Risk Mitigation of Hospital Acquired Infections Through the Use of Antimicrobial Copper Surfaces

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Introduction

Healthcare associated infections (HAI) result in significant patient morbidity and mortality. Each year, 2 million people contract a hospital-acquired infection; of those, 1 out of 20 die, or approximately 100,000[1]. In an ICU, the number is 1 out of 4. This is more than the number of people that die each year from HIV and breast cancer combined and enough to rank HAI's as the fourth leading cause of deaths in the U.S. In 2009, CMS stopped paying for the treatment of certain HAI's, meaning the costs to treat these infections would be paid by hospitals since the rules do not allow the hospital to charge patients.

Hospital-Acquired Infections

- 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
- CDC published study estimates HAI add 208% to hospital bill
- 2009-CMS prevents reimbursement for certain preventable conditions, mistakes & HAI
- 2012-CMS will incentivize non-rural acute care hospitals for lowering HAI rates with higher reimbursement rates

The contribution that pathogens from the environment provide to the incidence and rate with which HAI are contracted has not been well defined. High touch items commonly touched in the patient care setting have been shown to harbor significant concentrations of microorganisms in spite of aggressive hand hygiene campaigns and routine and terminal cleaning with EPA approved disinfectants. Frank pathogens such as *Staphylococcus aureus, Enterococcus, Clostridium difficile* can survive on environmental surfaces for substantial periods of time[2]. While cleaning methods can effectively remove pathogens from surfaces, studies have shown that more than half of the surfaces are not adequately terminally cleaned, and may become re-contaminated within minutes3. Other studies have shown that microbial surface contamination can be readily transmitted to the hands of staff or visitors who subsequently have direct contact with patients. The importance of hand washing in reducing the transmission of pathogens has been proven extensively. Compliance with hand washing mandates frequently fall short and even with an adherence level of 100% the risk of pathogen transmission is still present. Consequently there is ever present need to develop methods that will facilitate the continuous reduction of microorganisms on high touch surfaces in order to reduce microbial contamination and answer the role that pathogens from the environment provide to the incidence and rate with which HAI are contracted.

Persistence of Bacteria on Dry Surfaces[2]

Acinetobacter spp.	3 days to 5 months
C. difficile	5 months
Enterococcus spp.	5 days to 4 months
Staph aureus	7 days to 7 months

The inherent antimicrobial activity of copper surfaces offers an advantage to conventional cleaning, as bacterial reduction is continuous rather than episodic. Under laboratory conditions U.S. Environmental Protection Agency (EPA)-approved antimicrobial copper surfaces killed more than 99.9% of common viable bacteria within 2 hrs of exposure. Copper's antimicrobial efficacy against six pathogenic organisms was registered with EPA, much like the efficacy of hospital-grade disinfectants and sanitizers[4]. Other research has demonstrated copper's antimicrobial efficacy against a broad spectrum of pathogenic organisms; these studies have not been reviewed by EPA, but will be submitted for evaluation[5].

EPA Registration of Antimicrobial Copper

- Only 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*
- Registered after rigorous, independent and EPA audited performance testing
- Surfaces kill more than 99.9% of bacteria within 2 hours
- Materials offer continuous antimicrobial activity

The U.S. Department of Defense funded a multi-center study to assess the clinical performance of these antimicrobial materials. The study took place from 2006 to 2011 in the Medical Intensive Care Units (MICU) of three hospitals: The Ralph H. Johnson VA Medical Center and The Medical University of South Carolina (both in Charleston S.C.), and Memorial Sloan-Kettering Cancer Center (New York, NY). It was conducted in three phases. The first phase examined the levels of bacteria on six commonly touched objects within patient rooms. The second phase introduced copper objects into 8 of the 16 study rooms within the three MICU. The bacterial concentration on the copper objects was measured and compared to bacterial levels from simultaneously sampled equivalent non-copper objects. The third phase examined the rate with which HAI and colonization with MRSA and VRE was established for patients in either the copper or non-copper arm of the trial throughout the duration of the study, no changes were made to the manner by which any of the rooms were utilized or cleaned.

Clinical Trial Phases

1. Measure bacterial levels on frequently touched surfaces in ICU rooms
2. Introduce copper objects in randomly selected rooms, measure and compare bacterial levels on copper and non-copper objects
3. Examine Hospital-Acquired Infection rates for patients in rooms with copper objects vs. patients in rooms without copper objects

Objective

The objective of this study was to assess whether or not a lower environmental microbial burden on critical touch surfaces within an ICU would result in a lower risk of contracting an infection while being hospitalized in the ICU.

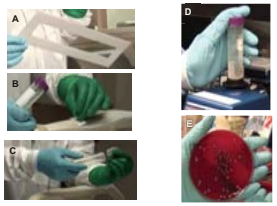
Description of the Project

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.

Sampling the Built Environment



Calculations and Statistical Analysis

The microbial burden (MB) was determined as colony forming units (cfu) per 100cm^2. 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.

Selection of Surfaces to Sample

Can solid copper and its alloys be effective in the reducing bacteria that cause infectious disease?

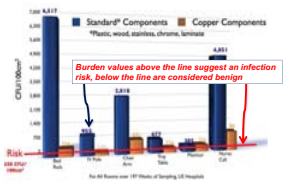
Copper Objects Introduced in ICU Rooms

Results

Phase I: Objects closest to patients had the highest microbial burden, while Staphylococcus aureus was the most common organism found[6].

- Bed rails averaged the highest concentrations
  - Total MB: 13,028 cfu/100cm^2
  - MRSA: 123 cfu/100cm^2 of MRSA …VRE: 500 cfu/100cm^2
- Other objects had lower total staph and MRSA.
  - Call button > Chair arms > Overbed tray table > Data input device > IV pole

After Intervention with Copper, Risk Mitigation



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: Copper surfaces reduced the MB on common touch surfaces in MICU's[7]. The reduction was significant and consistent. The median microbial burden on the copper objects was 98% lower than on the non-copper objects. This level of reduction approached the levels observed in the laboratory (i.e. 99.9%) where conditions are carefully controlled.

The reduction observed on copper surfaces routinely approached the targeted terminal cleaning levels. Additionally, copper surfaces frequently reduced the MB to levels below the benchmark which researchers consider to represent a significant risk of infection to patients[8], 250 cfu/100cm^2.

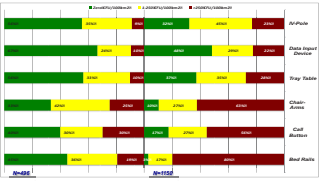
Methicillin-resistant Staphylococcus aureus (MRSA) was only isolated five times from the 3,610 copper objects that were sampled. The incidence level was 15 times higher on the non-copper objects.

Phase 3: The third phase of the trial concluded on June 14, 2011. The data are currently being analyzed. Additionally, critical outcome data are being evaluated by a team of independent, blinded, reviewers. Preliminary findings suggest that the limited placement of copper surfaces within the built ICU environment improved the HAI rates. The following preliminary observations have been made:

- **HAI rates for patients in rooms with copper objects were 40.4% lower** than for patients in rooms without copper objects (n=651, p=0.039).
- During the study, some of the beds with copper rails were displaced from their rooms. Phase one showed that the bedrails are the most contaminated objects within the rooms. It's believed that due to their proximity to patients, they have a very significant impact on patient outcomes. **Patients treated in rooms with copper objects and present in beds with copper rails (n=541) acquired 61.0% (p=0.006) fewer infections** than patients treated in rooms without copper objects.
- Throughout the study, several of the other mobile copper objects (IV poles and overbed tray tables) travelled into rooms without copper objects. **Patients treated in rooms with copper objects and in which all six copper objects never left the room (n=462) acquired 69.1% (p=0.008) fewer infections** than patients treated in rooms with no copper objects.

Frequency of Distribution of Microbial Burden on Study Objects

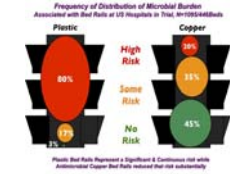
With Copper Without Copper



Copper reduced the microbial burden on commonly touched items in a clinical setting to levels below those considered to represent a risk while non-copper objects continue to represent a significant risk.

Take Home Message

Copper routinely achieves the terminal cleaning standard during routine clinical care, and mitigates the risk facilitated by care



Preliminary Results: Hospital-Acquired Infections Reduced

- ***40.4%* Fewer Infections** – Patients in rooms with copper objects vs. patients in room with non-copper objects; some copper objects travelled out of the room
  - *N=651, p=0.039*
- ***61.0%* Fewer Infections** – Patients that utilized beds with copper rails and stayed in rooms with other copper objects; some copper objects travelled out of the room
  - *N=541, p=0.006*
- ***69.1%* Fewer Infections** – Patients in rooms where copper objects never travelled out
  - *N=462, p=0.008*

Lessons Learned

Preliminary findings suggest that the built environment plays a substantial role in the contraction of HAIs likely accounting for at least 50% of the HAIs contracted in the MICU. The limited placement of a continuously active antimicrobial surface, metallic copper, facilitated a substantial reduction in the rate with which HAI were acquired in the MICU. Given that the average HAI in a US hospital results in an additional 19 days of hospitalization, an additional $43,000 in costs, which may have to be absorbed by hospitals, and increased deaths, the use of antimicrobial copper surfaces warrant consideration.

The use of antimicrobial copper surfaces represents the first instance where an infection control measure that does not require human intervention was able to significantly reduce the rate at which infections were contracted by hospitalized patients.

The domestic and international supply chain of antimicrobial surfaces is currently being developed. A portfolio of end-use products is currently available and many more are expected to reach the marketplace in the near future. Hospital owners and administrators can benefit by specifying products that utilize antimicrobial copper surfaces. The use of these products can potentially reduce operating costs and save lives.

Summary and Lessons Learned

- **Use of Antimicrobial Copper Surfaces represents the first instance where a passive, but continuously active antimicrobial material was able to significantly reduce the rate at which infections were contracted by hospitalized patients.**
- **Hospital acquired infections (HAI) result in a substantial loss of life and an additional cost to the US healthcare system of $45 billion dollars.**
- **Changes in CMS reimbursement policies for HAI treatment are affecting hospital profit margins.**
- **A reduction in the environmental bacterial levels resulted in a 40.4% reduction of the HAI rates for patients treated in rooms with antimicrobial copper touch surfaces.**
- **Thus, additional studies evaluating the critical and optimal placement of antimicrobial copper touch surfaces within the built environment is warranted.**
- **Incorporation of copper into essential items within the built environment of hospitals offers a unique solution to control and limit HAIs in a pragmatic and aesthetically satisfying way.**

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Published in-vitro laboratory tests demostrated that, when cleaned regularly, antimicrobial copper kills greater than 5 logs or 99.9% of the following bacteria within 2 hours of exposure: MRSA, Vancomycin- Resistant Enterococcus faecalis (VRE), Staphylococcus aureus, Enterobacter aerogenes, Pseudomonas aeruginosa, and E. coli O157:H7. Antimicrobial copper surfaces are a supplement to and not a substitute for standard infection control practices and have been shown to reduce microbial contamination. However, like other disinfectants and sanitizers, they do not necessarily prevent cross contamination; users must continue to follow all current infection c1ontrol practices.

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