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Brief Report

Effectiveness of a shielded ultraviolet C air disinfection system in an inpatient pharmacy of a tertiary care children's hospital

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Key Words: Infection control Sterile compounding Airborne spread of infection Viable air particles pose a risk in areas where sterile preparations are compounded. This study investigated the efficacy of an innovative air purification technology that uses a shielded ultraviolet C light lamp to continuously purify the air in an inpatient pharmacy. Mean airborne fungal and bacterial colony forming units were obtained preinstallation and again in 6 months. A statistically significant decrease of 78% and 62% was observed for fungal and bacterial particles, respectively. This study demonstrates a potential role for this novel technology in decreasing the spread of airborne pathogens.

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The US Pharmacopeial Convention chapter 797 guideline for the compounding of sterile preparations acknowledges that microbial contaminants pose great risk to patients. Strict environmental monitoring is required in and around areas that compound sterile preparations. Volumetric (1 m³) viable airborne particles must be assessed every 6 months for maintenance of certification. Based on the sterility requirements of the medication being prepared, thresholds have been established for each medication preparation area. A colony forming unit count that exceeds threshold prompts an evaluation of cleaning practices, personnel work practices, operational procedures, and air-filtration effectiveness. In the direct compounding area (International Organization for Standardization 5 classification), 1 CFU/m³ bacteria or fungus is considered actionable. In the surrounding anteroom (International Organization for Standardization 7 classification), the threshold is higher at >10 CFU.^{1,2}

Under the influence of controllable and uncontrollable factors, indoor air quality is in a constant state of flux. The individual human

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microbiome, ventilation, outdoor air, plumbing systems, and foliage all contribute to the airborne particulate burden.^{3,4} The potential for indoor air to be a vehicle for the spread of infectious pathogens has led to development of new technologies and methods for decontamination, including ultraviolet (UV) germicidal irradiation.^{3,5}

UV germicidal irradiation has been shown to be effective in reducing transmission of airborne infections in hospitals, classrooms, and military housing.⁶ Historically, there have been 3 methods of UV air disinfection: duct irradiation, upperair irradiation, and inroom cleaners.7 A novel air purification technology employs the former methods using a shielded UV-C (100-280 nm) lamp to continuously purify the air. The unit is an enclosed air disinfection device incorporated into a ceiling light fixture, where an internal fan pulls air into a reflective, aluminum-covered chamber housing a UV-C lamp. A filter rated to remove large dust and debris is in line just before the UV-C chamber to prevent loss of efficacy overtime from dust accumulation (Fig 1). The reflectivity of the aluminum and the airflow of approximately 250 ft/minute are proposed to enhance the germicidal activity of the apparatus.8 In this study, we compared viable airborne particles in and around our inpatient pharmacy pre- and postinstallation of this unique product.

MATERIALS AND METHODS

The inpatient pharmacy is a 5,152-sq ft space located on a midlevel floor of the hospital. A 600-sq ft rectangle anteroom is adjacent to the main pharmacy work area preceding both a 264-sq ft intravenous (IV) preparation room and 88-sq ft chemotherapy

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American Green Technology, South Bend, IN, donated the 52 units used in this study. They had no role in the collection of the samples, analysis, or manuscript preparation. An evidence-based agreement was completed before the study removing any restrictions on the publication of negative results.

preparation room on opposing ends of the anteroom. There is relative positive pressure throughout the pharmacy with exception of the chemotherapy room, which is negative pressure relative to the anteroom. Fifty-two units were installed in the main pharmacy and adjacent anteroom of the compounding area (Tables 1 and 2). The number of units and placement were based on manufacturer guidelines stating a maximal effectiveness of 1 U/100 sq ft. Due to the high efficiency particulate air filtered laminar airflow, units were not placed in the IV preparation room or the chemotherapy preparation room. It was believed that decreasing the viable airborne

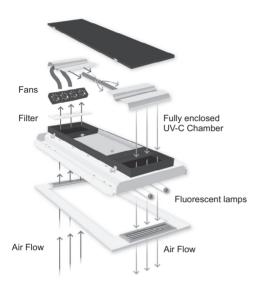


Fig 1. De-constructed view of the shielded UV-C air disinfection unit.

particle burden in the adjacent anteroom would be effective in reducing particles that might enter the preparation rooms during transient disruption in the unidirectional airflow from those areas. The units were continuously operational 24 hours/day following its installation.

An accredited independent environmental sampling company previously used by our facility for certification obtained viable air samples preinstallation and 6 months later. Eight samples were taken in each location with exception of the anteroom, where 16 samples were obtained due to inherently lower microbial burden and the need for statistical significance. The measurements were obtained in identical locations and using the same protocol, in accordance with the US Pharmacopeial Convention chapter 797 guidelines.¹ Surface Air System microbial air samplers (BioScience International, Rockville, MD) were used to influence 1,000 L air onto agar plates (Hardy Diagnostics, Santa Maria, CA). One media was chosen to isolate mold and another to isolate bacteria. The samples were refrigerated and shipped to an accredited independent laboratory where they were incubated for 5 days at $32^{\circ}C \pm 2^{\circ}C$. All bacteria and fungi colony forming units were tabulated by the laboratory using published guidelines.^{1,9}

There were no changes in the cleaning or disinfection practices between the sampling time points. Preinstallation sampling occurred during the last week of September with poststudy sampling during the last week of March. The deciduous trees in the area had begun to defoliate before the initial sampling; therefore, the majority of the study period was believed to have a similar outdoor ambient microbial burden, which is an important factor because the facility is served by the same filtered heating, ventilation, and air conditioning system with airborne particles being brought in by human movement. The exterior hall is an interior thoroughfare just outside the main pharmacy and the means by which staff members enter and exit. It was used as a control because no units were placed

Table 1Air fungal data

	Mean CFU/m ³ Preinstallation	Mean CFU/m ³ Postinstallation	Mean CFU/m³ change	95% Confidence interval	P value
Exterior hall	10.75	14.10	+3.375	-11.64 to 4.89	.396
IV room (ISO 5)	3.25	0	-3.250	-4.44 to 10.94	.351
Chemo room (ISO 5)	2.25	0.38	-1.875	-0.70 to 4.45	.131
Interior hall	10.50	2.14	-8.71	3.04 to 14.39	.008*
Breakroom	11	2.50	-8.50	3.92 to 13.08	.003*
Storage room	25.6	2.60	-23	-9.68 to 55.68	.140
Anteroom (ISO 7)	1.8	0.18	-1.56	0.63 to 2.50	.003*
Work area 1	11.5	6.10	-5.50	-3.67 to 14.67	.219
Work area 2	7	2.25	-4.75	0.55 to 8.95	.031*
Overall	8.30	1.82	-6.48	2.78 to 10.17	<.001*

ISO, International Organization for Standardization.

Table 2Air bacteria data

in pacteria data								
	Mean CFU/m³ Preinstallation	Mean CFU/m ³ Postinstallation	Mean CFU/m³ change	95% Confidence interval	P value			
Exterior hall	95.13	59.8	-35.38	14.00 to 84.75	.141			
Intravenous line room (ISO 5)	1.5	0.125	-1.38	0.36 to 2.39	.014*			
Chemo room (ISO 5)	27.6	8	-19.63	3.89 to 35,36	.020*			
Interior hall	74.3	74.9	0.063	-109.3 to 108.1	.990			
Breakroom	87.3	20.8	-66.50	41.48 to 91.52	<.001*			
Storage room	110.9	34	-76.88	76.88 to 20.15	.013*			
Anteroom (ISO 7)	35.3	4.85	-30.44	5.85 to 55.02	.019*			
Work area 1	86.6	29	-57.63	6.18 to 109.10	.032*			
Work area 2	51.8	19.6	-32.13	-0.01 to 64.26	.050			
Overall	56.72	21.79	34.93	18.47 to 51.39	<.001*			

ISO, International Organization for Standardization.

^{*}P < .05.

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in that area; it was separated from the main pharmacy; the airflow was comparable to the study area; and it was served by the same heating, ventilation, and air conditioning system.

Using Surface Air System software, preinstallation and poststudy colony forming units per meters cubed mean values from each area were compared with a 2-tailed independent t test. An overall preand poststudy mean colony forming units per meters cubed was also obtained. A change with a P value < .05 was considered significant.

RESULTS

A mean colony forming units per meters cubed count from the entire pharmacy revealed an overall significant decrease in both fungal and bacterial viable air particles by 78% and 62%, respectively. There was a statistically significant decrease in mean air fungal colony forming units per meters cubed in the interior hall, breakroom, work area 2, and the anteroom. A decrease in mean fungal colony forming units per meters cubed in the IV and chemotherapy rooms was noted; however, it was not statistically significant (Table 1). Similarly, mean air bacterial colony forming units per meters cubed were significantly decreased in the breakroom, storage room, work area 1, and the anteroom. We also saw a significant decrease in the IV and chemotherapy rooms (Table 2). There was no significant change noted in the control exterior hall for fungal or bacterial particles (Tables 1 and 2).

DISCUSSION

This study was undertaken to determine the ability of a novel enclosed UV-C air disinfection system to decrease viable air particles adjacent to the sterile compounding area of an inpatient pharmacy. Because viable particles in the IV and chemotherapy rooms were not primary end points, the impressive decreases in both fungal and bacterial counts in the anteroom are most relevant. Decreasing microbial air burden in the periphery of the pharmacy space, where one would expect a higher air microbial burden due to influx and efflux of staff and deliveries, and creating a zone around the sterile compounding areas was effective. We believe that this zone reduces the likelihood of contamination in the compounding areas

when transient disruptions of positive or negative airflow occur. This is suggested by the significant decrease in mean bacterial colony forming units per meters cubed in the IV and chemotherapy room as well as the downward trend in the fungal colony forming units per meters cubed, where lack of significance seems to be due to a lack of statistical power.

CONCLUSIONS

This novel air purification system was effective in decreasing viable airborne microbes in our inpatient pharmacy. We believe these units are advantageous to other technologies currently available in that they allow for constant, in-room UV-C air purification. Moving forward, further studies will be required to determine clinical significance, sustainability over time, and additional applications.

References

- The United States Pharmacopeial Convention. Pharmaceutical compounding sterile preparations (general information chapter 797). In: The United States pharmacopeia, 36th rev., and the national formulary. 31st ed. Rockville (MD): 2013. p. 361-98.
- American Society of Health System Pharmacists. ASHP guidelines on compounding sterile preparations. Am | Health Syst Pharm 2014;71:145-66.
- Ijaz MK, Zargar B, Wright KE, Rubino JR, Sattar SA. Generic aspects of the airborne spread of human pathogens indoors and emerging air decontamination technologies. Am J Infect Control 2016;44:S109-20. doi:10.1016/j.ajic.2016.06.008.
- 4. Meadow JF, Altrichter AE, Bateman AC, Stenson J, Brown GZ, Green JL. Humans differ in their personal microbial cloud. PeerJ 2015;3:e1258. doi:10.7717/peerj.1258.
- Sattar SA, Kibbee RJ, Zargar B, Wright KE, Rubino JR, Ijaz MK. Decontamination
 of indoor air to reduce the risk of airborne infections: studies on survival and
 inactivation of airborne pathogens using an aerobiology chamber. Am J Infect
 Control 2016;44:e177-82. doi:10.1016/j.ajic.2016.03.067.
- Guidelines for preventing the transmission of Mycobacterium tuberculosis in health-care facilities, 1994. Centers for Disease Control and Prevention. MMWR Recomm Rep 1994;43:1-132.
- 7. Jensen P, Lambert L, lademarco MF. Guidelines for preventing the transmission of mycobacterium tuberculosis in health-care settings, 2005. MMWR Recomm Rep 2005;54:1-141.
- 8. Kowalski W. Report on the Performance of the VidaShield System. 2011. Available from: http://vidashield.com/files/whitepaper/dr-kowalski-vidashield-final-report.pdf. Accessed June 19, 2017.
- The United States Pharmacopeial Convention. Microbiological control and monitoring of aseptic processing environments (general information chapter 1116). In: The United States Pharmacopeia, 36th rev., and the National Formulary. 31st ed. Rockville (MD): 2013. p. 784-94.