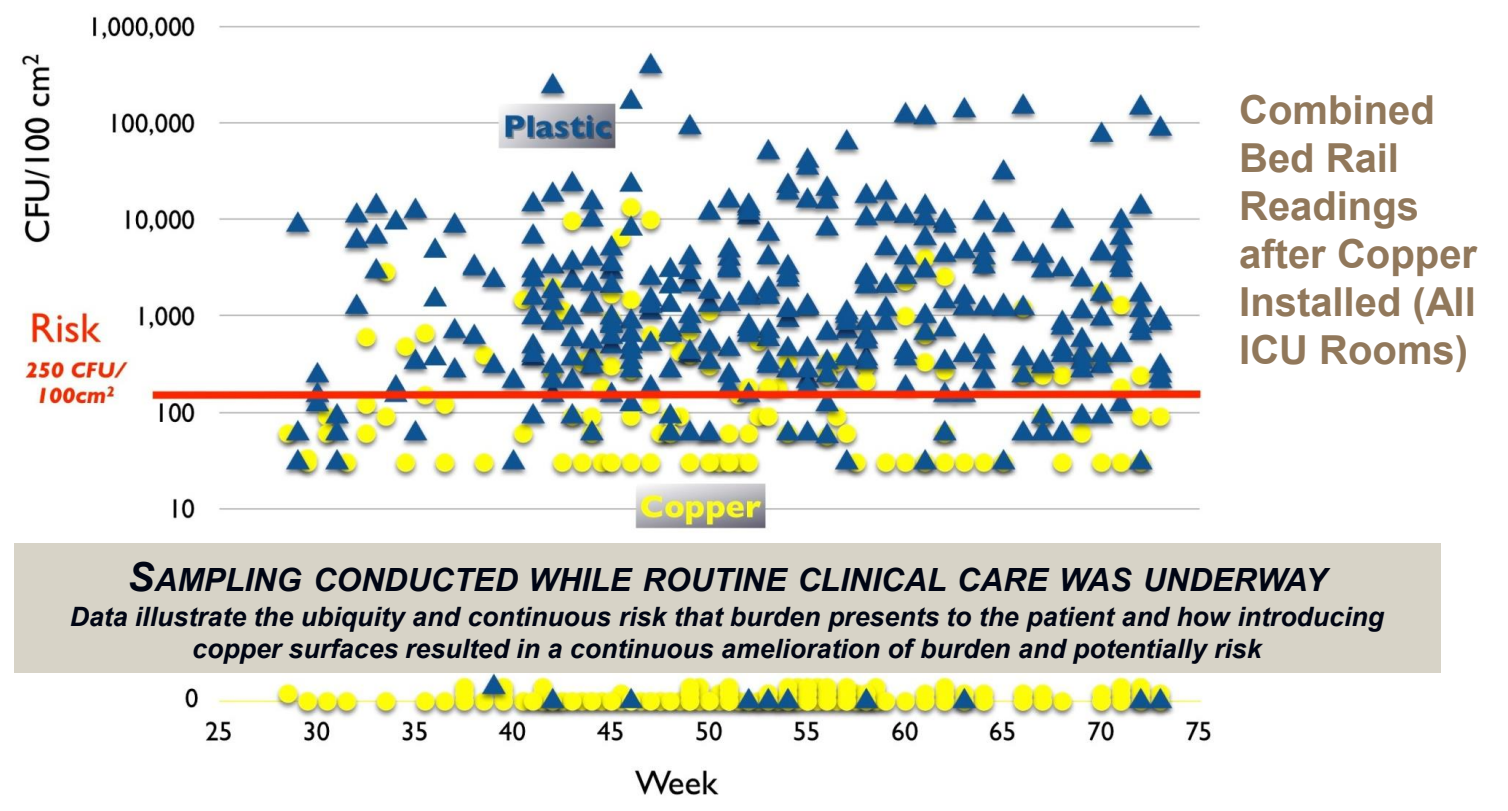
*Clinical environments carry an average microbial burden **28 times higher** than the levels commonly accepted as benign (under 250 CFU/100cm² – Mulvey, 2011)*

Phase 2 Results: Bacteria decreased by 83% on copper surfaces[11]



Average from All Rooms, 215 Weeks Sampling Non-Copper Rooms; 81 Weeks Sampling Copper Rooms

Phase 2 Results: Routine clinical care is heterogeneous, resulting in a heterogeneity of risk



SAMPLING CONDUCTED WHILE ROUTINE CLINICAL CARE WAS UNDERWAY

Data illustrate the ubiquity and continuous risk that burden presents to the patient and how introducing copper surfaces resulted in a continuous amelioration of burden and potentially risk

Phase 2 Results: Principal observations

*Copper surfaces consistently achieved the **terminal cleaning standard** of 2.5 Aerobic Colony Forming Units/cm² during clinical care[11]*

*MRSA was only isolated once from 3,384 copper surfaces… a **99.9% reduction** vs.*

ICU control surfaces. (30 CFU/100 cm² vs. 29,029 CFU/100 cm²)

Phase 3: Principal observations[12]

The HAI rate was significantly lower in rooms with copper items vs. control rooms[14]

Copper: 8.95 HAI per 1000 patient days

Control: 15.16 HAI per 1000 patient days

N = 564, 95% Confidence Interval, p=0.00003

Study Conclusions

- **Objects surfaced with copper consistently had bacterial burdens 83% less than equivalent non-copper objects which was below the recommended value of 2.5 CFU/cm²**
- **Limited placement of copper surfaces significantly reduced the rates of HAI and HAC in the ICU**
- **Built Environment likely accounts for at least 50% of the HAI in the ICU**
- **Use of Antimicrobial Copper surfaces represents the first instance where a passive, continuously active antimicrobial material was able to significantly reduce the rate of HAI**
- **Incorporation of copper into essential items within the built environment of hospitals offers a unique solution to control and limit HAIs in an efficient and cost effective manner**

ACKNOWLEDGEMENTS

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