MAJOR ARTICLE

Ultraviolet-C Light Evaluation as Adjunct Disinfection to Remove Multidrug-Resistant Organisms

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Background. Our objective was to determine if the addition of ultraviolet-C (UV-C) light to daily and discharge patient room cleaning reduces healthcare-associated infection rates of vancomycin-resistant enterococci (VRE) and *Clostridioides difficile* in immunocompromised adults.

Methods. We performed a cluster randomized crossover control trial in 4 cancer and 1 solid organ transplant in-patient units at the Johns Hopkins Hospital, Baltimore, Maryland. For study year 1, each unit was randomized to intervention of UV-C light plus standard environmental cleaning or control of standard environmental cleaning, followed by a 5-week washout period. In study year 2, units switched assignments. The outcomes were healthcare-associated rates of VRE or *C. difficile*. Statistical inference used a two-stage approach recommended for cluster-randomized trials with <15 clusters/arm.

Results. In total, 302 new VRE infections were observed during 45 787 at risk patient-days. The incidence in control and intervention groups was 6.68 and 6.52 per 1000 patient-days respectively; the unadjusted incidence rate ratio (IRR) was 0.98 (95% confidence interval [CI], .78 − 1.22; *P* = .54). There were 84 new *C. difficile* infections observed during 26 118 at risk patient-days. The incidence in control and intervention periods was 2.64 and 3.78 per 1000 patient-days respectively; the unadjusted IRR was 1.43 (95% CI, .93 − 2.21; *P* = .98).

Conclusions. When used daily and at post discharge in addition to standard environmental cleaning, UV-C disinfection did not reduce VRE or *C. difficile* infection rates in cancer and solid organ transplant units.

Clinical Trials Registration. NCT02605499.

Keywords. UV-C light; environmental cleaning and disinfection; *C. difficile* transmission; infection prevention; VRE transmission.

There are an estimated 687 000 healthcare-associated infections (HAIs) annually in US acute care hospitals and about 72 000 associated deaths [1]. The patient room environment has an important role in pathogen transmission in the healthcare setting [2]. High touch surfaces (HTS) in the patient room can harbor multidrug-resistant organisms (MDROs), which can transmit to patients. Manual cleaning and disinfection of HTS removes the MRDO bioburden interrupting the transmission pathway. However, this process may not be thorough, and detection of MDROs on surfaces post cleaning is common [3]. Ultraviolet-C (UV-C) light, when added to manual cleaning

at the time of patient hospital discharge, further reduces the MDRO burden, including methicillin-resistant *Staphylococcus aureus* (MRSA) [4–6], vancomyin-resistant *Enterococcus* spp. (VRE), and *Clostridioides difficile* [6, 7] in the patient room environment.

Studies evaluating the impact of UV-C light on patient outcomes are typically quasi-experimental pre-post studies performed in response to an MDRO rate increase or concern for an outbreak on a unit [8–11]. Although implementation of infection prevention practice bundles, including UV-C light, have been associated with outbreak resolution, the impact of UV-C light or any individual bundle element is uncertain. A recent randomized clinical cluster trial, the Benefits of Enhanced Terminal Room (BETR) Disinfection Study, using a composite measure of *C. difficile* and MDROs, assessed room disinfection with UV-C and found that standard cleaning with the addition of either bleach or UV-C disinfection decreased risk of transmission of the previous patients pathogen to the next room occupant [12]. This study also suggested that UV-C in a targeted subset of high-risk rooms led to a decrease in hospital-wide incidence of *C. difficile* and VRE [13]. Studies to date have primarily evaluated UV-C disinfection as an addition to discharge or

terminal cleaning, which may reduce the risk of direct transmission from a contaminated environment (eg, bed rails) to the next patient room occupant. However, little is known about the potential impact of daily UVC disinfection on patient-to-patient MDRO transmission via healthcare worker hands or shared equipment, for instance.

Our objective was to determine if the addition of UV-C light to daily and discharge patient room cleaning reduces new onset healthcare associated VRE and *C. difficile* infection rates in immunocompromised adults.

METHODS

The study was conducted in 4 cancer and 1 solid organ transplant in-patient units, with all private patient rooms with own bathroom, at the Johns Hopkins Hospital (JHH), a 1059-bed academic medical facility in Baltimore, Maryland. Each study unit had longstanding VRE surveillance programs and collected patient perianal Eswabs (COPAN Diagnostics, Murrieta, California, USA) at unit admission (defined as ≤2 calendar days from unit entry) and weekly thereafter [14]. These units had a robust pre-existing program of routine environmental cleaning, including quality assurance evaluation of environmental cleaning using a metered applicator florescent gel marker monitoring program, with addition of hydrogen peroxide vapor (Bioquell©) in an ad hoc fashion, at the time of patient discharge for patients who harbored a MDRO or *C. difficile*.

The study was an investigator initiated nonblinded, cluster-randomized, 2-phase crossover trial. We randomized each unit to an intervention of UV-C light plus standard environmental cleaning or a control of standard environmental cleaning for study phase one (1 December 2015 to 16 December 2016), followed by a 5-week washout period and then study phase 2 (23 January 2017 to 7 February 2018) during which time units switched assignments. During intervention, the UV-C device was used daily in all occupied patient rooms and after each patient discharge. For occupied rooms, the UV-C device was used in the room and bathroom during an interval when the patient was out of the room. For patients who did not leave the room, the UV-C device was used only in the bathroom with the door shut. For discharged patient rooms, UV-C was used after routine manual discharge cleaning and disinfection. The UV-C device (Clorox Healthcare Optimum-UV device, Clorox, Oakland, California, USA) is a mobile device emitting UV-C light at a wavelength of 254 nm via 157.7 cm (62-inch) maximum-output mercury lamps. Device dose indicator cards, where color change indicated emission of adequate UV-C light to kill *C. difficile* and MRSA, were used weekly for quality control. To understand the fidelity to the intervention, and assess for compliance differences by unit, we divided the frequency of UV-C light usage in daily patient rooms and bathrooms by the number of patient-days over the intervention period for each unit. For the discharge patient room and bathroom, we performed a similar

analysis but used the number of discharges as the denominator. The Johns Hopkins Medicine Institutional Review Board approved the study, which is registered at ClinicalTrials.gov (identifier NCT02605499).

Outcomes

The primary outcome was new VRE infection during the hospital stay, defined as either a clinical culture (eg, blood, sputum, or wound sample) or surveillance culture (perianal sample), which grew VRE on day 3 or later into unit admission. The primary outcome measurement was new VRE infections per 1000 patient at-risk days. To ensure at-risk time included was adequate to develop a healthcare associated infection, we only included admissions to a unit when the length of stay was more than 3 days. To exclude episodes where VRE was most likely preexisting and not acquired during that admission, we excluded admissions when a culture grew VRE within the first 3 days of admission. Patient-days after a VRE infection were not included in at-risk time and were censored as the outcome had already occurred. The primary outcome was a composite of clinical and surveillance cultures, for secondary outcomes, we evaluated clinical cultures and surveillance cultures separately.

After the start of the trial, additional funding was secured for *C. difficile* polymerase chain reaction (PCR) testing on perianal samples, which were submitted to the microbiology laboratory for VRE surveillance culture. This occurred during the last 6.5 months of study phase 1, washout period and first 6.5 months of study phase 2. The perianal sample *C. difficile* testing was in addition to routine clinical care, where stool samples from patients with clinical suspicion of CDI were analyzed. The PCR analysis was performed using the BD MAX™ Cdiff Assay, as previously studied [15]. This outcome was new *C. difficile* infection, defined as either a clinical stool sample, or surveillance perianal sample, with a positive PCR result on day 3 or later into unit admission. The outcome measurement was new *C. difficile* infections per 1000 patient at-risk days. CDI at risk days were calculated in a similar manner to VRE at risk days (see above).

Statistical Methods and Sample Size

We estimated sample size using aggregated baseline VRE incidence rates from each study unit. There were 117 cultures, including clinical and surveillance, which grew VRE during 26 920 patient-days, an incidence rate of 4.35 per 1000 patient-days. We subtracted 10% of patient-days to exclude days not at risk, giving an incidence rate of 4.83 per 1000 patient-days. We used a Poisson regression model and 2-sided significance level of 0.05. For a 2-year study (12-month study phase 1, washout, 12-month study phase 2) we estimated 97.5% power to detect a 30%, or 80% power to detect a 23%, relative reduction in VRE incidence.

Based on study unit aggregate *C. difficile* rate of 8.67 per 1000 in patient-days, we used a Poisson regression model and 2-sided significance level of .05. To detect a 30% relative reduction in *C. difficile* incidence rate we needed 30 235 patient-days

(15 118 in study phase 1 and 2). This corresponded to approximately 6.5 months for each study phase. Sample size analysis was performed using PASS 11. NCSS, LLC. Kaysville, Utah, USA [16].

For each study unit, we described number of admissions, patient length of stay and the following covariates during the intervention and control periods: hand hygiene compliance, antibiotic utilization, hydrogen peroxide vapor use, and environmental cleaning monitoring with metered applicator florescent gel marker removal rates.

To evaluate the impact of UV-C light on the primary and secondary outcomes, we used a two-stage approach for statistical inference recommended for cluster-randomized trials with <15 clusters/arm [17, 18]. At the first stage, Poisson regression on unit-month data from all study periods was used to compute E, the expected number of events (new VRE infections) with use of an offset. The Poisson regression model also adjusted for study phase (study phase 2 vs study phase 1), and any variables which were statistically significant in the bivariable analysis. Metered applicator florescent gel marker removal rate was the only variable which was statistically different between intervention and control periods ($P < .1$). At the second stage, two-way analysis of variance was carried out on log(O/E) (log ratio-residuals), where O was the observed number of events. The test statistic is the estimated difference in means of log(O/E) between study periods, with 2-sided P-values and 95% confidence intervals (CI) computed using the t-distribution and weighted paired t tests. The corresponding rate ratios and 95% CI for the overall comparison between intervention and control periods, and each unit's intervention and control, were calculated with exponentiation.

RESULTS

Four cancer, and 1 solid organ transplant, in-patient units at the Johns Hopkins Hospital were enrolled, completed, and were included in the study analysis. For study phase 1, 3 units were randomized to intervention, and 2 to control, and all crossed over for study phase 2. The study stopped as planned on 7 February 2018. During intervention and control periods, units were similar for patient admissions, patients' days, hand hygiene, antibiotic utilization, and use of hydrogen peroxide vapor (Table 1). Four out of 5 units had lower metered applicator florescent gel marker removal rates, indicating lower environmental cleaning of high touch surfaces, in the intervention period compared to the control period ($P = .07$).

Over the study periods, 302 incident VRE cases were observed during 45 787 at risk patient-days (overall incidence, 6.60 per 1000 patient-days). The weighted mean incidence of VRE cases was 6.68 per 1000 patient-days in the control period and 6.52 per 1000 patient-days in the intervention period; the unadjusted rate ratio was 0.98 (95% CI, .78 – 1.22; $P = .54$).

There were 84 incident *C. difficile* cases observed during 26 118 at risk patient-days (overall study incidence, 3.22 per 1000 patient-days). The weighted mean incidence of *C. difficile* cases was 2.64 per 1000 patient-days in the control period and 3.78 per 1000 patient-days in the intervention period; the unadjusted rate ratio was 1.43 (95% CI, .93 – 2.21; $P = .98$) (Table 2). Comparing the control and intervention periods, there were no differences in secondary outcomes of VRE or *C. difficile* clinical sample positivity, or VRE or *C. difficile* perianal surveillance positivity (Supplementary materials, Supplementary Table 1).

Regarding UV-C light device use, frequency of use in patients' rooms post discharge cleaning was highest, ranging from 46 to 99 per 100 discharges. Daily patient room cleaning had the least use, ranging from 90 to 190 per 1000 patient-days (Table 3).

CONCLUSION

This study showed that the addition of daily and discharge UV-C disinfection to standard patient room cleaning did not significantly reduce new VRE or *C. difficile* infection rates in cancer and transplant in-patient units in a US academic tertiary referral center. This is among the first cluster randomized cross-over design studies to evaluate UV-C light disinfection. The lack of pre-existing robustly designed studies

Table 1.   Study Phase 1 Assignment of Each Unit and Characteristic Comparison Between Intervention and Control Periods

Unit	Study Phase 1 Assignment	No. of Patient Admissions	No. of Patient-days	Hand Hygiene Compliance (%)	Antibiotics per 1000 Patient-days	ECC (%)	HPV per 100 Admissions
				(Intervention, Control)			
A	Intervention	540/ 545	4853/ 5247	94/ 97	358/ 373	95/ 99	0.2/ 1.8
B	Intervention	439/ 488	4907/ 5487	95/ 94	365/ 386	94/ 100	5.0/ 4.9
C	Control	641/ 641	5356/4931	92/ 92	335/274	100/ 98	5.3/ 5.3
D	Intervention	517/ 583	3797/ 4455	94/ 94	326/ 397	97/ 100	4.5/ 5.2
E	Control	1406/1372	9915/8628	90/ 89	160/ 149	86/ 93	11.9/ 7.7
P value[a]		.39	.97	.96	.77	.07	.71

Abbreviations: ECC, Environmental Cleaning Compliance - % of high touch surfaces with pre-placed metered applicator florescent gel marker removed post cleaning; HPV, hydrogen peroxide vapor.

[a]P value from paired t tests.

Table 2. Vancomycin-Resistant *Enterococcus* (VRE) and *Clostridioides difficile* (*C. difficile*) Incidence Rate Ratios With 95% Confidence Intervals (CI) Between Intervention and Control Phases

	Intervention			Control			Rate Ratio	
	No. of Events	No. at Risk, patient-days	Incidence rate/1000 at risk Patient-days	No. of Events	No. at Risk Patient-days	Incidence Rate/1000 at Risk Patient- days	IRR, (95% CI)	P Value[a]
VRE								
Primary	149	22869	6.52	153	22918	6.68	0.98 (.78 – 1.22)	.54/ .69
Secondary: clinical	12	24128	0.52	13	23962	0.57	0.92 (.42 – 2.01)	.28/ .27
Secondary: surveillance	149	22907	6.50	150	22967	6.53	1.00 (.79 – 1.25)	.54/.69
C. difficile								
Primary	50	13238	3.78	34	12880	2.64	1.43 (.93 – 2.21)	.98/ .89
Secondary: clinical	13	13472	0.96	11	13040	0.84	1.14 (.51 – 2.55)	.57/ .50
Secondary: surveillance	42	13264	3.17	26	12968	2.00	1.58 (.97 – 2.58)	.99/ .69

Abbreviations: IRR, incidence rate ratio; VRE, vancomycin-resistant enterococci.

[a] Paired *t* tests/ Wilcoxon rank sum tests for residual ratio from Poisson regression models adjusted for study period and Environmental Cleaning Compliance.

evaluating UV-C light may be in part because UV-C disinfection is still an evolving area in HAI prevention [19]. Prior to 2015, there are few peer-reviewed publications evaluating UV-C disinfection.

In many existing studies, UV-C disinfection has been employed as 1 facet of a multiprong intervention in response to elevated HAI rates or an unexpected cluster of infections with a specific organism. Although in those situations, a reduction in HAIs, or resolution to the cluster, was typically reported, it is often unclear how significant the role of UV-C disinfection was in the resolution of the issue [20]. However, this preplanned study evaluated the impact of UV-C light disinfection on incident VRE and *C. difficile* cases in the endemic setting and allows for a highly focused evaluation of UV-C disinfection as an intervention. Interestingly, although small and not statistically significant, we saw an overall increase in CDI, and an overall decrease in VRE, during the intervention phase. Some others have reported similar or higher CDI rates during UV-C disinfection usage and similarly disparate findings based on pathogen type [13, 21, 22]. The array of findings regarding the benefit, or lack thereof, of UV-C disinfection on HAI rates is intriguing. Although (1) MDROs and *C. difficile*

are common on high touch surfaces near the patient, with this reservoir playing an important role in spread to patients in healthcare settings [23], and (2) in laboratory-based studies, and simulated studies of surfaces in patient rooms, UV-C light kills these organisms [5, 24], it has remained challenging to conclusively demonstrate the downstream effects of reduction of MDRO and CDI rates in response to UV-C disinfection as an intervention. MDRO and *C. difficile* spread is multifactorial, related to complex interactions between hand hygiene, other infection prevention precautions, and antimicrobial stewardship. One plausible reason that rates may not decrease in response to UV-C disinfection interventions is that the near patient environment was not the main contributor to the MDRO spread in that study setting. Of note, on these study units, it was very rare to have *C. difficile* or VRE transmission to the following patient occupant of the room, a potential surrogate marker of environmental transmission. Crude HAI rates do not give any further information as to the mechanism of pathogen spread, and exploration to develop more nuanced measures to understand a priori which targeted interventions may be most successful at reducing MDRO or CDI spread could be of benefit.

Table 3. Frequency of Ultraviolet-C (UV-C) Light Use During Intervention by Study Unit

	No. per 1000 Patient-days[a]		No. per 100 Discharges	
Unit	Daily Bathroom Cleaning	Daily Main Room Cleaning	Discharge Bathroom Cleaning	Discharge Main Room Cleaning
A	310	180	36	77
B	270	190	40	84
C	230	90	47	99
D	300	160	39	77
E	390	150	22	46

The analysis included 54 unit-months with UV light data.

[a] Denominator: No. patient-days minus no. patient admissions.

Additional strengths of this study include the use of peri-anal surveillance during the entire study period to detect VRE colonization, and during a nested, shorter time frame to detect *C. difficile*, colonization, as a potentially more sensitive way to capture pathogen transmission, rather than relying on clinical cultures alone. The use of daily UV-C also allowed evaluation of a more robust use of the technology during patients' hospitalization rather than only using it at the time of patient discharge.

Specifically, for this study, there are limitations that could explain why we found no reduction in VRE or *C. difficile*. However, as this was a cross-over trial, limitations balance across intervention and control arms, biasing toward the null of not finding a difference in infection rates due to intervention. The UV-C light device was only used in a proportion of rooms each day. This reflects the real-world implementation challenges of UV-C light device use. Although the daily use of UV-C daily in patient rooms was acceptable to patients and families [25], the room needed to be vacated, which for daily use was sometimes not possible and required complex coordination. The UV-C light device was used by the study team during routine working hours, which did not include weekends or night shifts. Our findings might also reflect the fact that there may not have been room for additional improvement as, over the preceding years, we had focused on enhancing standard patient room environmental cleaning and had a robust objective cleaning monitoring and improvement program in place, as indicated by high metered applicator florescent gel marker removal rates throughout the study period. This premise has been suggested in another study where *C. difficile* incidence after UV light discontinuation remained stable [26]. At JHH, including on these units, if *C. difficile* rates are above a threshold, a sporicidal disinfectant is used universally on all daily and discharge room cleanings. During the study, as with the rest of JHH, we use hydrogen peroxide vapor technology, when possible, post manual cleaning of rooms where the occupant was known to have *C. difficile* or other epidemiologically significant MDROs. Although there may be a measurable impact of UV-C disinfection in hospitals when baseline cleaning is less optimal, this possibility remains to be clarified. This study was performed in a tertiary hospital cancer and transplant center, without shared rooms, so may have limited applicability outside this setting. However, it may be reasonable to consider that if no benefit was seen in this group, then no benefit would be seen in the less at-risk patients' groups. Room selection for UV-C disinfection did not preferentially focus on rooms where the occupant had a known MDRO or *C. difficile* but rather targeted all rooms independent of occupant MDRO status. It may be that a more focused, intense approach on rooms where the occupant was known to have VRE or *C. difficile* may have yielded different results. Finally, we may have been underpowered with our sample size and number of clusters to detect a difference, a

recent review of cluster-randomized trial design in hospital infection control suggests that many more clusters are needed to detect a difference than previously appreciated [27]. Although our findings support the possibility that UV-C disinfection as an adjunct intervention may not be effective at reducing VRE or *C. difficile* in a real-world application, pathogen transmission is a complex multifactorial process, which we believe will be further elucidated by the evolving science of genomic microbial epidemiology.

This study did not find significant improvement in incident VRE and *C. difficile* cases with addition of daily and discharge UV-C disinfection to standard cleaning in cancer and transplant units of an academic medical center.

Supplementary Data

Supplementary materials are available at *Clinical Infectious Diseases* online. Consisting of data provided by the authors to benefit the reader, the posted materials are not copyedited and are the sole responsibility of the authors, so questions or comments should be addressed to the corresponding author.

Notes

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