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Major Article

Methodology for analyzing environmental quality indicators in a dynamic operating room environment

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Key Words:
Air quality in operating rooms
Operating room ventilation rates
Air changes per hour
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Mock surgical procedures
Environmental quality indicator (EQI)

Background: Sufficient quantities of quality air and controlled, unidirectional flow are important elements in providing a safe building environment for operating rooms.

Methods: To make dynamic assessments of an operating room environment, a validated method of testing the multiple factors influencing the air quality in health care settings needed to be constructed. These include the following: temperature, humidity, particle load, number of microbial contaminants, pressurization, air velocity, and air distribution. The team developed the name environmental quality indicators (EQIs) to describe the overall air quality based on the actual measurements of these properties taken during the mock surgical procedures. These indicators were measured at 3 different hospitals during mock surgical procedures to simulate actual operating room conditions. EQIs included microbial assessments at the operating table and the back instrument table and real-time analysis of particle counts at 9 different defined locations in the operating suites. Air velocities were measured at the face of the supply diffusers, at the sterile field, at the back table, and at a return grille.

Results: The testing protocol provided consistent and comparable measurements of air quality indicators between institutions. At 20 air changes per hour (ACH), and an average temperature of 66.3°F, the median of the microbial contaminants for the 3 operating room sites ranged from 3-22 colony forming units (CFU)/m^3 at the sterile field and 5-27 CFU/m^3 at the back table. At 20 ACH, the median levels of the 0.5-μm particles at the 3 sites were 85,079, 85,325, and 912,232 in particles per cubic meter, with a predictable increase in particle load in the non–high-efficiency particulate air-filtered operating room site. Using a comparison with cleanroom standards, the microbial and particle counts in all 3 operating rooms were equivalent to International Organization for Standardization classifications 7 and 8 during the mock surgical procedures.

Conclusions: The EQI protocol was measurable and repeatable and therefore can be safely used to evaluate air quality within the health care environment to provide guidance for operational practices and regulatory requirements.

BACKGROUND

Potentially high risk medical procedures are performed in hospital operating rooms (ORs) across the country on a daily basis. As a result, there are detailed and stringent procedures in place for routine clinical practices, such as hand washing and instrument sterilization, and for the HVAC (heating, ventilation and air conditioning) systems, such as relative humidity and ventilation rates. To provide

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a safe environment for surgery, ventilation rates in ORs, which are measured in air changes per hour (ACH), are understandably higher than any other space in a hospital. While the highest air change rates may be required to provide a quality indoor environment to help minimize the risk of surgical site infections, there are significant capital and operating costs associated with meeting these requirements.

The purpose of this applied research project was to develop a reproducible and verifiable method to compare the air quality in ORs under dynamic conditions currently being used in the health care industry. The testing protocol was developed by an interdisciplinary team, which included medical clinicians, air quality experts, engineers and industrial hygienists experienced in OR proceedings. The process for the testing included a "mock" surgical procedure directed by a board-certified surgeon in real ORs. The procedure used industry standard gowning and sterilization practices and was supported by experienced OR staff in order to simulate actual conditions during a routine surgical procedure. The results after testing at three different hospitals showed that meaningful and statistically relevant data could be obtained for use in evaluating the quality of the air in actual OR conditions. The testing protocol developed was measurable and repeatable, and thus, provides an effective method to measure air quality in ORs and potentially other critical spaces in a hospital environment.

The health care industry is consistently faced with the dual challenge of improving the quality of care while simultaneously reducing costs. A recent study reported the health care industry sustains $10 billion in annual costs related to infections acquired after admission.[1] Similarly, the Centers for Disease Control and Prevention reported that 1 in 20 patients admitted to hospitals will contract a hospital-acquired infection.[2] Medical insurance companies and government payers have taken note of these costs and are reducing reimbursement for health care–associated infections. These include surgical site infections, which can be impacted by the quality of the air in the OR environment.[3]

Because of the many confounding variables and factors, it is not feasible to make a direct connection from poor air quality to surgical site infections.[4] However, it is generally accepted that poor air quality and airborne contaminates contribute to increased rates of surgical site infections. Studies suggest that over one-third of hospital-acquired infections could be a result of airborne transmission.[5] Another study reported that the air in the OR is considered a route for microbes to enter the surgical wound.[6]

The ventilation rates, in ACH, vary in different state regulations and in actual practice. These air change rates are often "based on tradition rather than science."[7] Therefore, there is notable variety in hospitals across the country regarding ACH, use of high-efficiency particulate air (HEPA) filters, ultraviolet or ozone systems, overhead diffuser layouts, and routine heating, ventilation, and air conditioning (HVAC) system maintenance. We found that the different indicators varied significantly during the 3 tests. For example, the air velocity at the sterile field varied from 4 to 74 feet per minute. This is similar to results from a study that showed the indoor air quality of different active ORs varied from month to month. Another similarity in the studies was that the particle count increased in direct relationship to the number of people in the room.[8]

There is often a sense of more air is better, and although this philosophy may not always lead to cleaner ORs and better outcomes, it will typically increase the operating costs of the hospital. Given the variation in these parameters, research in this field could provide more scientific evidence to optimize clean space guidelines while simultaneously minimizing costs and improving positive clinical outcomes. Because there are no standardized methods for bacterial air sampling or its frequency, we developed a testing methodology which encompassed metrics from other industries and countries, such as particle counts and number of microbial contaminants, and standard hospital criteria, such as air velocity and temperature. We developed the concept of environmental quality indicators (EQIs) to evaluate overall air quality using these multiple metrics that provided measurable, repeatable, and verifiable results in a dynamic hospital setting.[9]

The specific purposes of this methodology were (1) to develop a reproducible testing model using a mock surgical procedure that could be used for clinical assessment of clean spaces, and (2) to evaluate quantifiable EQIs with measurable criteria, which were defined as microbial contaminants measured in colony forming units (CFU) per cubic meter and particle counts in particles per cubic meter.

MATERIALS AND METHODS

Locations

Three different ORs in 3 different hospitals in 2 different states were chosen for experimentation. The ORs in 2 hospitals were associated with academic medical schools (ORs A and B). Both had HEPA-filtered air supplies to the rooms and were 638 and 554 ft^2, respectively. They were opened in 2013 and 2011, respectively. The third OR (OR C) was located in a private community hospital, had minimum efficiency reporting value 14 filters, and was 505 ft^2. It was opened in 2004. Studies took place from the summer of 2015 to the spring of 2016.

Instrumentation setup

To detect microbial contamination, 2 critical locations in the OR were selected: the operating table where procedures are performed and the back table where the surgical instruments are opened and prepared.[10]

Bioscience viable surface air samplers (SAS180; Bioscience International, Rockville, MD) were placed at both locations to detect the contaminants. Petri plates with tryptic soy agar media were used in the samplers and were changed in regular cycles to collect microbial data during the entire mock procedure. The samplers were factory calibrated and set to collect 1,000 L of air over a 5.5-minute period. Each set of 3 samples was run 8 times for a total of 24 samples per sampling location—the operating table or sterile field and the back table. The viable microbial samples were sent under chain of custody to a third-party microbiology laboratory for qualitative and quantitative analysis of bacteria. Bacterial genus and species were identified and quantified as CFUs per cubic meter. Because there are no current guidelines for airborne microbial sampling in ORs, sample collection procedures and data analysis followed the recommendations set forth for the pharmaceutic industry by the U.S. Pharmacopeia Society (USP 797).[11]

Particle contamination was measured using a CJ-750T 75 liters per minute counter (Climet Instruments, Redlands, CA) or handheld 3016-IAQ particle meters (Lighthouse World Wide Solutions, Freemont, CA). These were calibrated prior to testing. International Organization for Standardization (ISO) 14644 standards were used, which requires measuring the number of particles at 9 points based on the size of the space. The particle sizes recorded were 0.3, 0.5, 1.0, and 5.0 μm in particles per cubic meter.

To verify that the ORs were functioning in compliance with industry standards and to provide more data on the actual airflow patterns, the velocity of the air was measured at the face of ceiling-mounted diffusers, at the operating table, at the back table, and at one return grille using a calibrated air velocity meter (Model 9565; TSI Velocicak, Shoreview, MN). The pressure relationships with the adjacent spaces were also monitored to verify compliance with the

MOCK SURGICAL PROCEDURE

5 to 8	9 to 12	13 to 16	17 to 20
Scrub and glove	Prep patient and draping	Pass instruments	Use Bovie for 10 seconds every minute on the minute
Scrub and glove	Prep patient and draping	Prep Bovie; pass instruments	Time Bovie use
Verify return grilles are not blocked; review testing to make sure info needed for CFD modeling is being obtained	Take pictures and video	Take media plates out of room and label	Verify info for CFD modeling being collected
Monitor particle counters	Measure air velocity and temp/humidity at surgical field and at outside points	Monitor particle counters; check function of temp/humidity measuring devices	Walk around the room to check location of devices and room pressurization
Monitor particle counters	Adjust mask, scratch arm and forehead	Stop samplers at 15 min; media change, seal samplers and hand to Damon	Clean sampler, install plates and start sampler
Open instruments and set up back table	Move instruments	Pass instruments	Watch timing of installing plates and restarting samplers
Verify location of samplers and particle counters	Move instruments	Stop samplers at 15 min; media change, seal samplers and hand to Damon	Clean sampler, install plates and start sampler

Fig 1. Excerpt from mock surgical procedure script. The research team followed a detailed script that provided specific direction of actions every 4 minutes to closely simulate an actual surgery. This allowed for consistent, repeatable action patterns at all 3 hospitals. *CFD*, computation fluid dynamics.

regulations using an ADM Meter 860 C (Shortridge Instruments, Scottsdale, AZ). The temperature was monitored and held at consistent levels using the building automation system.

Mock surgery procedure

To provide consistent execution of the mock procedure and to ensure repeatability at each location, a detailed, timed process was developed. This script defined the physical actions for each of the research team members to perform in 4-minute increments during the 1-hour mock surgical procedure to simulate as many actual OR conditions as practical (excerpt of script is shown in Fig 1). The research team consulted with 2 board-certified surgeons to develop the mock procedure. The script simulates the actual steps undertaken by OR staff and includes gowning and gloving, passing instruments, personnel entering and leaving the room, and use of electrocautery on an uncooked steak to generate particulate tissue matter (Fig 2).

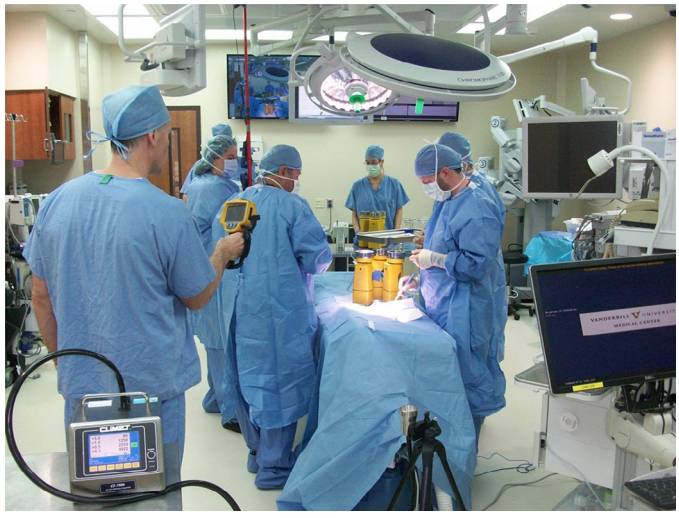

Fig 2. Picture of mock surgical procedure. The multidisciplinary team consisted of a surgeon, nurse, engineers, industrial hygienist, and microbiologist to provide input on the different perspectives of the research project. The same core team performed the mock surgical procedure and testing at all sites and used a steak to cut with an electrocauterization device to simulate the particles generated in actual cases.

Personnel

Because this research involved different perspectives on the OR systems and functions, a multidisciplinary team was developed for the project to provide a comprehensive approach. The clinical practices were an important factor to ensure the EQIs could be sampled in a setting that closely resembled a real surgical procedure. The team included surgeons and nurses to provide the practical clinical input. The same practicing surgeon led the mock procedure at all sites to provide consistency. A practicing OR nurse from each hospital participated in each mock procedure to provide direction on the specific equipment, supplies, and practices at their facility. Each OR nurse also assisted the team with scrubbing and gowning to closely simulate actual procedures.

An understanding of the engineering aspects of the OR HVAC system was also crucial; therefore, an experienced health care mechanical engineer was included. This individual determined the steps needed to adjust the HVAC systems to maintain the proper pressure relationships, velocities, temperatures, and relative humidity levels. Determining air quality was another critical factor in the research, and there were 2 team members who added this expertise, an air quality expert and microbiologist, and an industrial hygienist. They worked with the entire team to develop practical methods to measure the air quality in terms of microbial and particle load.Because there is no standard in the current building codes related to airborne CFUs or particle counts in an ORs, USP and ISO

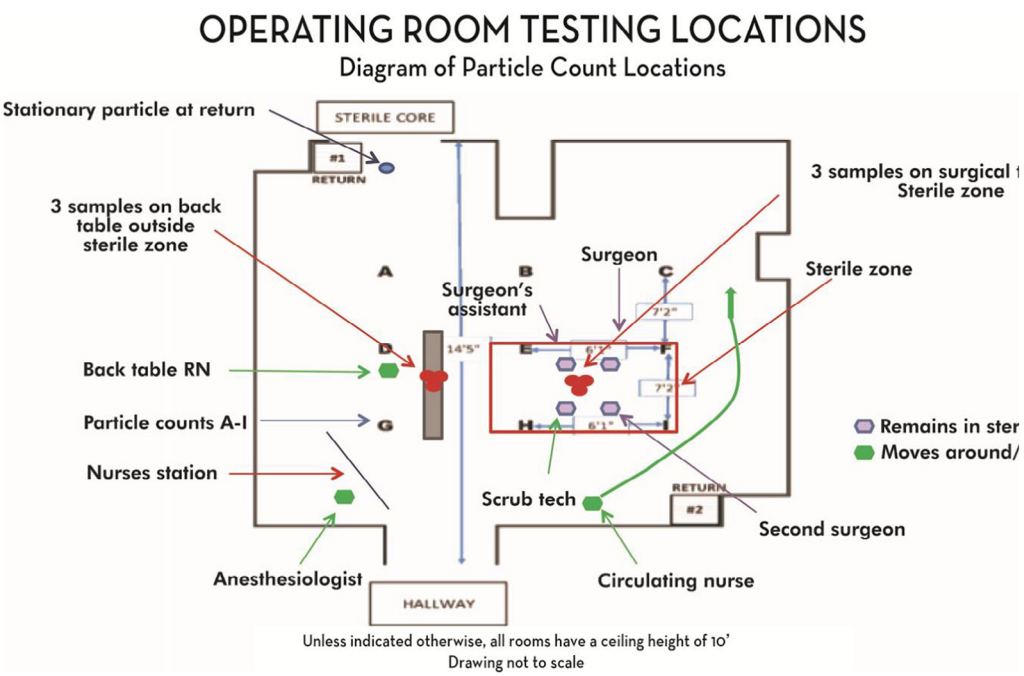

Fig 3. Floor plan showing testing locations. Although the layout of the operating rooms differed at each facility, the same approach was used for testing locations based on this layout. The microbial samples were taken at the operating table or sterile field and at the back table where the instruments are opened and prepared prior to use with the patient. The particle samples were taken at 9 locations in the room. *RN*, registered nurse.

standards were adapted to this application to compare the ORs and design a method to test and develop quantifiable EQIs for health care spaces. The air sampling locations were well defined and repeated exactly at each site (Fig 3).

Implementation

The testing was completed over a weekend so it did not impact the use of the ORs because it was essential to make sure the rooms were ready for use again on the following Monday morning. This required developing a process that could be completed in 1 day, did not require any physical or hardwired modifications of the HVAC system, did not impact the adjacent spaces in the surgical suite, and did not introduce any additional contaminants into the room. Coordination with the hospital cleaning staff was required to arrange for routine cleaning between tests and terminal cleaning on Sunday so the ORs were ready and safe for use after testing.

Statistical analyses

Skewness and kurtosis statistics were used to test the assumption of normality for microbial values. The Levene test for equality of variances was used to test the assumption of homogeneity of variance. Given the meeting of statistical assumptions, 1-way analysis of variance were used for between-subject comparisons. For continuous outcomes, the Scheffe test was used for pairwise comparisons in a post hoc fashion. When statistical assumptions were violated, nonparametric Kruskal-Wallis tests were used. Significant main effects were examined using Mann-Whitney *U* tests in a post hoc fashion. Medians and interquartile ranges (IQRs) were reported. An α value of 0.001 assumed statistical significance. All analyses were conducted using SPSS version 21 (IBM, Armonk, NY).

RESULTS

Air velocity

The air velocity was measured at the face of one of the ceiling-mounted diffusers, directly below at 6 in above the surface of the operating table, at the back table, and at one low-wall return grille. The mean air velocities at the face of the diffuser were consistent at the academic medical centers at 29 and 30 ft/min, whereas it was 50 ft/min at the third site. The results were similar at the operating table at 30.59 and 30.85 ft/min for the academic medical centers and were lower at 13.63 ft/min for the third site. The mean velocities at the back table were more consistent at the 3 sites, with a range of 9.5-13.9 ft/min (Table 1).

Table 1
Air velocities and temperatures at 20 air changes per hour

Operating room	Velocity at surgical table upper supply (ft/min)	Velocity at surgical table lower supply (ft/min)	Velocity at back table (ft/min)	Temperature at surgical table upper supply (°F)	Temperature at surgical table lower supply (°F)	Temperature at back table (°F)
A	29.22 ± 1.17	30.59 ± 8.16	13.89 ± 4.76	64.49 ± 0.72	66.47 ± 0.40	68.81 ± 0.38
B	31.04 ± 2.43	30.85 ± 5.15	13.30 ± 5.15	64.65 ± 0.24	66.89 ± 0.23	67.60 ± 0.19
C	50.81 ± 8.86	13.63 ± 7.18	9.52 ± 5.24	70.37 ± 0.31	65.55 ± 1.65	65.47 ± 1.64

NOTE. Values are mean ± SD.

Table 2
Microbial data for operating and back tables and 0.05-μm particle data at 20 air changes per hour

	OR A			OR B			OR C		
Metric	Median	Range	ISO	Median	Range	ISO	Median	Range	ISO
Microbial, CFU/m^3									
Sterile field	3.0	1-10	7	22.0	14-41	8	6.0	0-13	8
Back table	27.0	16-51	8	16.0	10-24	8	5.0	2-15	8
	Median	Average	ISO	Median	Average	ISO	Median	Average	ISO
0.5 μm, particles/m^3	8.51×10^4	1.69×10^5	7	8.53×10^4	2.02×10^5	8	9.12×10^5	9.57×10^5	8

CFU, colony forming units; *ISO*, International Organization for Standardization classification; *OR*, operating room.

Temperature, humidity, and pressurization

The goal of the testing process was to hold the temperature and relative humidity constant at 68°F and 50% and to maintain the code-required minimum positive pressure of 0.01 in. The building automation systems were used to measure these factors. The room temperature results at the sampling points were consistent at all 3 sites, being within 5% of the target during the procedures. The pressure relationships to the adjacent spaces were maintained during the testing, and all the humidity ranges were held within the American Society of Heating Refrigerating and Air-Conditioning Engineers guidelines of 30%-60%.

Microbial data

As shown in Table 2, the microbial loads in the sterile field were comparable and had a consistent range at 20 ACH. The upper limit CFU per cubic meter counts place ORs A, B, and C into extrapolated USP ISO classes of 7, 8, and 8, respectively (Table 2).

A significant main effect was found when comparing each OR on microbes in the sterile field using a Kruskal-Wallis test ($\chi^2_{2,\ n=65} = 48.31$, $P < .001$). Post hoc Mann-Whitney *U* tests found that the air in the sterile field in OR A had statistically significantly fewer microbes than the air in ORs C ($U = 91.0$, $P = .001$) and B ($U = 171.0$, $P < .001$).

At 20 ACH, the microbial loads at the back table, outside the sterile field, were also comparable and had a range from 2-51 CFU/m^3, with medians ranging from 5-27 CFU/m^3 (OR A: 16-51 CFU/m^3; median, 27.0; IQR, 10.5; OR B: 10-24 CFU/m^3; median, 16.0; IQR, 6.3; OR C: 2-15 CFU/m^3; median, 5.0; IQR, 3.8). The upper limit CFU per cubic meter counts placed ORs A, B, and C into extrapolated USP ISO class 8 for all 3 ORs (Table 2). Kruskal-Wallis test found a significant main effect for microbes between the ORs ($\chi^2_{2,\ n=65} = 48.31$, $P < .001$). Post hoc Mann-Whitney *U* tests found the air at the back table in OR C had statistically significantly fewer microbes than the air in both ORs A and B ($U = 50.5$, $P < .001$). The air at the back table in OR B had significantly fewer microbes than the air in OR A ($U = 5.4$, $P < .001$). In 1 of the 3 sites (OR A), the back table had statistically significantly higher levels of microbial contaminants than the air at the sterile field (sterile field median, 3.0 CFU/m^3; back table median, 27.0; $U = 1{,}000.0$, $P < .001$). However, in both ORs B and C, the air in the sterile field compared with the air at the back table was not significantly different ($U = 2{,}545.0$; $P = .10$ and $U = 2{,}779.0$, $P = .35$, respectively).

Particle counts

At 20 ACH, the particle counts were consistent at the 2 sites with the HEPA filters mounted in the diffusers (ORs A and B), with no significant differences at any of the 4 particle sizes (0.3, 0.5, 1.0, and 5.0 μm; medians in particles per cubic meter: 0.3 μm = 15.90×10^4, 13.44×10^4, $U = 329.0$, $P = .54$ for ORs A and B; 0.5 μm = 8.51×10^4, 8.53×10^4, $U = 340.0$, $P = .67$ for ORs A and B; 1.0 μm = 4.46×10^4, 6.01×10^4; $\chi^2_{2,\ n=81} = 0.90$; $P = .65$ for ORs A, B, and C; 5.0 μm = 2.6×10^3, 1.8×10^3, $\chi^2_{2,\ n=81} = 3.46$; $P = .18$ for ORs A, B, and C, respectively). Additionally, the particle counts in the non–HEPA-filtered OR C were also consistent with ORs A and B at the 1.0- and 5.0-μm sizes, with no statistical difference (medians in particles per cubic meter for OR C: 1.0 μm = 6.06×10^4; 5.0 μm = 2.4×10^3). However, at smaller particle sizes (0.3 and 0.5 μm), statistical analysis revealed significantly higher particle counts in the non–HEPA-filtered OR C (medians in particles per cubic meter for OR C: 0.3 μm = 11.14×10^6; 0.5 μm = 91.22×10^4) compared with ORs A ($U = 27.0$, $P < .001$) and B ($U = 26.0$, $P < .001$). Applying ISO 14644 standards to the average 0.5-μm particle count data in particles per cubic meter placed ORs A, B, and C in extrapolated ISO class 7 (1.69×10^5), 8 (2.02×10^5), and 8 (9.57×10^5), respectively (Table 2).

DISCUSSION

Proper ventilation of the OR is a multifaceted challenge of OR design and engineering. The role of the HVAC system is to maintain proper air velocity, air flow patterns, humidity, temperature, and pressure relationships and assist with asepsis. To this end, cleanrooms for drug compounding and microchip manufacturing have historically defined protocols for testing and data interpretation (USP 797 and ISO 14644) to ensure appropriate levels of air cleanliness, measured in either particles or microbes, that range from zero to hundreds of thousands depending on the intended application of the room. These cleanrooms also have action levels that trigger defined responses when the data exceed a target quantifiable numerical level. These protocols are standardized across the industry and adhered to by successful manufacturers. The development of these protocols was driven, in part by the ability to define a connection between airborne contamination and product end quality, and by the negative financial impact of contaminated pharmaceuticals or microchip defects.[8] The variation in state codes and practical applications for ORs, which ranges from 15-30 ACH, and sometimes even higher, indicates the need to define appropriate, evidence-based protocols and action levels for health care settings.

In this study, a method was designed to test the EQIs in a working, dynamic, OR suite. Air velocity and temperature, and microbial and particle contamination, were able to be consistently and repeatedly measured in ORs at 3 different institutions during the mock procedures. This method can therefore be used to study multiple different aspects of a functional OR, including alteration of air exchange rates, use of specialized air scrubbers or filtration devices, use of microbial sterilizers, and aspects of staff workflow.

Although the connection between surgical site infections and airborne contaminants has not yet been thoroughly defined, it stands to reason that if the contaminant is not present in the air, it does not have the opportunity to land on surgical instruments, staff hands, or the patient. There are several models which suggest the assumed

chain from contaminants to infections. Potential sources are patients, health care workers, visitors, outside air, and the so-called reservoir of contaminants, which exist in the hospital environment.[12] Achieving near-zero contaminants in an OR, as is required in some cleanrooms, is not practical and is likely unnecessary. Therefore, determining the point of diminishing returns for more air changes and a practical level of cleanliness for ORs is the key. In essence, what is clean enough and how will it be measured?

This research suggests that the application of a performance metric, such as EQIs, may be more effective for ORs and other health care spaces than ventilation rates. The study also suggests defining an evidence-based best practice may be readily achievable rather than following the more is better concept for design and operation of environmental controls in health care settings. Applying these principals will help define the cost-benefit relationship of implementing codes and guidelines while potentially reducing operating costs and improving clinical outcomes.

This testing protocol for EQIs provided consistent and repeatable results at 3 different sites. At the same time, the process provided predictable results that allowed for identification of differences in the HVAC systems and room performance at the various sites. For example, the 2 ORs with HEPA filters (ORs A and B) predictably had lower particle counts. Additionally, 1 OR (OR C) had not been used for surgery for several days prior to the EQI testing; therefore, lower CFU per cubic meter levels were detected than in ORs A and B, in which surgeries had been performed the day before the EQI testing. These results suggest this protocol provides a valid approach to measure air quality, room performance, and the effectiveness of ventilation systems. This testing process could also be used to compare health care spaces within a facility and across facilities to provide scientific data for establishing benchmarks and appropriate numerical levels for air quality indicators. A study linking air quality to levels of surgical site infections using this defined testing process would be an important future research opportunity.

LIMITATIONS

There were several limitations in this study which should be noted. First, our experiments were performed during a mock procedure rather than during real operations with patients. Because of health privacy laws and ethical considerations, we were not able to perform these experiments during patient operations. However, the conditions of the mock procedures were very similar to that of real operations; therefore, these data are likely able to be extrapolated.

Additionally, the layout of the 3 ORs was not the same as related to size, locations of air diffusers, type of air filtration devices, overhead lights, and other factors. The outside air conditions were also different at the sites given the variation in geographic locations and time of year. However, all the sites were modern ORs that were properly maintained and used the week before and the week after the testing for surgery.

CONCLUSIONS

This interdisciplinary team developed and implemented protocols to measure quantifiable EQIs for this study. The process used proven techniques and benchmarks used in pharmaceutic and semiconductor industries to measure airborne contamination in these ORs and to compare them based on numerical classification schemes used in cleanrooms. This simulated surgical procedure and testing tool was implemented accurately at 3 different OR testing sites. Meticulous, detailed scripting and testing protocols yielded measurable data on microbial and particle trends across sites, consistently classifying these ORs into numerical ISO classes extrapolated from cleanrooms.

This application of using quantifiable EQIs to OR contamination control can be used in other health care spaces and to address the efficacy of air change rates and velocity guidance, staff movement, room setup, and other variables. Finally, applying these principals will assist with development of future evidence-based guidelines and codes and could help define the cost-benefit relationship of implementing these guidelines with the potential to reduce operating cost and energy consumption while increasing environmental stewardship and positive clinical outcomes.

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