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Comprehensive and Live Air Purification as a Key Environmental, Clinical, and Patient Safety Factor: A Prospective Evaluation

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Abstract

Healthcare organizations strive to provide optimal patient experience by improving care quality and enhancing clinical outcomes, while containing associated costs. In the United States, the Center for Disease Control (CDC) estimates that more than 1.7 million people suffer from an infectious complication annually, representing between 5 and 10% of all hospital admissions and costs ranging between \$35B and \$88B. Most infectious surface fomites originate from air. Consequently, reducing airborne pathogens should be associated with reduced surface fomites. This study represents the first comprehensive evaluation of infectious and aerosolized pathogens and their speciation, location and concentration within a typical hospital setting. The study provides data regarding the relationship between airborne pathogens and air filtration methodologies in the context of the molecular and microbial epidemiology of illness and infections in the clinical setting. The results demonstrated that using a transformational air purification system provided comprehensive remediation of airborne pathogens and significantly reduced surface-oriented infectious fomites. Overall reduction of airborne and surface bacterial and fungal pathogens responsible for illness and infections will result in a reduction of associated illnesses and HAI rates and improved patient care metrics including stay duration and readmission rates. Improvements in these outcome metrics should correlate to risk mitigation and cost avoidance.

Keywords: airborne pathogens, hospital-acquired infections, HAI, patient care, bacterial pathogens, fungal pathogens, air filtration, air purification, hospital, molecular epidemiology, microbial epidemiology, illness, infection, length of stay, readmission rates, clinical outcomes, HEPA, biological particulates, VOC, volatile organic compounds, ambient air quality, viable particulates, nonviable particulates

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1. Introduction

In the United States, the Center for Disease Control and Prevention (CDC) estimated that more than 1.7 million people suffer from an infectious complication within the hospital environment annually, representing between 5 and 10% of all admissions [1]. Approximately 99,000 patients afflicted with hospital-acquired infections (HAIs) die each year [2]. The number of estimated patients with an HAI exceeds that of any required reportable disease in the United States, and the number of deaths attributed to HAIs exceeds many of the top ten leading causes of death reported from the US vital statistics [1]. Moreover, the above estimates likely under-represent the true magnitude of the problem due to erroneous reporting and biases inherent to voluntarily reported data.

Apart from the morbidity and mortality associated with HAIs, the estimated healthcare costs range between \$35B and \$88B annually [3]. The most recent Pennsylvania Healthcare Cost Containment Counsel (PHC4) Report indicated that hospitals and Medicare spent approximately \$3B and \$400 M, respectively, toward statewide care of patients affected by HAIs during the reporting year of 2010 [4].

The Centers for Medicare and Medicaid Services (CMS) announced in August 2007 that Medicare would no longer cover additional costs associated with many preventable errors, including those considered "never events" [5]. The list of events that should never occur in the healthcare setting has now been expanded to encompass 29 unique serious reportable events. HAIs represent one of the 29 unique "never events" that are no longer reimbursable and may even result in further economic penalties [6, 7].

It is estimated that full societal costs associated with HAIs arising in US acute care hospitals amount to approximately \$96–\$147 billion annually [8]. The corresponding per-hospitalization incremental cost ranges between \$17,070 and \$32,176 [8]. Consequently, it can be reasonably extrapolated that a three-room surgical suite, performing 1,000 annual surgeries with a reported 4% infection rate, would realize a cost avoidance savings of between \$171,000 and \$322,000 per year specific to the surgical suite with only a 1% decline in HAI rates.

Historically, it has been understood that the patient, the healthcare worker, and various surface areas collectively constitute the primary repositories of pathogens responsible for majority of HAIs [9]. To that end, infection control protocols, in-room sterilization techniques, patient preparation, and hand-washing protocols have been implemented in most hospitals and have been helpful in reducing overall HAI rates [10]. Moreover, recent literature suggests that a significant proportion of pathogens responsible for HAIs are airborne [11]. The Aire~HCX[™] (LifeAire Systems, Allentown, Pennsylvania) [12] was specifically designed to comprehensively address these airborne pathogens (AP) as they are inherently generated during routine clinical operations. In environments where Aire~HCX[™] is employed, infectious APs are remediated in both the supply and return air before entering the clinical space.

The LifeAire Systems' advanced air purification technology (LAS-APS) exceeds the limitations associated with commonly utilized mechanisms of air filtration [13]. Many in-room sterilization technologies require that the clinical space be vacated before use, leading to temporary loss of functional space. The in-room approaches also provide a "static" clean at the exact time

of use [14, 15]. Reentry of patients and healthcare workers and the initiation of clinical processes inherently serve as a source of rapid re-establishment of pathogen populations [16–18]. Unlike the "static" clean model of many of the in-room units, the LAS-APS provides real-time remediation of APs as they are generated during clinical operation. In addition, unlike the "capture" model of the commonly used HEPA filters, the LAS-APS uses a "kill" model and is mathematically and genomically modeled to destroy the DNA and RNA of all bacteria and viruses such that they are rendered noninfectious. HEPA filtration is based upon the capture of viable biological particulates, allowing the spores to grow and proliferate above the space being protected. Air flowing over the spores can disturb and dislodge them such that they enter the clinical space [19]. The "kill" mechanisms incorporated into the LifeAire Systems' technology eliminate these possibilities.

LifeAire Systems' Aire~HCXTM purification unit is installed within the healthcare facility's heating ventilation and air conditioning (HVAC) ductwork. The system is designed to deliver ultrapure, contaminant-free air to any clinical environment. Based on over a decade of research, development, and testing, the Aire~HCXTM system has been tested and proven to deliver air that is 99.99% free of any contaminants, with an associated air purity guarantee [12, 13]. In essence, the LAS-APS was designed to remove all airborne biological pathogens and thus enhance patient safety of the intended healthcare environment by reducing HAI incidence rates, as exemplified by the current collaborative effort between LifeAire and St. Luke's University Health Network (SLUHN). With 69–80% of the pathogens responsible for HAIs being airborne at some point, aggressive remediation of all airborne pathogens will provide for improved patient care and outcomes while reducing the financial burden associated with HAIs.

2. Genesis of LAS-APS air filtration paradigm

With more than a decade of clinical research into the critical role of ambient air quality, the principal investigator (KCW) designed, tested, and patented their transformational air purification technology [12, 13]. This work revealed that one of the key factors impacting successful clinical outcomes was that of the ambient air. Current standards and guidelines as stated are inadequate to provide ambient air optimal for the clinical and patient setting. The clinical environment is impacted by events both external and internal to the space in question. The research highlighted the significant contribution made by patients, healthcare workers, and various clinical processes [20]. External environmental events, even those outside of the immediate proximity of a clinical space, were also found to greatly impact positive outcomes [21–28]. By removing airborne chemical and biological pathogens to below-detection levels, the LAS-APS provides unprecedented control over air quality and significant positive impact on clinical outcomes [25–28].

The LAS-APS provides extremely high levels of filtration as it was designed to kill the anthrax spore (e.g., the most difficult biological pathogen to kill) [29]. The technology used in LAS-APS-patented technology has been tested by the National Homeland Security Research Center and by other third parties. Results indicate that the system renders a broad spectrum of pathogens inert and that it virtually eliminates threatening biological pathogens and volatile organic

chemicals from the air—to a level of effectiveness not previously commercially available. Because of its effectiveness toward *Bacillus anthracis*, the LifeAire Systems is able to remediate airborne pathogens such as *Clostridium difficile*, *Aspergillus*, *Streptococcus*, *Pseudomonas*, Staphylococcus (including methicillin-resistant variety), smallpox virus, *Mycobacterium tuberculosis*, influenza virus, etc., each representing a consistent threat to both the hospital environment and rates of HAIs [unpublished data].

3. Materials and methods

The design of the current study includes three zones within two medical surgical floors of a SLUHN Allentown hospital campus. The three geographic zones (**Figures 1–3**) include a control floor with air handling unit (CF-AHU) HEPA-filtration remediation, a zone with mixed AHU-HEPA and LifeAire remediation (MIXED) with recirculated air, and a zone with comprehensive LifeAire Systems Air Remediation (LSAR). Within each of these zones, two occupied and active patient rooms were selected for air quality testing. Each of the two rooms was comprehensively evaluated per zone. The patient rooms were chosen such that the effects of elevators/entrances/exits as well as zone barriers would be minimized. Rooms were further chosen to optimize direct comparisons of resulting data. **Table 1** illustrates the zones and rooms evaluated during the study.

During each testing event, one of the two rooms listed were chosen for the complete suite of particulate, biological, and volatile organic compound (VOC) testing. For this study, the two rooms in each zone were considered equivalent. For each specific testing event, room preference was for patient occupancy, followed by consistency within each room between measurements.

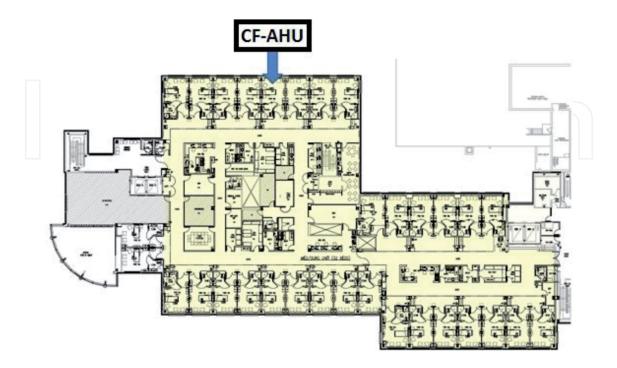


Figure 1. Schematic representing the CF-AHU on the control floor.

Each of the rooms underwent comprehensive evaluation for airborne and surface viable bacterial, fungal, and VOC loads. Three commonly touched patient surfaces and two commonly touched clinical surfaces were evaluated per testing assay (**Tables 2** and **3**). In addition, the final diffuser providing supply air to the patient room and the return vents were swabbed for viable bacteria and fungi (**Table 4**).

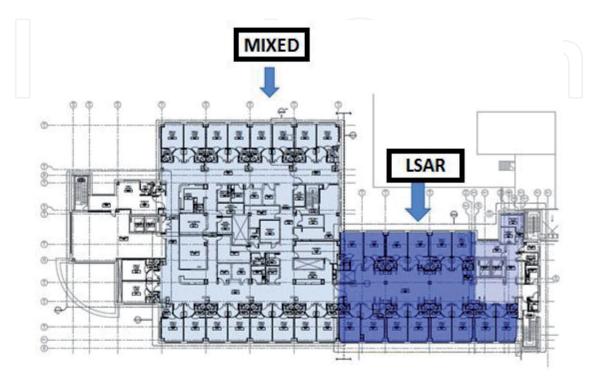


Figure 2. Schematic representing LSAR and MIXED zones, respectively.

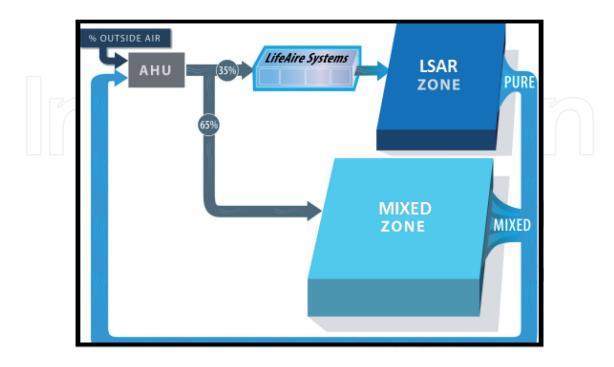


Figure 3. Schematic representation of HVAC layout of the MIXED and LSAR zones.

3.1. Testing assay: viable bacteria by air

Air testing was completed using the third-party laboratories, EMSL, and Galson Laboratories under their proprietary method MICRO-SOP-132 [30, 31]. Following the standard operating procedures (SOPs) provided by the third-party laboratories and using a Viable Andersen Cascade Impactor and calibrated pump, samples were gathered for 5 minutes at 28 liters per minute onto a soy agar plate. The five most concentrated species were then identified and quantified.

3.2. Testing assay: viable bacteria by swab

Surface testing was conducted following all SOPs of the third-party laboratories. Using a sterile swab, an area measuring 2-by-2 inch was sampled in each location with a smooth back-and-forth motion while rolling the swab for 10 seconds. The swab was then capped and sent to the third-party laboratory for testing under method MICRO-SOP-132 [30]. The most prominent five types of bacteria were identified and quantified.

Zone	HVAC design
CF-AHU	AHU-HEPA remediation
MIXED	AHU-HEPA and LifeAire systems remediation
LSAR	LifeAire systems air remediation

Table 1. HVAC design by study zone.

Bedside table (directly in front of patient)

IV support pole/IV support pole

Patient remote control—number buttons

Table 2. Patient surface sampling sites.

IV control faceplate

Pressure cuff bulb

Table 3. Clinical surface sampling sites.

HVAC room diffuser

HVAC room return

Table 4. HVAC surface sampling sites.

3.3. Testing assay: viable fungi by air

Air testing was completed using a third-party laboratory under their proprietary method MICRO-SOP-202 [30]. Following the SOPs provided by the third-party laboratories and using a Viable Andersen Cascade Impactor and calibrated pump, samples were gathered for 5 minutes at 28 liters per minute onto a MEA agar plate. The five most concentrated species were identified and quantified.

3.4. Testing assay: viable fungi by swab

Surface testing was conducted following applicable SOPs of the third-party laboratories. Using a sterile swab, an area measuring 2-by-2 inches was sampled in each location with a smooth back-and-forth motion while rolling the swab for 10 seconds. The swab was then capped and sent to the third-party laboratory for testing under method MICRO-SOP-202 [30]. The five most prominent species of viable fungi were identified and quantified.

3.5. Testing assay: volatile organic compounds (VOC) testing

The measured VOC load of each room was determined using the methodology described in EPA TO-15 [32]. Using an evacuated container, air was captured for 15 minutes. The TO-15 assay determines VOCs in air collected using specially prepared stainless steel canisters and subsequently analyzed by gas chromatography/mass spectrometry (GC/MS). Due to the live hospital setting and available locations to place the testing cylinder, longer sampling times were considered but not employed due to the risk of sample tampering by unmonitored patients, visitors, and clinical staff.

3.6. Testing assay: nonviable particulate testing

Particulate testing was conducted using a modified NIOSH 0500 method [33]. Sampling was conducted for 5 minutes at each testing site. The environmental testing was completed each month with sampling beginning in the morning and progressing through early afternoon. Clinical, housekeeping, operational staff and patients were blinded to both the study and zone locations to minimize any biases associated with behaviors or perceptions. Cleaning SOPs, patient care operations, patient appointment schedules, visitation, patient dining, and all operations of the floor remained unchanged. Sampling occurred during normal visitations, staff consultations, and meals to allow data acquisition and flow to simulate full hospital operations.

4. Results

The overall study results are presented in **Figure 4** and in **Tables 5–7**. All data were provided by independent third-party laboratories after sampling the air and designated surfaces in each patient room associated with the specific study zone, as outlined in the methodology section. A comprehensive environmental assessment of viable bacterial, fungal, and VOC pathogens was conducted each month and repeated a total of 4 times between March and July of 2018.

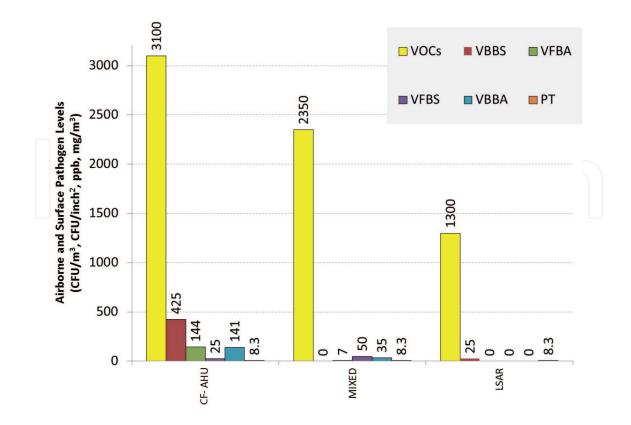


Figure 4. Results for viable airborne and surface bacteria and fungi and VOC load in each zone (CF-AHU, MIXED, and LSAR). Legend: AHU, air handling unit; VFBA, viable fungi by air (CFU/m³); VFBS, viable fungi by swab (CFU/in²); VBBA, viable bacteria by air (CFU/m³); VBBS, viable bacteria by swab (CFU/in²); VOCs, volatile organic compounds (ppb); PT, particulates (mg/m³).

Zone	VFBA	VFBS	VBBA	VBBS
CF-AHU	Aspergillus	Aspergillus	Micrococcus luteus	Micrococcus lylae
	Cladosporium	<i>Cladosporium</i> (remote, return)	Staphylococcus spp.: capitis, epidermidis, haemolyticus, saprophyticus	Staphylococcus spp.: capitis, haemolyticus (remote, return), hominis, saprophyticus (return)
			Gram-negative rod	Gram-negative rod (return)
			Bacillus spp.: clausii, licheniformis	Gram-positive cocci (remote, return)
			Dermabacter hominis	
			Kocuria palustris	
MIXED	Yeast	<i>Rhodotorula</i> (return)	Staphylococcus haemolyticus	Nil
			Bacillus licheniformis	
			Dietzia cinnamea	
			Streptococcus anginosus	

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Zone	VFBA	VFBS	VBBA	VBBS
LSAR	Nil	Nil	Nil	<i>Staphylococcus</i> spp.: capitis (patient remote), epidermidis (faceplate)
				<i>Corynebacterium</i> (patient remote)

Table 5. Identification	of viable bacteria ar	d fungi by air an	d on surface within the	e three study zone	es (CF-AHU, MIXED,
and LSAR).					

Pathogen	Association with patient illness	Location within clinical space
Aspergillus	Associated with pulmonary infections, infections to skin lesions	Circulating air in patient room
		Patient remote
		HVAC Return
Cladosporium	Associated with infections to skin, sinuses, and lungs; significant allergens impacting asthmatics and patients with respiratory	Circulating air in patient room
	diseases; spores produce toxic VOCs	Patient Remote
		HVAC Return
Staphylococcus	Associated with urinary tract infections	Circulating air
saprophyticus		in patient room
		Return
Staphylococcus pidermidis	Skin flora and low association with HAIs	Circulating air in patient room
Staphylococcus capitis	Natural skin flora often associated with infections caused by catheters and aortic valves	Circulating air in patient room
		Patient Remote
		HVAC Return
Micrococcus luteus	Source is typically patient-oriented, mouth, mucosae, oropharynx, and upper respiratory tract, often associated with ill patients	Circulating air in patient room
Staphylococcus haemolyticus	Antibiotic resistant and associated with skin flora	Circulating air in patient room
		Patient Remote
		HVAC Return
Bacillus clausii	Associated with respiratory infections and GI disorders, produces antimicrobial substances active against <i>Staphylococcus aureus</i> , <i>C. difficile</i> , and <i>Enterococcus faecium</i>	Circulating air in patient room
Bacillus licheniformis	Associated with soil and bird plumage	Circulating air in patient room
Dermabacter hominis	Associated with wound infections, abscesses, and positive blood cultures	Circulating air in patient room

Pathogen	Association with patient illness	Location within clinical space
Kocuria palustris	Pathogen responsible for UTIs	Circulating air in patient room
Gram-positive cocci	Staphylococcus aureus and Streptococcus pyogenes are two of the most common causes of hospital-acquired pneumonia, septicemia, folliculitis, and surgical site infections	Patient Remote HVAC Return
Gram-negative rods	Associated with <i>E. coli, Salmonella, Shigella, Pseudomonas,</i> severe GI illness	Circulating air in patient room HVAC Return
Micrococcus lylae	Associated with skin flora, opportunistic pathogen in immunocompromised patients	HVAC Return
Staphylococcus hominis	Associated with infections in immunocompromised patients	HVAC Return

Table 6. Pathogen characteristics of zone CF-AHU (the control zone).

Pathogen	Association with patient illness	Location within clinical space	
Yeast	Associated with pulmonary infections and skin lesion infections	Circulating air in patient room	
Rhodotorula	Common clinical contaminant associated with soil and water	HVAC Return	
Staphylococcus haemolyticus	Antibiotic resistant and associated with skin flora	Circulating air in patient room	
Bacillus licheniformis	Associated with soil and bird plumage	Circulating air in patient room	
Dietzia cinnamea	Associated with catheter and orthopedic prosthesis- associated infections in immunocompromised patients	Circulating air in patient room	
Streptococcus anginosus	Common cause of abscesses, abdominal and thoracic infections, endocarditis, and bacteremia	Circulating air in patient room	

Table 7. Pathogen characteristics of MIXED zone-partial remediation (CF-AHU and 35% LSAR).

Pathogen	Association with patient illness	Location within clinical space
Staphylococcus epidermidis	Skin flora and low association with HAIs	IV control faceplate
Corynebacterium	Normal skin flora, low association with infections, prosthetic devices	Patient Remote
Staphylococcus capitis	Natural skin flora often associated with infections caused by catheters and aortic valves	Patient Remote

Table 8. Pathogen characteristics of LSAR zone patient rooms.

There were 3100 ppb VOCs and <8.3 mg/cubic meter of nonviable particulates in CF-AHU Zone (**Table 6**).

There were no viable bacteria by swab, 2350 ppb VOCs, and <8.3 mg/cubic meter of nonviable particulates in the MIXED Zone (**Table 7**).

Finally, there were no viable bacteria by air, no viable bacteria by swab, no viable fungi by air, 1300 ppb VOCs, and < 8.3 mg/cubic meter of nonviable particulates in LSAR Zone (**Table 8**). The reduction in VOCs is due to the remediation of viable fungal spores and their concomitant production of fungal VOCs. As there was a HEPA filter in place on the serving air handling unit, all air was HEPA-filtered. This was confirmed by the nonviable particulate assessment of <8.3 mg/cubic meter in all study zones.

5. Discussion

Often neglected, indoor air quality is an important component of ensuring healthy and safe environment across various healthcare facilities [34]. It is well established that there exists "strong and sufficient evidence" of the association between ventilation, air movements in buildings, and the transmission of bacterial, fungal, and viral infectious diseases [35]. Consequently, the need for high efficiency/reliable air filtration becomes a necessity, especially in critical environments such as acute care wards, critical care units, isolation units, and operating rooms [36–38]. The current project highlights the importance of an integrated system, such as the LAS-APS, in the modern healthcare environment. The subsequent discussion will synthesize our study's results in the context of acute care hospital setting.

Perhaps most importantly, we noted a substantial decrease in air contaminants across all measurement categories. As the degree of air remediation increased from CF-AHU Zone or the control floor to comprehensive coverage in the patient rooms in LSAR Zone, a significant decrease in airborne bacterial, fungal, and VOC load was observed. The decrease in both bacterial and fungal loads within the air was concomitant with a significant decrease observed on commonly touched clinical and patient surfaces. Within the control zone, many of the pathogens identified in air samples from patient rooms were also found on commonly touched patient surfaces and on the return vents of the room. This data provides a significant contribution to our understanding of the airflow and path of aerosolized pathogens within the typical clinical space.

Previously published data show a strong relationship between the presence of airborne fungal spores and air quality in the hospital setting [39]. As part of the current study, viable fungi species of *Aspergillus* and *Cladosporium* were speciated and quantitated within the control zone patient rooms. Our results demonstrate a substantial decrease in fungal spore detection rates when using LAS-APS technology, as compared to the other approaches.

The presence of bacteria, both in the air and on various surfaces, has been shown to be deleterious to healthcare outcomes [40, 41]. In addition to the fungal species, viable bacterial

species were also identified within the patient rooms of the control zone. *Staphylococcus saprophyticus, Staphylococcus epidermidis, Staphylococcus capitis, Micrococcus luteus, Staphylococcus haemolyticus, Bacillus clausii, Bacillus licheniformis, Dermabacter hominis, Kocuria palustris, Gram-positive cocci, Gram-negative rods, <i>Micrococcus lylae,* and *Staphylococcus hominis* were found in both the recirculating air of the patient room and on the patient remote and HVAC return. Many of the aerosolized pathogens found within the recirculating air were found on the HVAC return vents. Presence of these pathogens on the return vents confirms their aerosolized nature and threat to the clinical spaces also served by the recirculated air. With the exception of *Bacillus licheniformis,* each of these pathogens are most likely the patient; visitors, and healthcare workers [42, 43].

It is also important to note that patient rooms in the MIXED Zone received approximately 35% of their recirculated air from the rooms from the LSAR Zone and thus benefited from the installed LAS-APS filtration capacity. The zone also served as an "internal control" as it was located on same the floor as LSAR Zone. Viable yeast was found in the circulating air of the patient rooms in LSAR Zone, and viable *Rhodotorula* was found on the HVAC return vent. Although at a significantly reduced level from that observed in CF-AHU Zone, viable bacteria were identified within the air of the patient rooms of MIXED Zone. *Staphylococcus haemolyticus, Dietzia cinnamea,* and *Streptococcus anginosus,* each a potential source of patient illness and infection, were identified in the patient rooms of MIXED Zone. *Bacillus licheniformis* was also identified but is not associated as a source of patient illness swabbed in MIXED Zone. VOCs were reduced over that assessed in CF-AHU Zone. The reduction of viable fungi in MIXED Zone corresponded to the simultaneous reduction in fungal VOC sources.

The patient rooms in LSAR Zone received all of their supply and recirculated air from the LAS-APS installation. There were no viable fungi by air or swab detected in the patient rooms in LSAR Zone. Likewise, there were no viable bacteria by air detected in the patient rooms in LSAR Zone. Low levels of *Staphylococcus epidermidis* were found on the IV control faceplate, and *Corynebacterium* and *Staphylococcus capitis* were found on the patient remote. Because no viable bacteria identified on the patient remote and IV control faceplate were most likely due to direct surface-to-surface contact. The lowest levels of VOCs were found in the patient rooms of LSAR Zone as these rooms demonstrated no viable fungi in the circulating air.

The vast majority of infectious surface fomites originate from the air and may be directed onto surfaces by air flow generated by in-room fans and air conditioning systems [44–46]. Consequently, a reduction in airborne bacterial and fungal pathogens should be associated with a reduction in surface fomites [44, 47]. Overall reduction of airborne and surface bacterial and fungal pathogens responsible for patient illness and infections should result in a reduction of associated illnesses, HAI rates, and improved metrics of patient care inclusive of, but not limited to, length of stay and readmission rates. Improvements in these outcome metrics should, by association, correlate to risk mitigation and cost avoidance.

It is important to note that the current, preliminary study represents the first comprehensive evaluation of infectious and aerosolized pathogens and their speciation, location, and concentration within a typical hospital setting. The study provides important data regarding the complex relationship between airborne pathogens and air filtration methodologies in the context of the molecular and microbial epidemiology of illness and infections in the clinical setting. A greater understanding of the role of airborne pathogens in illness in the clinical setting will help facilitate the identification of proper and more optimal levels of remediation.

6. Summary

In the modern healthcare environment, organizations strive to provide optimal patient experience by improving the quality of patient care, enhancing clinical outcomes, while at the same time containing associated costs. Rarely is there an opportunity to utilize technology that positively impacts quality and cost of hospital care without a detrimental "trade off" or major changes in existing behaviors or protocols. We hypothesized that LAS-APS implementation within the SLUHN facility will lead to notable enhancements in air quality across areas serviced by this air filtration/purification system. The current study clearly demonstrates a significant reduction across all forms of air contamination following the installation of LAS-APS. These results represent an important milestone for further research in this critical and often neglected area of healthcare facility operations and maintenance.

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