Measuring the impact of continuous disinfection strategies on environmental burden in outpatient settings: a prospective randomized controlled trial

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Selections of this data were submitted and accepted as an abstract for a poster presentation at IDWeek 2019.

Main point: Neither “near-UV” lights or a persistent organosilane quaternary ammonium disinfectant reduced environmental contamination in two outpatient clinics compared to control rooms but did reduce the number of CIPs recovered.

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Abstract

Objective: Our primary objective was to determine the effectiveness of two enhanced disinfection strategies compared to standard disinfection: “near-UV” light (Arm 1) and a persistent organosilane quaternary ammonium disinfectant (Arm 2) using a triple-blind study design. Our secondary objective was to characterize environmental contamination of outpatient clinics.

Setting: Wound and pulmonary outpatient clinics at Duke University Health System in Durham, North Carolina.

Interventions: In Arm 1, room overhead lights were replaced with 405nm “near-UV” visible lightbulbs. In Arm 2, the organosilane quaternary ammonium disinfectant was applied to all room surfaces. The control arm received no intervention. All arms received routine disinfection. Room contamination was measured twice daily (before and after clinic) over 25 clinic days.

Primary outcome: The primary outcome was the change in total contamination, measured in colony forming units, (CFU) on environmental surfaces at the end of the clinic day compared to the beginning of the clinic day. Results from each intervention arm were compared against results from the control arm.

Results: The median delta total CFU for Arm 1 was 2,092 CFU [IQR: -1,815-8,566]; the median delta for Arm 2 was 2,016 CFU [IQR: -1,443-7,430]. Compared to the control arm (median delta = 1,987 [IQR: -1,611-15,857]), neither intervention led to a significant decrease in daily room contamination change (p for Arm 1=0.78 and p for Arm 2=0.71).

Conclusion: Neither “near-UV” lights or a persistent organosilane quaternary ammonium disinfectant reduced environmental contamination in two outpatient clinics compared to control rooms but did reduce the number of clinically important pathogens (CIPs) recovered.

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Introduction

Approximately 1 in 25 inpatients contract a healthcare-associated infection (HAI) each year in the US, and approximately 75,000 die in the hospital as a result of their HAI.[1] Infections caused by multidrug-resistant organisms (MDROs) occur in 2 million people in the US each year.[2] In fact, many HAIs are caused by MDROs. These HAIs and MDROs lead to adverse patient outcomes, including increased length of hospitalization, morbidity, and mortality.[3–5]

Traditionally, the majority of transmissions and exposures to pathogens that cause HAIs are from healthcare providers (HCP), but there is growing evidence that the healthcare environment definitively plays a role in transmission as well.[6,7] As a result, surface disinfection is a key strategy to prevent HAIs and pathogen transmission. Several challenges prevent effective disinfection through routine chemical disinfection application.[8,9] Thus, enhanced strategies for disinfection are needed.

In general, liquid chemical disinfectants are highly effective when applied, but are only active for a short time after application (i.e., until surface touched or disturbed). Thus, one potential solution to decrease risk of transmission through the environment is continuous disinfection strategies, disinfection technologies that have constant disinfectant action as opposed to only when applied. To date, the majority of studies on enhanced environmental disinfection have focused on inpatient settings. Thus, environmental contamination levels and risk of pathogen transmission in outpatient settings is largely unknown, though still suspected to be a hazard for HAIs.[10] We completed a prospective randomized controlled trial to evaluate the efficacy of two enhanced disinfection strategies on surface contamination in two outpatient clinics and, secondarily, to measure the baseline environmental contamination. The first intervention studied was a "near-UV" light system that runs constantly and has demonstrated efficacy against vegetative pathogens in a trauma room and laboratory setting.[11,12] The second intervention was a persistent organosilane quaternary ammonium salt disinfectant that persists for 90-days following application and has demonstrated efficacy in patient rooms and an intensive care unit.[13,14] Our hypothesis was that the

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addition of an enhanced, continuous disinfection technology to routine disinfection would decrease the environmental bioburden in outpatient clinical settings compared to routine disinfection.

Methods

Objectives

Our primary objective was to determine the effectiveness of two enhanced disinfection strategies compared to standard disinfection: “near-UV” light (Vital Vio, Troy, New York USA) and a persistent organosilane quaternary ammonium salt disinfectant (Allied Biosciences, Plano, Texas USA). Our secondary objective was to describe and characterize environmental contamination of outpatient clinics.

Study Setting

We performed a randomized controlled trial in two outpatient clinics at Duke University Health System in Durham, North Carolina: the wound care clinic and the pulmonary clinic, in which patients with cystic fibrosis, lung transplant and other chronic pulmonary diseases are treated. Three patient care rooms from each clinic were chosen based on proximity to one another and similar room design and setup. Within each clinic the rooms were randomized (1:1:1) to one of the two interventions or control arms. Rooms were randomized by using a random number generator where the room with largest number was assigned to intervention Arm 1, the room with the lowest number was assigned to intervention Arm 2 and the third was assigned to the control arm. Thus, we evaluated a total of six study rooms with two rooms (1 from each clinic) included in each study arm. All clinic, study, laboratory, and statistical staff were blinded to intervention assignment (i.e., triple blind study).

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Study Protocol

In Arm 1, room overhead lights were replaced with "white" light bulbs that emitted a blend of 405 nm "near-UV" light and ambient white light. These lights were "on" continuously for the course of the study, which was ensured by removing light switches from all six study rooms. In Arm 2, a persistent organosilane quaternary ammonium salt disinfectant was applied to all surfaces in the room. Application was performed by the disinfectant manufacturer. The control Arm received no intervention.

Routine standard disinfection was continued in both intervention arms and the control arm. Standard disinfection in the pulmonary clinic included environmental services (EVS) visiting each room twice a day. In the morning EVS would dispose of non-biomedical waste and in the evening, they would dispose of non-biomedical waste again, sweep and mop. Nurses were responsible for wiping down surfaces with a disinfectant in all study areas (exam, patient and clinician) and doorknobs between patients. Oxivir^{R} (hydrogen peroxide) wipes were used in most rooms and Avert^{R} (bleach) sporicidal wipes were used in rooms with cystic fibrosis patients and patients with known multidrug-resistant organisms (MDRO). Standard disinfection in the wound clinic included EVS coming in once a day in the evening after clinic hours and disposing of non-biomedical waste. Nurses were responsible for wiping down surfaces with a disinfectant in all study areas (exam, patient and clinician) between patients. In the morning the open-faced wound care carts containing wound cleaning and dressing supplies were emptied, wiped down, and then restocked. Between patients the supplies stay on the cart and the handles and drawers were wiped off. Oxivir^{R} wipes were used to disinfect all surfaces.

Environmental cultures were taken each study day at the beginning of the clinic day, prior to the 1st patient, and after the clinic day, after the last patient but prior to routine cleaning. Cultures were obtained from three locations within each study room: exam area, patient area, and clinician area. The exam area included the patient exam bed and the handles of various medical instruments.

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The patient area included the patient's chair, including seating area and chair rails. The clinician area included the clinician's chair, desk, keyboard and mouse. Sampling protocols were used to ensure the same locations and surface area were cultured each time. Cultures were collected in all six study rooms before and after clinic days for 25 study days over a 3-month period, based on the manufacturer's reported duration of efficacy of the persistent organosilane quaternary ammonium disinfectant.

Microbiological Methods

All cultures were obtained directly from the clinical environment using the sponge and stomacher technique per the Centers for Disease Control and Prevention protocol.[15] Sponges were placed in stomacher bags with 45 mL of PBST, phosphate buffered saline with 1% Tween20, and homogenized for 60 seconds at 260 RPM. Homogenates were then centrifuged at 3200 RPM for 15 minutes and all but approximately 5 mL of the resulting supernatant was discarded. Then each sample was re-homogenized via vortex. 100 µL of the final homogenate was plated onto trypticase soy agar with 5% sheep's blood for overall bioburden and 200 µL of the homogenate was plated onto selective media: bile esculin agar for *Enterococcus spp.*, mannitol salt agar for *S. aureus* and MacConkey agar for Gram-negative species of interest. *Enterococcus spp.* and *S. aureus* were confirmed using standard laboratory procedures and Gram-negative bacterium were speciated using MALDI-TOF mass spectrometry.

Outcomes

The primary outcome was the change in total contamination, measured in colony forming units, (CFU) on environmental surfaces at the end of the clinic day compared to the beginning of the clinic day. Results from each intervention arm were compared against results from the control arm. Total CFU was determined by adding the CFU detected by individual cultures to yield a single value.

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Our secondary outcomes were the change in total CFU at the beginning of the clinic day during the study and the proportion of samples positive for individual clinically important pathogens (CIPs): *S. aureus* (MRSA or MSSA), *Enterococci spp.* (VRE or VSE), *Acinetobacter spp., Pseudomonas spp.*, and Enterobacteriaceae of interest such as *E. coli* and *Klebsiella spp.*, and the number of positive cultures – overall and at each culture location.

Data Analysis

The Mann-Whitney U test was used to compare all CFU measurements, the unpaired t-test was used to compare linear regression slopes for the change in morning CFU over time and the Z score proportionality test was used to compare proportions of samples with CIPs. A p-value of <0.05 was considered significant, all statistical tests were 2-tailed, and all testing was completed using R software (R Foundation for Statistical Computing, Vienna, Austria).

Results

From December 2018 to February 2019, 408 patients were seen in study rooms, 244 in the wound clinic (daily median of 3 per room [IQR: 2.00-5.00]) and 164 in the pulmonary clinic (daily median of 2 per room [IQR 1.00-3.00]). 26 patients with previous or active MDRO infections were seen in study rooms, 8 in the wound clinic and 18 in the pulmonary clinic. A total of 900 environmental cultures were obtained, 450 from each clinic. A total of 450 pre-clinic cultures were obtained and 450 post-clinic. The total sample areas in the wound and pulmonary clinic were 12,732 cm^2 and 16,396 cm^2, respectively.

The median total CFU in all study rooms was 8,067 [IQR: 1,959-21,102]. The median total CFU for the wound clinic was 20,700 [IQR: 11,140-26,544] compared to the pulmonary clinic 2,812 [IQR: 1,123-6,566, $p<0.001$]. The median daily change in CFU (delta), the difference between post-clinic and pre-clinic samples, in all study rooms was 2,081 [IQR: -1,734-9,507] (Table 1). The median

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delta CFU in the wound clinic was 2,710 [IQR: -2,580-13,384] and in the pulmonary clinic was 1,648 [IQR: -662-4,678] (Table 1).

Table 1 summarizes the median CFU for clinical areas at each clinic type. The median delta CFU for the exam, patient and clinician areas in the wound clinic were 430 [IQR: -1,200-2,989], 1,700 [IQR: 130-4,215] and 212 [IQR: -2,100-2,694], respectively. The median delta CFU for the exam, patient and clinician areas in the pulmonary clinic were 208 [IQR: -224-1,830, p=0.49], 420 [IQR: -266-1,984, p=0.01] and 138 [IQR: -354-1,011, p=0.88], respectively (Table 1). The sample areas in the pulmonary clinic for the exam, patient and clinician areas were 5,029 cm^2, 3,961 cm^2 and 7,406 cm^2, respectively, and 3,226 cm^2, 3,600 cm^2 and 5,906 cm^2, respectively, in the wound clinic.

Compared to the control arm 7,918 [IQR: 2,939-18,855], the median total CFU for intervention Arm 1 (near-UV) was 17,371 [IQR: 1,419-24,810, p=0.38], and the median total CFU for intervention Arm 2 (organosilane quaternary ammonium salt) was 6,331 [IQR: 1,978-16,410, p=0.20] (Table 2). The median delta total CFU for intervention Arm 1 was 2,092 CFU [IQR: -1,815-8,566]; the median delta for intervention Arm 2 was 2,016 CFU [IQR: -1,443-7,430]. Compared to the control arm (median delta = 1,987 [IQR: -1,611-15,857]), neither intervention led to a significant decrease in daily room contamination change (p for intervention arm 1=0.78 and p for intervention 2=0.71; Table 2). Similarly, the median delta CFU for the exam, patient and clinician areas in the intervention arms were largely unchanged compared to the control arm (Table 3).

We evaluated trends in morning contamination over the study period to determine if either disinfection method led to decreasing contamination over time. We did not identify any trends over time in any of the three study arms (Figure 1). Due to the stochastic nature of sampling results, the R2 values were low for all three trends.

Ninety CIPs were found in environmental samples during the study, 63 in the wound clinic and 23 in the pulmonary clinic (p<0.001) (Table 3). The proportion of patients seen in study rooms

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with known MDRO infections was similar between study arms; 7% in control arm rooms compared to 5% in intervention Arm 1 and 8% in intervention Arm 2 (*p*=0.40, p=0.37, respectively). While interventions did not decrease overall bioburden, we observed that fewer epidemiologically important pathogens were identified in interventions arms; 43 were found in the control arm compared to 25 in intervention arm 1 and 21 in intervention arm 2 (*p*=0.02, *p*=0.004, respectively) (Table 3).

Discussion

It is increasingly clear that the healthcare environment plays a role in transmission of clinically important pathogens (CIP). Standard chemical disinfection is effective but faces many challenges such as low compliance and incomplete application.[16,17] Therefore, enhanced strategies for disinfection are of interest and need. Our initial hypothesis was that the addition of continuous disinfection strategies “near-UV” light or a persistent organosilane quaternary ammonium disinfectant to routine disinfection would decrease the environmental bioburden in outpatient clinical settings compared to routine disinfection. In our randomized controlled trial, neither intervention made a significant impact on median total CFU or delta CFU. However, fewer CIPs were found in both intervention arms compared to control. These findings suggest that our initial hypothesis was incorrect and that these two enhanced disinfection technologies were not effective at reducing overall bioburden in the outpatient setting. However, even though fewer CIPs were found in intervention arms, due to the low number of CIPs recovered overall it is unclear if this was attributable to either intervention.

Our results are novel, as since there are few studies examining the environmental contamination of outpatient clinics and few investigations of disinfection strategies using randomized clinical trial methodology. However, the data of the two enhanced disinfection technologies is discordant with prior research that demonstrated efficacy for both technologies.[11–

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[14,18–20] For example, Sutton et al showed efficacy for near-UV lights in a trauma room on surface microbial load and Tamimi et al showed long-term efficacy for a persistent quaternary ammonium organosilane compound in an intensive care unit against surface microbial load and antibiotic resistant bacteria found on surfaces. More recently, Ellingson et al observed a decrease in CFU and healthcare associated infections in six non-randomly selected units in two hospitals after application of the same quaternary ammonium product used in our study[14]. In contrast, Boyce et al also failed to show an impact on environmental contamination after application of an quaternary ammonium organosilane compound.[21] Additionally, Rutala et al showed relatively low efficacy for “white” near-UV light on vegetative bacteria and spores in experimental conditions compared to the more intense “blue” near-UV light after 24 hours of exposure.[22] These differences in study results may be related to differences in study methodology, including randomization with controls vs. non-randomized, testing location, experimental versus clinical environment, and differences in sampling techniques: contact plates versus sponge and stomacher techniques.[23,24] Contact plates measure 25 cm^2 each and can miss or hit areas of higher contamination due to heterogeneity of contamination; in contrast, the sponge and stomacher method can sample a much larger surface area resulting in an average bioburden.

The wound clinic had significantly higher room and sample area contamination compared to the pulmonary clinic. However, both clinics had similar daily changes in bioburden. Additionally, significantly more CIPs were found in the wound clinic compared to the pulmonary clinic. These results indicate that wound clinic s may be higher-risk locations for potential environmental contamination and transmission, given high baseline contamination and higher numbers of CIPs.

Our study has limitations. First, only two types of outpatient clinics were included; thus, our results may not be generalizable to other clinic types. Second, routine disinfection was not monitored, though our randomized and blinding approach was designed so that all rooms within a clinic would be treated similarly. Third, the average bioburden between the clinics varied

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significantly. Fourth, in order to maintain blinding, the intensity of the near-UV lights was not increased during non-work hours per manufacturer's instructions. This may have limited the ability of this technology to make an impact. Finally, patient acquisition and outcomes were not measured.

In conclusion, "white" light bulbs emitting a blend of 405 nm "near-UV" light and ambient white light and a persistent organosilane quaternary ammonium salt disinfectant did not reduce overall environmental contamination compared to control rooms in two outpatient clinics in our randomized controlled trial. We observed higher levels of environmental contamination in the wound clinic, suggesting that additional disinfection measures may be required in this location to reduce relatively high baseline contamination and number of CIPs recovered. Our study confirms that future studies of enhanced disinfection technologies must be performed in real world clinical settings using randomized trial methods.

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Patient Consent Statement

This study was approved by the Duke University Health System Institutional Review Board (IRB) as exempt from IRB review and a waiver of informed consent was obtained from said IRB.

Acknowledgements

Financial Support

This work was supported by the Centers for Disease Control and Prevention: Duke-UNC Prevention Epicenter Program for Prevention of Healthcare-Associated Infections [Grant number 1U54-CK000483]

Potential conflicts of interest

None

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Figures

Figure 1. Morning room CFU over study days

Figure 1 legend: a) Intervention Arm 1 b) Intervention Arm 2 c) Control

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Tables

Table 1. Median CFU and median delta CFU for Wound and Pulmonary clinic individual and summed samples

	Median CFU (IQR)	*P* (Wound v Pulm)	Median Delta CFU (IQR)	*p* (Wound v Pulm)
Overall	8,067 (1,959-21,102)		2,081 (-1,734-9,507)	
Wound Clinic Room	20,700 (11,140-26,544)	<0.001	2,710 (-2,580-13,384)	0.50
Exam Area	15,000 (4,170-18,000)	<0.001	430 (-1,200-2,989)	0.49
Patient Area	1,950 (900-4,830)	<0.001	1,700 (130-4,215)	0.04
Clinician Area	2,023 (726-4,845)	<0.001	212 (-2,100-2,694)	0.88
Pulmonary Clinic Room	2,812 (1,123-6,566)		1,648 (-662-4,678)	
Exam Area	452 (171-1455)		208 (-224-1,830)	
Patient Area	671 (263-2,183)		420 (-266-1,984)	
Clinician Area	543 (273-1,548)		138 (-354-1,011)	

Comparisons are between clinics. CFU, colony forming units; IQR, interquartile range; Median Delta CFU, the difference between post-clinic and pre-clinic samples; Clinic Room, total room CFU including pre- and post-clinic samples

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Table 2. Median CFU and median delta CFU for study arms: Intervention arm 1 (Near-UV), Intervention arm 2 (organosilane quaternary ammonium) and the control arm (no intervention).

	Median CFU (IQR)	*p*	Median Delta CFU (IQR)	*p*
Intervention Arm 1				
Room	17,371 (1,419-24,810)	0.38	2,092 (-1,815-8,566)	0.78
Exam Area	9,375 (240-18,000)	0.14	582 (-38-1,860)	0.64
Patient Area	1,146 (303-3,100)	0.04	1,115 (1-3,133)	0.53
Clinician Area	1,606 (420-5,220)	0.06	132 (-2,787-2,119)	0.24
Intervention Arm 2				
Room	6,331 (1,978-16,410)	0.2	2,016 (-1,443-7,430)	0.71
Exam Area	1,449 (536-7,590)	0.36	362 (-442-2,556)	0.93
Patient Area	1,014 (308-2,892) *	0.03	810 (-18-3,347)	0.61
Clinician Area	882 (360-2,361)	0.86	142 (-449-1,200)	0.49
Control Arm				
Room	7,918 (2,939-18,855)		1,987 (-1,611-15,857)	
Exam Area	2,090 (537-10,508)		133 (-996-2924)	
Patient Area	1,524 (573-4,605)		643 (-1,920-3,877)	
Clinician Area	960 (371-2,183)		256 (-518-2,113)	

Comparisons are between individual intervention arms and the control arm. CFU, colony forming units; IQR, interquartile range; UV, ultra-violet light; Median Delta CFU, the difference between post-clinic and pre-clinic samples

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Table 3. Number of clinically important pathogens (CIPs) recovered overall, by clinic, and by study arm.

	Overall (%) N = 900	Wound Clinic (%) N = 450	Pulmonary Clinic (%) N = 450	Intervention Arm 1 (%) N = 300	Intervention Arm 2 (%) N = 300	Control (%) N = 300
S. aureus	27 (3)	14 (3)	13 (3)	3 (1)	9 (3)	15 (5)
Enterococcus spp.	25 (3)	16 (4)	9 (2)	8 (3)	6 (2)	10 (3)
Acinetobacter spp.	4 (1)	4 (1)	0 (0)	2 (1)	0 (0)	2 (1)
Enterobacter spp.	2 (1)	1 (1)	1 (1)	1 (1)	1 (1)	0 (0)
Klebsiella spp.	5 (1)	4 (1)	1 (1)	0 (0)	4 (1)	1 (1)
Proteus mirabilis	2 (1)	2 (1)	0 (0)	1 (1)	0 (0)	1 (1)
Pseudomonas spp.	4 (1)	2 (1)	2 (1)	3 (1)	0 (0)	1 (1)
Serratia marcescens	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)
Other Gram-negatives	20 (2)	19 (4)	1 (1)	7 (2)	1 (1)	12 (4)
All species	90 (10)	67 (15)	23 (5)	25 (8)	21 (7)	43 (14)

"Other Gram-negative" include *Stenotrophomonas spp, Citrobacter spp.* etc.

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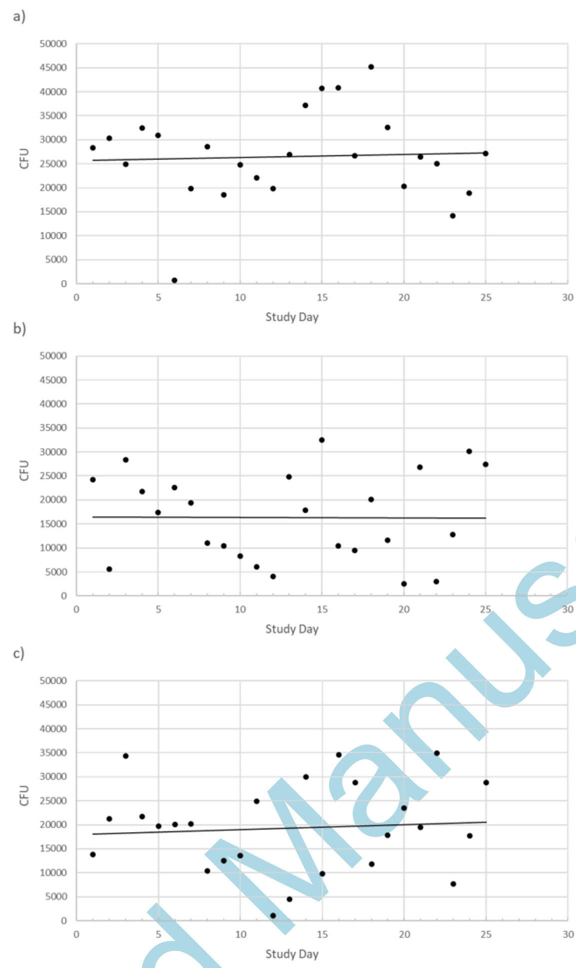
Figure 1



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