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## Original Article

# Efficacy of a continuously active disinfectant wipe on the environmental bioburden in the intensive care unit: A randomized controlled study

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### Abstract

Objective: To evaluate the efficacy of a new continuously active disinfectant (CAD) to decrease bioburden on high-touch environmental surfaces compared to a standard disinfectant in the intensive care unit.

Design: A single-blind randomized controlled trial with 1:1 allocation.

Setting: Medical intensive care unit (MICU) at an urban tertiary-care hospital.

Participants: Adult patients admitted to the MICU and on contact precautions.

Intervention: A new CAD wipe used for daily cleaning.

Methods: Samples were collected from 5 high-touch environmental surfaces before cleaning and at 1, 4, and 24 hours after cleaning. The primary outcome was the mean bioburden 24 hours after cleaning. The secondary outcome was the detection of any epidemiologically important pathogen (EIP) 24 hours after cleaning.

Results: In total, 843 environmental samples were collected from 43 unique patient rooms. At 24 hours, the mean bioburden recovered from the patient rooms cleaned with the new CAD wipe (intervention) was 52 CFU/mL, and the mean bioburden was 92 CFU/mL in the rooms cleaned the standard disinfectant (control). After log transformation for multivariable analysis, the mean difference in bioburden between the intervention and control arm was −0.59 (95% CI, −1.45 to 0.27). The odds of EIP detection were 14% lower in the rooms cleaned with the CAD wipe (OR, 0.86; 95% CI, 0.31–2.32).

Conclusions: The bacterial bioburden and odds of detection of EIPs were not statistically different in rooms cleaned with the CAD compared to the standard disinfectant after 24 hours. Although CAD technology appears promising in vitro, larger studies may be warranted to evaluate efficacy in clinical settings.

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In the United States, ~75,000 patients die in the hospital annually as a result of healthcare-associated infections (HAIs).[1] These infections contribute to significant morbidity, mortality, extended length of hospital stay, and costs to the healthcare system and the patient.[2,3] Most HAIs are caused by epidemiologically important pathogens (EIPs),[4] and it is now well established that the healthcare environment plays a crucial role in the transmission of EIPs.[5] Healthcare personnel may contaminate their hands by touching environmental surfaces, which can lead to the transmission of EIPs to patients.[6] Hence, effective surface disinfection remains a cornerstone to preventing transmission of EIPs and reducing HAI.[6]

Despite increasing evidence that disinfecting the environment can reduce the transmission of infectious pathogens, most surfaces in hospital settings are inadequately cleaned.[7–9] Though newer technologies, such as ultraviolet devices and hydrogen peroxide systems, are available to optimize terminal cleaning in patient rooms, there are challenges associated with the implementation of these approaches.[10] Furthermore, although surface disinfection reduces the bioburden, pathogens are repeatedly reintroduced onto a cleaned surface. Recontamination of environmental surfaces is multifactorial and could be affected by the prolonged survival of EIPs, suboptimal cleaning, the level of contamination of rooms related to pathogen shedding from both symptomatic and asymptomatic patients with EIPs, and suboptimal hand hygiene practices.[11,12] However, if daily cleaning can be done with a

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continuously active disinfectant (CAD) that remains active on the environmental surface for a longer duration by forming a multilayer protective shield, it has the potential to reduce the overall bioburden and prevent recontamination with EIPs.[13,14]

Although most studies evaluating CAD effectiveness have been performed in vitro, very few studies have been done in situ.[15–18] Some major limitations of the studies conducted in the clinical setting include the fact that patient-level variables were not assessed, and most were not randomized trials. We conducted a randomized controlled trial to study the efficacy of a new CAD compared to a standard disinfectant to reduce environmental bioburden in the intensive care unit (ICU) setting.

## Methods

### Study design and setting

We conducted a parallel randomized controlled trial with a 1:1 allocation ratio. The study was conducted in the medical intensive care unit (MICU), a 29-bed unit, at the University of Maryland Medical Center (UMMC), where a single patient occupies each room. The study was approved by the University of Maryland Institutional Review Board (IRB) as exempt from IRB review, and a waiver of informed consent was obtained from this IRB. Enrollment for the study took place between November 2021 and April 2022.

A room was eligible for inclusion in the study if the patient currently in the room was aged >18 years, admitted to the MICU, and on contact precautions. Patients with confirmed or suspected *Clostridioides difficile* infections or confirmed or suspected COVID-19 were excluded. Patients who were incarcerated or had a discharge or transfer from the MICU planned within the next 24 hours were also excluded.

During the study period, a daily list of eligible patients on contact precautions in the MICU was automatically generated from the hospital's electronic health record database based on the inclusion criteria. Eligible patients were randomized to the intervention arm or control arm using a pregenerated random allocation sequence. The random allocation sequence was implemented using a sequential number system, and the study arms were deidentified in the observation sheet and database during entries. All patients enrolled in the study were unique.

### Intervention

The new CAD used in the intervention group is a persistent, organosilane quaternary ammonium product and the first and currently the only Environmental Protection Agency (EPA)–registered surface disinfectant with 24 hours of sustained antimicrobial activity marketed by Professional Disposables International (Woodcliff Lake, NJ). Rooms assigned to the control group were cleaned with the standard disinfectant which in this case was an accelerated hydrogen peroxide product marketed by Diversey.

### Implementation

After a patient's room was randomized, the research staff placed signage on the door to remind healthcare personnel (HCP) to only use the wipes available in the room. To ensure consistency of product application and to standardize cleaning, the research staff thoroughly wiped down all 5 high-touch environmental surfaces using 1 wipe per surface. Environmental samples were then obtained from the 5 high-touch surfaces at 1, 4, and 24 hours after cleaning by the research staff. At each sampling time, the research staff also documented whether the correct wipes were in the room and whether any other wipes were present.

Based on previous work on the transmission of EIPs, the 5 high-touch environmental surfaces selected for sampling included (1) bed rails, (2) bedside table, (3) trash can, (4) sink, and (5) supply cart.[19,20] The samples were obtained using a sterile 25×25-cm (10×10-inch) stencil. Cellulose sponge sticks (3M, St. Paul, MN) with a neutralizing buffer that inactivates halogen disinfectants and quaternary ammonium compounds were used, and the CDC recommended technique for environmental surface sampling was followed.[21] In total, 20 swabs were obtained for each enrolled patient in the study (ie, 5 high-touch surfaces were sampled at 4 times).

### Study outcomes

The primary outcome was the mean bacterial (pathogenic and nonpathogenic) bioburden measured in CFU/mL from all 5 environmental high-touch surfaces at 24 hours. The secondary outcome was the detection of any one of the EIPs (ie, *Staphylococcus aureus* and methicillin-resistant *Staphylococcus aureus*, vancomycin-resistant *Enterococcus faecalis*, *Enterococcus faecium*, *Pseudomonas aeruginosa*, *Klebsiella peumoniae*, *Acinetobacter baumannii*, and *Enterobacter aerogenes*) from any of the 5 high-touch surfaces at 24 hours.

### Blinding

The laboratory team was blinded to the study arm, time of sampling, and the surface from where the samples were obtained. It was not feasible to blind research staff and frontline HCP since the 2 disinfectant wipes were of different sizes, textures, and smells.

### Microbiological methods

Each sponge was extracted using a stomacher for bacteria and plated on Pseudosel agar, Cetrimide agar, CHROMagar SA, Bile Esculin Azide agar with vancomycin, and MacConkey agar for identification of the specific pathogenic bacteria. Colonies were counted if growth was between 30 and 300 to calculate the average colony count, and the colonies were also subcultured in TSB enrichment media and incubated for 24 hours. Identification of the isolates was performed using the VITEK MS (bioMeriuex, France). On all isolates, the laboratory personnel performed susceptibilities using the appropriate Vitek antimicrobial susceptibility testing cards.

### Sample size

Sample size calculations were done a priori to determine the number of rooms necessary for adequate statistical power. Using 2 sample means, it was determined that at least 40 rooms were necessary to obtain power >80% to detect an effect size difference of 150 CFU/mL at 24 hours between the 2 study arms (accounting for a crossover of 5% and 2% loss to follow-up).[15]

### Statistical analysis

Results were analyzed on an intention-to-treat basis. We assessed statistical differences between the 2 groups using the $\chi^2$ test or Wilcoxon-Mann-Whitney test. The bioburden (CFU/mL) from the 5 high-touch surfaces was log-transformed (x+1) for the primary outcome analysis. A composite binary outcome variable of

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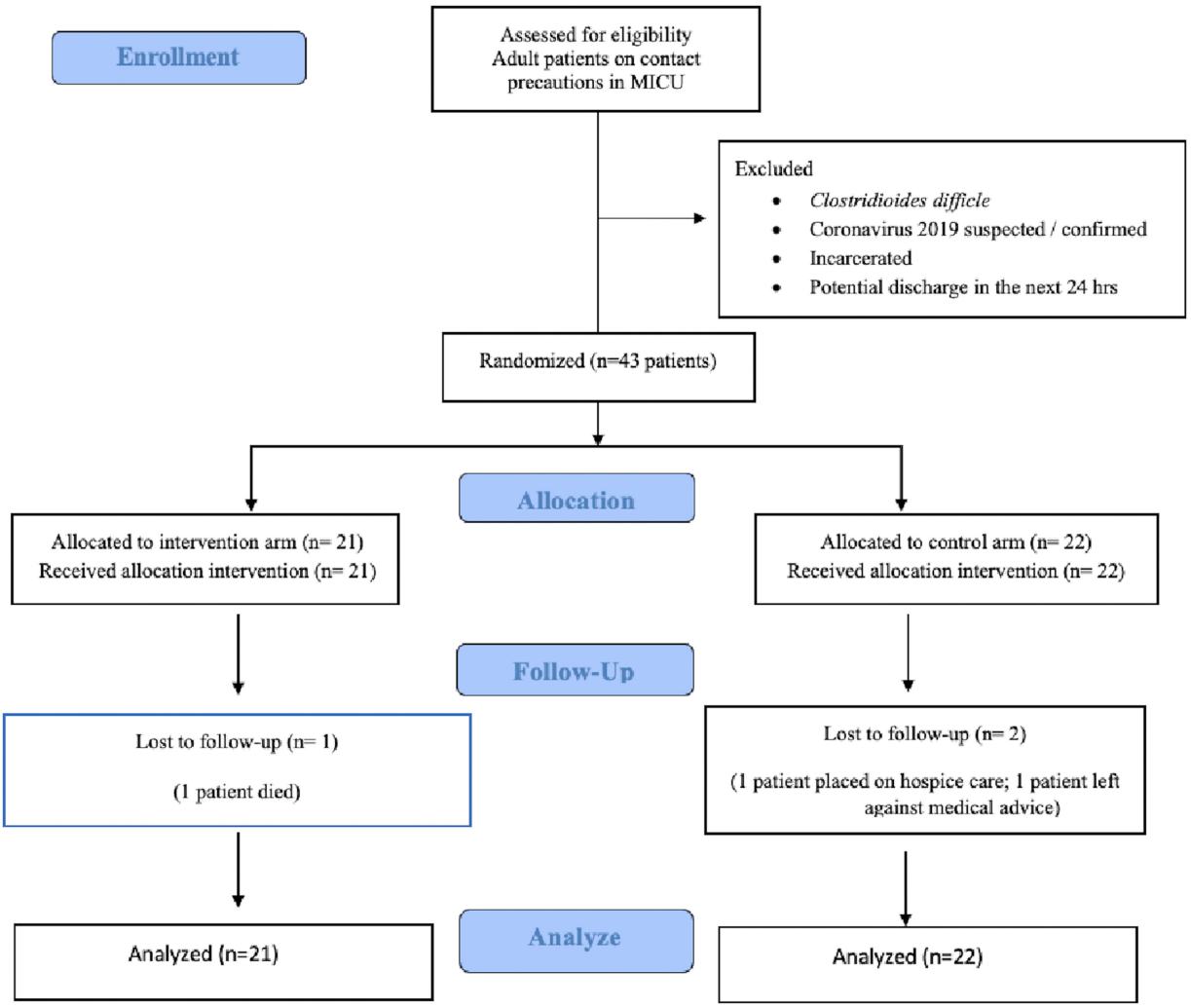


**Figure 1.** CONSORT flow diagram showing patient enrollment.

any detectable EIP on any of the 5 high-touch surfaces was created for the secondary outcome. We restricted our analyses to postcleaning samples at 1 hour, 4 hours, and 24 hours after cleaning. For the primary outcome, we used a general linear model for repeated measures with unstructured covariance to study the association between the log-transformed mean bioburden (CFU/mL) and the 2 disinfectants at 24 hours. For the secondary outcome, we used logistic regression to calculate the odds (OR) of EIP detection between the 2 disinfectants at 24 hours. All *P* values were 2-tailed, and analyses were performed using SAS version 9.4 software (SAS Institute, Cary NC).

## Results

We enrolled 43 patient rooms during the study period between November 2020 to April 2021; 21 patients were randomized to receive the new CAD and 22 patients were randomized to receive the standard disinfectant. In total, 843 samples were obtained during the study. Some samples from 3 patients (2 in the control arm, and 1 in the intervention arm) were missing as the patients were lost to follow-up (Fig. 1). Removal of the environmental markers from the environmental surfaces in the patients' room assessing the quality of cleaning by the environmental services staff was not significantly different between the new disinfectant and the standard disinfectant (41% vs 40%). To ensure standardized application of the assigned disinfectant to the environmental surfaces studied, research staff recleaned each surface until 100% of the environmental markers were removed. As illustrated in Table 1, the baseline characteristics of patients enrolled in the study were similar between the 2 study arms.

### *Primary outcome*

Figure 2 illustrates the overall mean bioburden for each sampling time by study arm. At all sampling times, the mean bioburden in the intervention arm was lower than in the control arm. At 24 hours, the mean bioburden recovered in the intervention arm was 52.0 CFU/mL (95% CI, 46.1–184.9) and was 92.0 CFU/mL (95% CI, 27.9–95.6) in the control arm. As shown in Figure 3, the mean bioburden was also lower in the intervention arm on 3 of 5 high-touch environmental surfaces. Table 2 shows the results of the multivariable analysis and suggests that the mean difference of the overall bioburden between the intervention arm and control arm was −0.59 (95% CI, −1.45 to 0.27).

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**Table 1.** Baseline Characteristics of Unique Medical Intensive Care Unit Patients (n=43)

| Characteristic | Total (n=43), No. (%) | Intervention (n=21), No. (%) | Control (n=22), No. (%) | *P* Value[a] |
|---|---|---|---|---|
| Age, mean y (SD) | 57 (16) | 57 (16) | 60 (16) | .53 |
| Sex, male | 25 (58) | 13 (62) | 12 (55) | .62 |
| Length of stay, median d (IQR)[b] | 11 (4–27) | 8 (3–23) | 16 (7–29) | .20 |
| Unweighted Elixhauser score, median (IQR)[c] | 6 (4–8) | 7 (5–7) | 5 (4–8) | .56 |
| **Clinical characteristics of patients[d]** | | | | |
| Wound | 37 (86) | 19 (91) | 18 (82) | .41 |
| Central venous catheter | 34 (80) | 16 (76) | 18 (82) | .65 |
| Endotracheal tube/tracheostomy | 34 (79) | 16 (76) | 18 (82) | .65 |
| Surgical drains | 13 (30) | 5 (24) | 8 (36) | .37 |
| Feeding tubes | 34 (79) | 15 (71) | 19 (86) | .23 |
| Indwelling urinary catheter | 31 (72) | 13 (62) | 18 (82) | .15 |
| **Infection status at time of enrollment[e]** | | | | |
| Current colonization | 15 (35) | 7 (33) | 8 (36.4) | .83 |
| Current infection | 18 (42) | 7 (33) | 11 (50.0) | .27 |
| Past colonization or infection | 10 (23.3) | 7 (33) | 3 (13.6) | .16 |
| **Culture source** | | | | |
| Clinical cultures | 28 (65) | 13 (62) | 15 (68) | .66 |
| Surveillance cultures | 22 (52) | 12 (57) | 10 (45) | .44 |
| **EIPs at time of enrollment[f]** | | | | |
| Methicillin-resistant *Staphylococcus aureus* | 11 (26) | 7 (33) | 4 (18.2) | .31 |
| *Pseudomonas aeruginosa* | 8 (19) | 4 (19) | 4 (19.1) | 1.00 |
| *Enterococcus* | 8 (19) | 4 (20) | 4 (18.2) | 1.00 |
| *Acinetobacter baumanni* | 2 (5) | 0 | 2 (9.1) | .48 |
| *Klebsiella pneumoniae* | 2 (9) | 2 (9) | 2 (9.3) | 1.00 |
| *Burkholderia gladioli* | 1 (2) | 0 | 1 (4.6) | 1.00 |
| *Burkholderia vietnamiensis* | 1 (2) | 1(5) | 0 | .48 |
| *Escherichia coli* | 1 (2) | 0 | 1 (4.6) | .32 |
| *Enterococcus cloacae* | 2 (5) | 1 (5) | 1 (4.6) | 1.00 |
| *Klebsiella aerogenes* | 1 (2) | 0 | 1 (4.6) | 1.00 |
| *Proteus mirabilis* | 3 (7) | 1 (5) | 2 (9.1) | 1.00 |

[a]*P* value obtained using the $\chi^2$ test or Fisher exact test when cell count <5 for categorical variables and using the Wilcoxon-Mann-Whitney test or Student *t* test for continuous variables.
[b]Length of stay in days on the day of enrollment calculated by subtracting date of enrollment from date of admission.
[c]Comorbidities present at the time of current admission. Obtained using *International Classification of Disease, Tenth Revision, Clinical Modification* (ICD-10-CM) codes and standardized Agency for Healthcare Research and Quality (AHRQ) software to obtain the Elixhauser score.
[d]Characteristics documented during current admission.
[e]Current colonization, positive surveillance culture during current admission; past colonization or infection, positive surveillance culture from a previous admission and negative during current admission; current infection, positive clinical culture during current admission.
[f]Organism identified from clinical and/or surveillance culture during current admission.

### *Secondary outcome*

Of the 843 samples analyzed, 57 (6.7%) had EIPs identified. Of 627 postcleaning samples, 38 (6.1%) EIPs were identified: 23 (3.7%) in the control arm and 15 (2.4%) in the intervention arm. At 24 hours, EIPs were identified on 17 (8.4%) of 202 samples: 8 (47.1%) from the intervention arm and 9 (52.9%) from the control arm ($P = .80$). Table 3 shows the distribution of the EIPs by study arm. Figure 4 shows EIPs detected by high-touch environmental surface at 24 hours. Multivariable models showed that the odds of EIP detection were 14% lower in the rooms cleaned with the intervention wipe compared to those cleaned with the standard wipe (OR, 0.86; 95% CI, 0.31–2.32; $P = .76$), though not statistically significant.

## Discussion

In this randomized controlled trial conducted in an ICU, we observed a 0.59 CFU/mL lower mean bioburden in the rooms cleaned with the new CAD compared to the standard disinfectant. Given that the 95% confidence interval ranged from −1.45 to 0.27,

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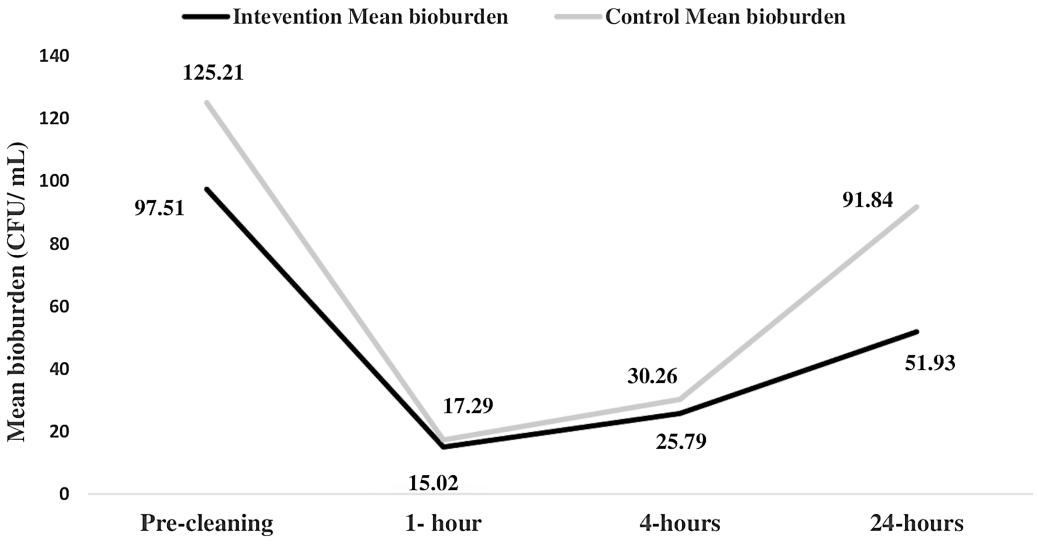


**Figure 2.** Distribution of mean bioburden (CFU/mL) by time points stratified by study arm.

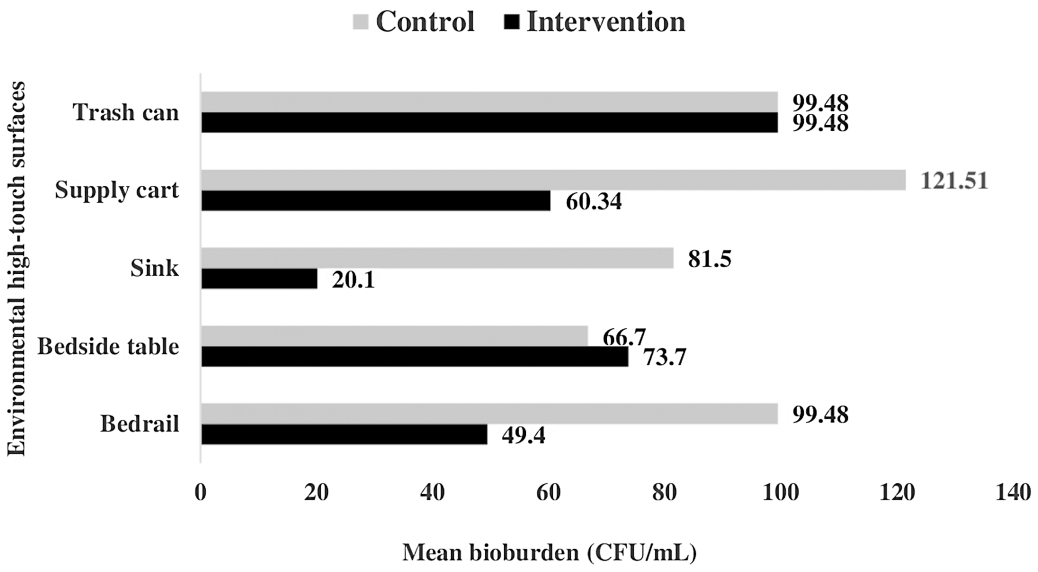


**Figure 3.** Distribution of mean bioburdn (CFU/mL) stratified by environmental high-touch surface and study arm at 24-hour timepont.

the mean bioburden may be 1.45 CFU/mL less in the rooms cleaned with CAD but also could be 27 CFU/mL higher in the rooms cleaned with the standard disinfectant. Similarly, while there were lower odds of EIP recovery from the rooms cleaned with the new CAD in comparison to the control disinfectant at 24 hours, this was not statistically significant.

The CAD product used in this study showed persistent decrease of bioburden in previously published studies. A study by Schmidt et al[15] compared the CAD to 2 other disinfectants. This study was a nonrandomized, prospective, cohort study performed on a convenience sample of ICU patients, and the product was tested on a single high-touch surface (bed rail). Although each disinfectant was able to significantly reduce bioburden for the first hour, the CAD was associated with a significantly lower bioburden at 6 hours and 24 hours after cleaning.[15] Tamimi et al[17] performed a before-and-after intervention study with no control group. This study was performed in an ICU where high-touch and non-high touch surfaces were cultured before application and then at 1, 2, 4, 8, and 15 weeks after application of an organosilane-based quaternary ammonium compound. These researchers concluded that the average bacterial count on all treated surfaces was reduced by > 99% (2 logs) for at least 8 weeks after treatment. Antibiotic-resistant bacteria were found on 25% of the sites tested before treatment but were isolated at only 1 site during the 15 weeks after treatment.[17] Ellingson et al[22] also reported a decrease in environmental bioburden and a decrease in HAIs in six non-randomly selected units in 2 hospitals after application of a quaternary ammonium antimicrobial surface coating. The differences between the results presented here and prior studies may be ascribed to variations in study methodology, population, comparison groups, sampling techniques, surfaces sampled, and laboratory procedures.

Compared with previously published in vitro studies in which the CAD was effective in lowering environmental bioburden, we did not find similar results in a real-world clinical setting.[14,23] Some postulated explanations for these discordant findings are (1) unintentional removal of CAD by HCP (using soap or other wipes) during patient care activities; (2) heterogeneity of the material

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**Table 2.** Mean Difference in Bioburden (CFU/mL) Between Intervention and Control Arms

| Environmental Surface | Mean Difference in Bioburden (CFU/mL)[a] | 95% Confidence Interval |
|---|---|---|
| Overall | −0.59 | −1.45 to 0.27 |
| Bed rail | −0.76 | −2.07 to 0.55 |
| Bedside table | −0.07 | −1.60 to 1.46 |
| Supply cart | −0.70 | −2.11 to 0.71 |
| Sink | −1.48 | −2.68 to −0.28 |
| Trash can | −0.002 | −1.14 to 1.13 |

[a]Reference, control disinfectant, log (x+1) transformed.

**Table 3.** Distribution of Epidemiologically Important Pathogens (EIPs) detected on environmental surfaces sampled (n=843)

| | Before Cleaning (n=216) | | | 1 Hour After Cleaning (n=215) | | | 4 Hours After Cleaning (n=210) | | | 24 Hours After Cleaning (n=202) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| EIP | Intervention (n=105) | Control (n=111) | *P* Value[a] | Intervention (n=105) | Control (n=110) | *P* Value[a] | Intervention (n=105) | Control (n=105) | *P* Value[a] | Intervention (n=102) | Control (n=100) | *P* Value[a] |
| **Any EIP[b]** | 8 (7.6) | 11 (9.9) | .55 | 1 (0.9) | 4 (3.6) | .36 | 6 (5.7) | 10 (9.5) | .30 | 8 (7.8) | 9 (9.0) | .76 |
| MSSA | 0 | 5 (4.5) | .06 | 0 | 4 (3.6) | .12 | 3 (2.9) | 7 (6.7) | .33 | 2 (2.0) | 7 (7.0) | .09 |
| MRSA | 3 (2.9) | 1 (0.9) | .36 | 1 (0.9) | 0 | .48 | 2 (1.9) | 1 (0.9) | 1.00 | 2 (2.0) | 0 | .50 |
| *E. faecium* | 3 (2.9) | 0 | .11 | 0 | 0 | . . . | 0 | 2 (1.9) | .50 | 0 | 2 (2.0) | .24 |
| *K. pneumoniae* | 1 (0.9) | 3 (2.7) | .62 | 0 | 0 | . . . | 1 (0.9) | 0 | 1.00 | 2 (2.0) | 0 | .50 |
| *E. faecalis* | 0 | 2 (1.8) | .50 | 0 | 0 | . . . | 0 | 0 | . . . | 0 | 0 | . . . |
| *A. baumanni* | 0 | 0 | . . . | 0 | 0 | . . . | 0 | 0 | . . . | 2 (2.0) | 0 | .50 |
| *P. aeruginosa* | 1 (0.9) | 0 | .48 | 0 | 0 | . . . | 0 | 0 | . . . | 0 | 0 | . . . |

Note. MRSA, methicillin-resistant *Staphylococcus aureus*; MSSA, methicillin-sensitive *Staphylococcus aureus*; *E. faecium*, *Enterococcus faecium*; *K. pneumoniae*, *Klebsiella pneumoniae*); *E. faecalis*, *Enterococcus faecalis*; *A. baumannii*, *Acinetobacter baumanni*; *P. aeruginosa*, *Pseudomonas aeruginosa*.
[a]*P* values obtained using the $\chi^2$ test or Fisher exact test.
[b]If any one of the specific pathogens were detected.

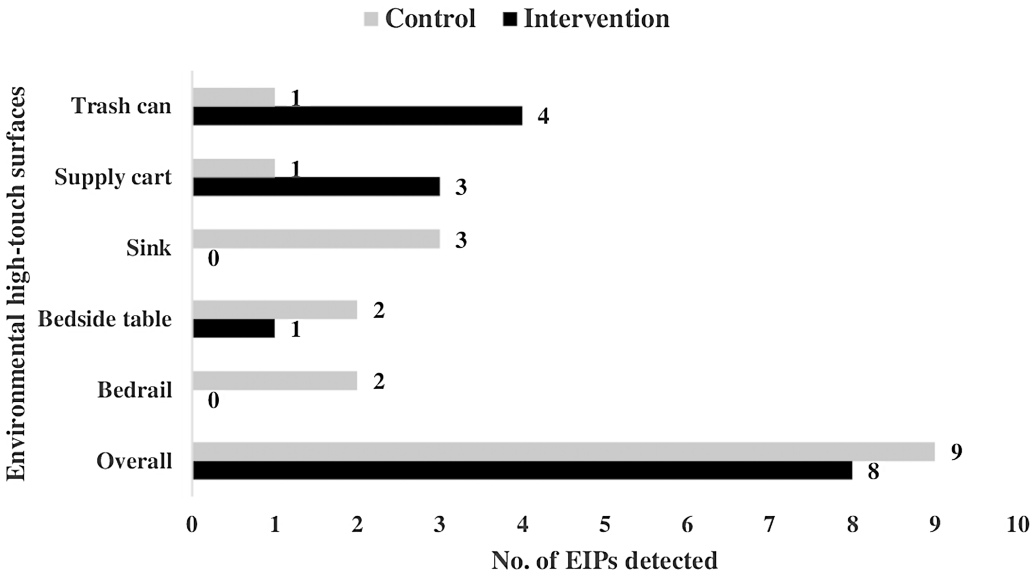


**Figure 4.** Distribution of EIP stratified by environmental high-touch surfaces and study arms at 24 hour timepoint.

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composition of surfaces sampled; (3) uniform product application using the applicator in the laboratory environment compared to nonuniform application in real-world settings; and (4) more frequent recontamination of surfaces.

A major strength of this study was the randomized controlled trial design, which ensured exchangeability between the 2 study groups. Standardization of the cleaning in both arms of the trial was also ensured by having the research staff wipe down the environmental high-touch surfaces and the quality of cleaning was documented using environmental markers. Finally, patient-level variables were included in the analyses.

This study also had several limitations. It is possible that the study was underpowered. The observed effect sizes were smaller than those reported in a previous study that was used to inform parameters included in our power calculations. However, little is known about the effect size that is clinically meaningful to reduce bioburden on high-touch environmental surfaces in the clinical setting. In addition, our sample size calculation was based on a prior study evaluating a CAD on a single environmental surface. The generalizability of our results may be limited because enrollment was performed only in 1 unit. Finally, it is possible that crossover of cleaning products may have occurred because we were unable to monitor cleaning in the rooms throughout the full 24-hour period. However, at all data collection times, the research staff did not observe any deviations from study arm assignment. The research staff and other HCP were not blinded to the disinfectant; however, the laboratory personnel were blinded to the study arm, surface, and time they received the swabs.

In this randomized controlled trial, we evaluated the efficacy of a new CAD. The intervention was associated with a lower mean bioburden and a decreased detection of EIP compared to the standard disinfectant; however, the results were not statistically significant. Although the positive effect of the CAD in in vitro studies has been well established, larger multicenter randomized trials in the healthcare setting may be warranted to more accurately estimate the effect size and potential benefits of novel disinfectants with sustained activity to aid in the ongoing quest to limit the transmission of infectious diseases in healthcare settings.

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**Competing interests.** All authors report no conflicts of interest relevant to this article.

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