A Randomized Controlled Trial of the Effect of Accelerated Copper Textiles on Healthcare-Associated Infections and Multidrug-Resistant Organisms: The "Investigating Microbial Pathogen Activity of Copper Textiles" (IMPACT) Study

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Background

- Healthcare-associated infections (HAIs) occur in as many as 10% of hospitalized patients and up to 75% are due to resistant organisms.
- Environmental surfaces are frequent reservoirs for pathogens causing HAIs including multidrug-resistant organisms (MDROs).
- Considerable variability in cleaning methods across institutions
- <50% of surfaces decontaminated by terminal room cleaning
- Copper is an essential trace element with antimicrobial properties
- Recent studies noted significantly lower concentrations of micro-organisms (including MDROs) on copper containing environmental hard surfaces (e.g., door handles) compared to control surfaces
- Few data on impact of copper on clinical outcomes (HAIs, MDROs)
- Results of past studies have conflicted. Some have noted reductions in MDROs with use of copper products while others have not.
- Past studies limited by focusing on unique populations; failure to control for differences in study groups ; and limited analyses.
- Studies have also varied considerably with regard to definitions of outcomes as well as whether MDROs were assessed as outcomes

Objective

- We conducted a randomized controlled trial (RCT) in medical and surgical ICU populations to determine the impact of use of CottonX™ accelerated copper textiles (CTs) on HAIs and MDROs.

Methods

- This randomized controlled trial (RCT) was conducted at the Hospital of the University of Pennsylvania , a 725-bed quaternary care center.
- Subjects enrolled in the Medical ICU (MICU), and Surgical ICU (SICU).
- The primary intervention was use of copper textiles (CTs) (CottonX™ accelerated copper linens, Argaman Technologies, Ltd.) in patient room.
- 4 products: 1) fitted sheet; 2) flat sheet; 3) pillowcase cover; 4) gown.
- Primary outcome of interest: development of a new HAI and/or MDRO.
- Any HAI or MDRO occurring between day three of the ICU stay through two days after ICU discharge was included
- All new MDROs were identified based on clinical cultures obtained as part of routine clinical care. MDROs were defined as one of the following: 1) methicillin-resistant Staphylococcus aureus (MRSA); 2) vancomycin-resistant enterococcus (VRE); 3) extended spectrum (third or fourth generation) cephalosporin-resistant Enterobacteriaceae (ESCR-EB); and 4) carbapenem-resistant Enterobacteriaceae (CRE).
- A subject could have more than one outcome during ICU stay.
- A subject could be included for distinct stays (or "episodes") in the ICU.
- Data included baseline variables and variables during follow up.
- Primary outcome was number of new HAIs and MDROs per 1000 patient days .Poisson regression model used to compare rates of events in the two study groups

Results

- Subjects enrolled from January 12, 2016 through July 31, 2016
- The 1,021 subjects accounted for 1,205 study episodes
  - 351 (29%) were in CT rooms, 854 (71%) were in non-CT rooms

Table 1. Baseline Variables in Copper Textile (CT) and non-CT Rooms

Variable	Copper (n = 351) No (%)	Non-Copper (n = 854) No (%)
Age, median years, (IQR)	62 (18.5)	61 (21)
Female sex, no. (%)	157 (45)	364 (43)
Non-White race, no. (%)	106 (33)	285 (36)
Length of stay prior to ICU, median days (IQR)	1 (5)	1 (4)
Recent antibiotic use[a], no. (%)	290 (83)	727 (85)
Presence of surgical wound (, no. (%)	127 (36)	262 (31)
Presence of open surgical wound, no. (%)	27 (7.7)	43 (5)
Presence of sacral decubitus ulcer, no. (%)	12 (3.4)	32 (3.7)
Presence of urinary catheter, no. (%)	237 (68)	551 (65)
Presence of central venous catheter, no. (%)	104 (30)	276 (32)
Presence of feeding tube, no. (%)	53 (15)	146 (17)
Presence of ventilator use or trach, no. (%)	119 (34)	329 (39)
Hepatic dysfunction, no. (%)	54 (15)	157 (18)
Diabetes mellitus, no. (%)	107 (31)	253 (30)
Renal dysfunction, no. (%)	58 (17)	148 (17)
Malignancy, no. (%)	126 (36)	292 (34)
Prior organ transplantation, no. (%)	39 (11)	121 (14)
HIV, no. (%)	2 (0.6)	9 (1)
APACHE II score, median score (IQR)	22 (13)	23 (14)

Table 2. Longitudinal Variables in Copper Textile (CT) and non-CT Rooms

Variable	Copper (n = 351) No (%)	Non-Copper (n = 854) No (%)
Comorbidities		
Surgical wound: open and closed (yes/no), no.(%)	127 (36)	262 (31)
Open surgical wound (yes/no), no. (%)	27 (7.7)	43 (5)
Fecal incontinence (yes/no), no. (%)	81 (23)	242 (28)
Urinary incontinence (yes/no), no. (%)	56 (16)	117 (14)
Diarrhea (yes/no), no. (%)	92 (26)	225 (26)
CHG bath (yes/no), no. (%)	263 (75)	624 (73)
Sacral decubitus ulcer (yes/no), no. (%)	12 (3.4)	32 (3.7)
Urinary catheter (yes/no), no. (%)	247 (70)	598 (70)
Central venous catheter (yes/no), no. (%)	115 (33)	319 (37)
Ventilator use or trach (yes/no), no. (%)	134 (38)	363 (43)
Feeding tube (yes/no), no. (%)	71 (20)	177 (21)
Rectal tube (yes/no), no. (%)	68 (19)	172 (20)
Antibiotic use (yes/no), no. (%)	276 (79)	670 (79)
Anti-CDI antibiotic use (yes/no), no. (%)	64 (18)	136 (16)
Immunosuppressive use (yes/no), no. (%)	125 (36)	289 (34)

- In the 1,205 study episodes, there were 108 outcomes.
  - 78 events that qualified as HAIs and 43 that qualified as MDROs
- **Overall (HAI + MDRO)** rates of outcome per 1000 patient days in the CT and non-CT groups were 11.7 and 15.4, respectively,
  - IRR (95%CI) = 0.76 (0.46, 1.19); p=0.22.
- When including only the **HAI outcome**, the rates of HAIs/1000 patient days in the CT and non-CT groups were 10.3 and 10.4, respectively
  - IRR (95%CI) = 0.99 (0.57, 1.64); p=0.97
- When including only **MDRO outcome**, rates of MDROs/1000 patient days in the CT and non-CT groups were 3.7 and 6.5, respectively
  - IRR (95%CI) = 0.57 (0.23, 1.26); p=0.15
- Secondary analyses showed similar results: 1) MICU v SICU; 2) Each subject only included once; 3) only the first outcome included

Conclusions

- Rates of the composite outcome (HAIs and/or MDROs) were ~25% lower with use of CTs, although difference not statistically significant.
- The lower composite rates in the CT group driven in large part by the incidence of new MDROs, which were over 40% lower in CT group.
- Findings were consistent among the various secondary analyses
- Future work in larger studies should further investigate the role of copper textiles in prevention of HAIs and particularly MDROs.

Limitations

- The study was underpowered to demonstrate significant differences.
  - Overall event rates lower than originally projected
- Intervention not blinded; while knowledge of room status could affect clinical practice, longitudinal variables which could reflect practice (e.g., antibiotic use, indwelling devices) were similar across groups.

Disclosure

Authors of this presentation have nothing to disclose concerning possible financial or personal conflicts of interest. This study has been approved by the Institutional Review Board of the University of Pennsylvania.

Acknowledgements

This work was supported by the CDC Cooperative Agreement FOA#CK000163 Epicenters for the Prevention of Healthcare Associated Infections (E.L.). Additional support was provided by the NIH grants K24-AI080942 (E.L.) and K01-AI103028 (J.H.H.). Argaman Technologies Ltd provided copper textile products for this study.

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