ORIGINAL ARTICLE

Evaluating a New Paradigm for Comparing Surface Disinfection in Clinical Practice

Philip C. Carling, MD;[1] Jennifer Perkins, BA, MBA;[2] JoAnn Ferguson, RN, BAN;[2] Anita Thomasser, BS[3]

BACKGROUND. Despite an increasing understanding of the importance of near-patient surfaces in the transmission of healthcare-associated pathogens, there remains a need to define the relative clinical effectiveness of disinfection interventions.

DESIGN. A serial 2-phase evaluation of the clinical effectiveness of 2 surface disinfectants.

SETTING. A general acute care hospital.

METHODS. A unique system for quantifying bioburden reduction while monitoring the possible impact of differences in cleaning thoroughness was used to compare the clinical effectiveness of a traditional quaternary ammonium compound (QAC) and a novel peracetic acid/hydrogen peroxide disinfectant (ND) as part of terminal room cleaning.

RESULTS. As a result of QAC cleaning, 93 (40%) of 237 cleaned surfaces confirmed by fluorescent marker (DAZO) removal were found to have complete removal of aerobic bioburden. During the ND phase of the study, bioburden was removed from 211 (77%) of 274 cleaned surfaces. Because there was no difference in the thoroughness of cleaning with either disinfectant (65.3% and 66.4%), the significant ($P < .0001$) difference in bioburden reduction can be attributed to better cleaning efficacy with the ND.

CONCLUSIONS. In the context of the study design, the ND was 1.93 times more effective in removing bacterial burden than the QAC ($P < .0001$). Furthermore, the study design represents a new research paradigm in which 2 interventions can be compared by concomitantly and objectively analyzing both the product and process variables in a manner that can be used to define the relative effectiveness of all disinfection cleaning interventions.

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Over the past several years, the importance of the near-patient surface environment in the transmission of healthcare-associated pathogens has become clear,[1-3] with an evolving clarification of both epidemiologic and interventional factors related to healthcare-associated pathogen transmission from environmental surfaces. However, there remains a substantial need to better understand the clinical effectiveness and magnitude of infection prevention derived from cleaning practices, disinfectants, application methods, and evolving technological systems.[4,5] Unfortunately, there are no studies that compare the relative effectiveness of various interventions with respect to surface disinfection interventions that can be used for evidenced-based guidance in deciding which interventions should be used in various clinical settings.

Environmental hygiene standards have long mandated the use of US Environmental Protection Agency (EPA)–approved disinfectants for the disinfection of surfaces that harbor and transmit pathogens.[6] Although the EPA process for evaluating the intrinsic efficacy of disinfectants in terms of their bactericidal, viracidal, and sporicidal efficacy provides the basis for EPA certification labeling, actual assessment of clinical effectiveness is not used as part of the approval process.[6] Although the effectiveness of different disinfectants in their ability to kill specific pathogens can be determined by in vitro studies, this report represents a new model for head-to-head evaluation of the relative bactericidal effectiveness of 2 different disinfectants on clinical surfaces, which has the potential for being used to clinically compare all interventions related to surface cleaning and disinfection in a range of healthcare settings.

METHODS

The 2 disinfectants studied were an EPA-registered quaternary ammonium compound-based disinfectant (QAC; Ecolab) and a novel EPA-registered sporicidal disinfectant (ND) with peracetic acid/hydrogen peroxide as the active ingredients (OxyCide; Ecolab). The disinfectants were evaluated in 48 rooms in an intensive care unit and related step-down unit as part of routine discharge cleaning. Each disinfectant was

Affiliations: 1. Carney Hospital and Boston University School of Medicine, Boston, Massachusetts; 2. Maple Grove Hospital, Maple Grove, Minnesota; 3. Ecolab, St. Paul, Minnesota.

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evaluated in an opportunity sample of rooms over 2 weeks several months apart to decrease the risk of a Hawthorne effect. Twelve high-touch surfaces were evaluated on the basis of recommendations in the Centers for Disease Control and Prevention (CDC) toolkit "Options for Evaluating Environmental Cleaning"[7] and included room inner door, bed rail, call button, telephone, tray table, room chair, bathroom inner door, bathroom light switch, bathroom sink, bathroom grab bar, toilet handle, and toilet seat. Each disinfectant was diluted as recommended by the manufacturer and applied using a cloth presaturated with disinfectant. The cleaning staff was trained on the safety information and instructions for use for the new disinfectant but received no guidance on cleaning process or practices.

Before cleaning each room, the 12 surfaces were concurrently marked with an invisible fluorescent marker (DAZO; Ecolab) and cultured for aerobic bacteria on an adjacent surface to the left of the fluorescent marker using an agar dip slide (10 cm^2 surface area) with neutralizer (BT2N; Russell Mainstream Supply; Figure 1). The slides were incubated for 24 hours, and the total aerobic colony count was determined by the test site microbiology laboratory, which was not provided information regarding the basis for the cultures. Following room cleaning, a black light was used to determine whether the fluorescent marker had been completely removed (the surface was cleaned) as previously described,[8] and a second dip slide culture of the surface adjacent and to the right of the fluorescent marker site was obtained and processed (Figure 2).

Culture results were recorded as the absolute number of aerobic colonies per slide after incubation (colony-forming units [CFU]/10 cm^2). Surfaces that had no detectable aerobic bacteria before cleaning were excluded from additional analysis, because the effectiveness of the disinfectant on such a surface could not be evaluated. Surfaces that had been overlooked during cleaning as evidenced by the persistence of the fluorescent marker were tabulated to determine the thoroughness of cleaning in each phase of the study. Only surfaces with no detectable bacterial burden (0 CFU) after documented cleaning were defined as effectively cleaned. Statistical analysis used a contingency table and Fisher exact test to evaluate the effectiveness of bacterial burden elimination. Overall thoroughness of cleaning and evaluation of relative preintervention bacterial burden were evaluated using an unpaired Student *t* test (GraphPad Instat, version 3.0).

RESULTS

A total of 571 surfaces were evaluated before and after cleaning. Of these, 60 (10.5%) had no measurable bacterial burden using the dip slide method before cleaning and were not evaluated further. The median precleaning bioburden was greater for QAC study surfaces (median, 17 CFU/slide) compared with ND surfaces (median, 15 CFU/slide), but the dif-



FIGURE 1. A dip slide system for enumerating aerobic bacteria on surfaces.

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FIGURE 2. The evaluation system used on near-patient surfaces to quantify the impact of disinfection cleaning on aerobic bioburden. Removal of the fluorescent marker was used to determine whether the surface had been cleaned.

ference was not significant ($P = .06$). An evaluation of only those surfaces actually found to have been cleaned was then performed. During the QAC and ND phases of the study, 66.4% and 65.3% of the surfaces, respectively, were cleaned, as evidenced by fluorescent marker removal ($P = .8$; Figure 3). During the QAC and ND phases, 93 (40%) of 237 and 211 (77%) of 274 evaluable surfaces, respectively, showed complete removal of bacterial burden (Figure 3). In the context of the study design, the ND was 1.93 times more effective in removing bacterial burden than was the QAC ($P < .0001$).

DISCUSSION

Although it is recommended that all US hospitals use EPA-registered disinfectants for cleaning of surfaces that harbor and transmit microbial pathogens,[6,9] the recent development of systems to directly measure the thoroughness of cleaning practice[7,10] has led to objectively grounded educational and process feedback programs that have sustainably improved thoroughness of disinfection cleaning practice.[11] Such systems can now be used to monitor cleaning thoroughness when comparing the clinical effectiveness of all disinfection interventions to improve near-patient surface cleanliness. By concomitantly evaluating the clinical bioburden impact of a disinfectant and, simultaneously, the objectively measured thoroughness of cleaning practice, it becomes possible to independently analyze both components of disinfection cleaning (practice and product) during actual clinical use. Given the propensity for cleaning to be more carefully performed when a new chemistry is being evaluated in an unblinded clinical study (Hawthorne effect),[12] the ability to objectively evaluate such an influence substantially improves the ability to interpret possible differences in effectiveness when comparing with surface disinfectants (or disinfection systems as discussed below).

This study was designed to compare the in-use efficacy of 2 hard-surface disinfectants with different active ingredients in removing endemic aerobic bacterial burden from high-touch surfaces. QACs are some of the most widely used disinfectants today because of their broad-spectrum effectiveness, which is due to their ability to denature the proteins of bacterial or fungal cell walls.[13] The ND contains hydrogen peroxide and peracetic acid, which immediately form a peroxygen compound when applied to a surface. These compounds irreversibly damage microbial cell membranes. In addition, the formation of hydroxyl radicals that occurs as these compounds encounter air creates oxidants that also attack cell membranes. Peroxygen compounds rapidly kill spores by denaturing proteins in the spore coat, exposing their core to disinfectant action not effected by the presence of organic matter.[13]

The relative effectiveness of bioburden reduction was studied on in-use patient care units as part of routine discharge cleaning. The ND was found to be 1.93 times more effective than the QAC ($P < .0001$) in eliminating detectable bacterial burden from the surfaces studied (Figure 3). Because the thoroughness of cleaning was essentially identical with both chemistries (Figure 3), it is likely that greater effectiveness of the ND was due exclusively to its increased efficacy in bioburden reduction. Importantly, our ability to both eliminate from evaluation surfaces that do not harbor measurable bioburden before cleaning and assess a potential Hawthorne effect when using the ND very much strengthen the likely relevance of the observed difference between the 2 chemistries.

Dip Slide Bioburden Measurement

Over the past decade, dip slide systems (Figure 1) have been used extensively to study the epidemiology of bacterial healthcare environmental surface contamination but have not been used to compare the clinical efficacy of surface disinfectants.[14] Culture swab samples have been used in the evaluation of disinfection cleaning of specific pathogens, such as vancomycin-resistant enterococci (VRE),[15,16] methicillin-resistant *Staphylococcus aureus* (MRSA),[16] *Clostridium difficile*,[17] and *Acinetobacter*,[18] but the high level of nonquantitative sensitivity (standard culture area is 100 cm^2) of swab samples or sponge culture systems precludes their use in general bioburden evaluation. Furthermore, it is likely that the performance variability when quantitatively swabbing an estimated or template 100-cm^2 surface is prone to both user variability and possible intervention bias. Although the dip slide system, because of its small culture surface, would be expected to have low sensitivity for frequently identifying by culture anaerobic healthcare-associated pathogens that are typically

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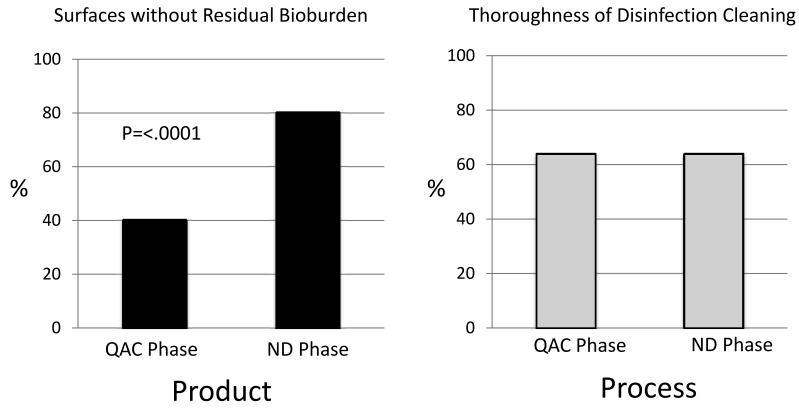


FIGURE 3. A comparison of the effectiveness of the 2 study disinfectants (product) and the thoroughness of cleaning during both arms of the study (process). ND, novel peracetic acid/hydrogen peroxide disinfectant; QAC, quaternary ammonium compound.

found at very low densities on or near patient surfaces, it is reasonable to assume that bioburden removal represents a good surrogate for healthcare-associated pathogen removal, because many studies have confirmed the absence of disinfectant resistance in pathogens such as MRSA, VRE, and drug-resistant gram-negative organisms. Although the relatively small area cultured by the dip slide (10 cm^2) raises the possibility that the method might not be sensitive enough to accurately measure surface bioburden, we found the system had both good sensitivity, with 472 (82.7%) of 571 precleaning surfaces having a quantifiable bioburden, and good dynamic range (1–158 CFU per 10 cm^2). In addition, the finding of similar precleaning bioburden in both arms of the study performed several weeks apart further supports the in-use accuracy of the system. Finally, it is of note that objects such as bathroom grab bars, bed rails, and call boxes were significantly more contaminated before cleaning than room and bathroom door plates and light switches (data not shown), which is a finding consistent with previously reported observations.[8]

The Challenge of Defining a Cleanliness Standard

Our findings also shed further light on the challenge of defining when an apparently clean healthcare surface might reasonably be considered bacterially contaminated enough to provide evidence of poor cleaning practice or be defined as dirty. Several years ago, it was suggested that the industrial hygiene threshold for defining food preparation surfaces as clean (aerobic colony count of less than 2.5 CFU/cm^2) could be used to evaluate the cleanliness of near-patient surfaces in healthcare and that surfaces containing heavier bacterial bioburdens be defined as cleaning failures.[19-21] Although a plausible concept, logistical limitations as well as the fact that the standard has yet to be correlated with the relative risk of transmission of healthcare-associated pathogens have been noted by several authors.[10,22-24] If our data were used to compare the 2 chemistries by applying the proposed standard of greater than 2.5 CFU/cm^2 to define a cleaning failure, only 7 (1.7%) of 425 tested surfaces would have failed to meet the standard following cleaning. As a consequence, no difference in the efficacy of the 2 chemistries would have been detected (QAC = 97% clean; ND = 98.3% clean). If such a standard were used to assure analysis of only dirty surfaces (precleaned surfaces with more than 2.5 CFU/cm^2), none of the surfaces on which the ND was used had more than 2.5 CFU/cm^2 following cleaning. Moreover, despite the fact that 11.8% of surfaces cleaned with the QAC had bioburdens of more than 2.5 CFU/cm^2 following cleaning, the difference would not have been significant (QAC, 4 [11.8%] of 30 failed; ND, 0 [0%] of 28 failed; $P = .12$) due to the small number of surfaces with more than 2.5 CFU/cm^2 bioburden before cleaning. As noted in Table 1,[10] all reported studies analyzing a broad range of near-patient surfaces have found, as we did, that only a small proportion (average, 16%) of healthcare surfaces have bioburdens of more than 2.5 CFU/cm^2 before cleaning. Although it is likely that the highly significant difference in the efficacy of the 2 chemistries seen when comparing total bioburden removal ($P \leq .0001$) could be realized using the 2.5 CFU/cm^2 breakpoint definition with dip slides (or calibrated adenosine triphosphate [ATP] methods,[30] which broadly correlate with aerobic colony counts) by measuring bioburden both before and after cleaning, such an approach would require a much larger study because of the need to exclude from analysis the approximately 85% of surfaces with bioburdens of less than 2.5 CFU/cm^2 before cleaning.

Although studies have evaluated the impact of disinfection cleaning interventions on surface contamination by pathogens such as VRE,[15] MRSA,[16] and *C. difficile*,[17] the relatively low prevalence of healthcare-associated pathogens on hospital surfaces as well as the necessity of using a quasiexperimental before-and-after study design would substantially increase confounders if used in a head-to-head comparison of different cleaning and disinfection interventions. Given the clear

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TABLE 1. Summary of Studies That Quantified the Aerobic Bioburden of Acute Care Area Surfaces before Cleaning

Study	No. of surfaces with <2.5 CFU/cm^2 aerobic bacterial CFU/2.5 cm^2 before cleaning	Total no. of surfaces sampled	Proportion of surfaces with <2.5 CFU/cm^2 before cleaning
White et al[25]	135	160	84
Dancer et al[14]	383	520	74
Dancer et al[26]	872	1040	84
Sherlock et al[27]	221	240	92
Al Hamad[28]	107	116	92
Boyce et al[29]	258	500	52
This study	512	592	87
Overall	2,488	2,898	86

NOTE. CFU, colony-forming unit.

evidence that healthcare-associated pathogens can be transmitted from low-bioburden surfaces, we believe that clinical studies that compare disinfectant system efficacy using the dip slide method can provide an accurate, simple, and logistically feasible approach to such investigations.

Evaluation before and after Cleaning

In addition, our findings and those noted in Table 1 further support the CDC guidance[7] regarding the need to measure bioburden both before and after cleaning to objectively evaluate the thoroughness of cleaning practice by culture swab, ATP monitoring systems, or dip slides. In our study, direct florescent marker measurement of cleaning thoroughness showed that 372 (66%) of 511 surfaces had been cleaned by the environmental services staff. Using overall bioburden removal (proportion of all contaminated surfaces before cleaning that had their bioburden removed), thoroughness of cleaning would have been found to be similar at 59%, despite the fact that 2 disinfectants with different efficacies were used. In contrast, cleaning thoroughness would have been incorrectly determined to be 98% if only postcleaning results for surfaces with less than 2.5 CFU/cm^2 (equivalent to less than 250 relative light units[20]) were used, and as a result, the actual thoroughness of cleaning would have been substantially overestimated. Indeed, the fact that more than 85% of general heathcare surfaces have bioburdens that would be considered clean in the food preparation industry before cleaning[10,22,23] highlights the limits of using a single numeric value by culture or culture correlated ATP measurements as a means for evaluating how well environmental cleaning is being performed. Although several studies have reported higher mean bioburdens on healthcare surfaces, these investigations focused exclusively on surfaces immediately adjacent to the patient's bed.[29,31]

The primary strength of this study relates to its simple design, which permitted the efficacy of 2 very different disinfectants to be directly compared in a nonoutbreak clinical setting. The dip slide culture system provided a quantitative enumeration of bacterial burden with a sensitivity that allowed for a well powered evaluation of the in-use comparative efficacy of the disinfectants in a manner that could be easily replicated for similar studies. Objectively monitoring cleaning practice allowed for analysis of a major confounding variable. Our study also has several important limitations. First, it was not possible to blind the environmental services staff with respect to the 2 disinfectants, which could have had an impact on cleaning practice. Although such an impact cannot be excluded, it would have been expected that such a result would have been reflected in greater thoroughness of cleaning during the ND phase of the study, which did not occur (QAC = 66.4%; ND = 65.3%; $P = .7$). Second, the small surface areas cultured raise the possibility that sampling bias may have affected the culture results, although both arms of the study should have been affected equally.

CONCLUSIONS

This study found that there was a significantly greater reduction in environmental bioburden associated with the clinical use of the ND in comparison with the QAC. Further evaluation is needed to measure the possible relative benefit of the ND in decreasing patient acquisition of environmental pathogens in patient care settings when incorporated into a disinfection cleaning program that includes appropriate processes and performance improvement strategies.[5]

Importantly, the modeling used in this study fulfills all elements of what Kuhn first described as a paradigm shift in 1962.[32(p85)] Kuhn specifically noted that such a shift leads to a "reconstruction of investigation" that allows "for the emergence of highly directed, or paradigm-based research."[32(p18)] As a result of the described modeling, 2 interventions can be compared by concomitantly and objectively monitoring the "process and product" elements of disinfection cleaning. This has potential for effectively defining the relative clinical efficacy of cleaning and disinfecting materials such as microfiber cloth, disposable disinfectant wipes, detergents without disinfectant activity, all forms of nontouch disinfection technologies, and self-disinfecting surfaces.[5,33] Such studies may

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then begin to objectively clarify best practices for decreasing the risk of pathogen transmission from contaminated surfaces to patients through the use of various cleaning modalities and chemistries while providing guidance for more in-depth clinical studies of cost-benefit issues and healthcare-associated pathogen transmission prevention.[5]

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Potential conflicts of interest. A.T. reports having been an employee of Ecolab at the time of the study and was responsible for submitted culture specimen processing and the provision of disinfectants to the study site. P.C.C. reports having served as a consultant to Steris and Ecolab and has licensed patents to and receives royalties not related to the objective of this study from Ecolab. All other authors report no conflicts of interest relevant to this article. All authors submitted the CIMJE Form for Disclosure of Potential Conflicts of Interest, and the conflicts that the editors consider relevant to this article are disclosed here.

Address correspondence to Philip C. Carling, MD, Carney Hospital, 2100 Dorchester Avenue, Dorchester, MA 02124 (philip.carling.md@steward.org).

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