Assessment of the Environmental and Economic Impact of Air Changes in a Hospital Operating Room

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CHAPTER I

INTRODUCTION

Background

The healthcare industry is faced with the dual challenge of improving quality while reducing costs. After the 1999 Landmark report – "To Error is Human" highlighted the number of deaths related to medical errors, there has been increased scrutiny on quality and reducing adverse events even to the point of non-payment for medical treatment mistakes. (Reference 1) The issue of medical errors is closely linked to the problem with hospital acquired infections. A 2009 study estimated that hospital acquired infections (HAI's) occur in 5% of all acute care hospitalizations and add $4.5 billion in expenses. (Reference 2) The problem continues as the Journal of American Medicine recently provided a Harvard study that showed $ 10 billion in costs related to infections acquired after admission and the CDC reports 1 of 20 patients admitted to hospitals will contract an infection (Reference 3). At the same time, the government and private insurers are cutting reimbursements to control healthcare costs which leads to budget deficits and lay-offs in the hospital industry. Growing costs for supplies, labor and utilities combined with additional regulations are adding to the cost pressure on hospitals.

The application of engineering principles offers the potential to provide solutions for the 5,000 plus hospitals in the United States to improve quality and reduce costs. The quality benefits could come in the form of air quality improvements and the savings could be through reducing energy bills for heating, cooling and ventilation. Due to the changing code requirements and different rates used in the healthcare industry and overseas, there is the need for new research in the relationship between air quality, costs and the required number of air changes in an operating room. Research recently published in the American Journal of Infection Control stated; "To our knowledge, only 6 studies have assessed the relationship between air particle counts and the presence of bacteria in the air, with conflicting results" (Reference 4 Brigand). Research is needed to compare current code requirements and industry

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practices, which are often not always the same, to provide pathways for improving or confirming the adequacy of the air quality and potentially reducing capital and operating costs. While indoor air quality is one of many factors that can impact hospital acquired infections, there are too many variables, both clinical and engineering, to make a direct correlation between air changes and specific infection rates. A healthy balance between air quality and cost is desirable and this research will provide data to help define the costs and benefits.

The requirements for air changes and outside air in a hospital operating rooms are primarily defined in the Guidelines for the Design and Construction of Healthcare Facilities and ASHRAE 170 (American Society of Heating, Refrigeration and Air Conditioning Engineers) (Reference 5 FGI) (Reference 6 ASHRAE 170). In the 2010 Edition of the Guidelines, these standards were combined. This resulted in a significant increase (33%) in the number of air changes required in operating rooms in many states in the US. The requirements went from 15 to 20 air changes per hour (ACH) and from 3 to 4 of these air changes being fresh or outside air. These are minimum standards and in practice most hospitals, including Vanderbilt Medical Center, use 25 to 30 ACH for their operating rooms. Little data is available to document the benefits from this change or the cost of the additional air changes.

Problem Statement

The industry would benefit from a study on the cost and benefits of different air change rates to provide research based data to inform operating practices and regulatory requirements for operating room environments.

One of the challenges with this research is obtaining the data from hospitals on the number of air changes being used and the quality indicators for the air. In many cases, the hospitals do not gather specific data relating air quality and surgical site infections on a regular basis. In other cases, there is a

concern about sharing this data from a risk management standpoint for the facility as it may indicate the potential for hospital acquired infections or quality issues.

To address this issue, the research team developed a testing methodology that measures air quality in tangible, quantifiable metrics other than the number of surgical site infections. This is also more realistic approach to isolate air quality as there are many other factors involved with surgical site infections beyond the potential for contamination by airborne bacteria. These quantifiable metrics of air quality are temperature, relative humidity, particle counts, number of microbial contaminants, pressurization and airflow which we defined as Environmental Quality Indicators or EQI's.

Hypotheses

Based on these observations and my background with the cost-benefit analysis for the Facility Guidelines Institute, I developed the following hypotheses:

- There is and imperceptible difference in air quality between 15 and 20 ACH.

- There is a significant difference in air quality from 5 ACH to 15 or 20 ACH.

- There are no additional benefits at 25 ACH and maybe higher particulate count.

- The use of HEPA filters and the diffuser configuration may allow for fewer ACH and improved air quality.

- The cost of additional air changes can be calculated for evaluation and could provide meaningful savings.

Means and Methods

With the quality indicators defined, the team developed a process to test the indicators in a dynamic operating room environment. We used air samplers to test for microbial contaminants and a modified ISO process from other industries to measure the number of particles. We used anemometers

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to measure the air speeds and flow. The building automation system was used to control outside air quantities, temperature, pressure relationships and relative humidity.

Due to the clinical risks and difficulty of obtaining approval, we chose not to test during actual surgery and developed a mock surgical procedure. A script of activities typically occurring in an operating room was developed on 4 minute period. The surgeon read from this from the overhead monitor and directed all of the clinical activities, while the technicians used this to time the test cycles. This allowed us to repeat the procedure as closely as possible for the three different sites.

The tests were completed at three sites and the data was accurate and provided statistically significant information on which to base our conclusions. Statistical analysis was completed and verified by a third party to provide meaningful and verifiable information.

The microbial testing confirmed the presence of airborne contaminants. The independent testing lab identified human derived *Micrococcus* and *Staphylococcus* and environmentally derived *Bacillus*. There were also *Coryneform* bacteria. These are all potentially opportunistic pathogens. While they are typically not threatening to a general, healthy population, they are potentially dangerous to hospital patients, who are sick or immunosuppressed. These airborne contaminants would be particularly risky with invasive surgical procedures which could provide a direct transmission path into the body.

The particle testing identified varying number of particles of different sizes in different locations in the operating rooms. The testing used a modified ISO process as there is not a code defined methodology for testing particles in operating rooms. The results showed the OR's to be typically at an ISO 6 to 8 classification levels. There were measurably higher levels in the OR that did not have the HEPA (high efficiency particulate air) filters.

The mechanical engineer on our team estimated the cost of 5 air changes per hour in the hospitals in our study and had the results verified by a third party. The costs are approximately $4800 per year per operating room. There would also be increased "first" or capital costs for construction of new operating rooms with higher air change rates.

Comparison of Actual Findings

- Imperceptible difference in air quality between 15 and 20 ACH

    o 20 Ach is significantly better than 15 ACH

- Significant difference in air quality from 5 ACH to 15 or 20 ACH

    o There is a significant difference so ventilation rate is clearly a factor in air quality

- No additional benefits at 25 ACH and maybe higher particulate count

    o The air at 25 ACH was not significantly better than at 20 ACH so 20 ACH seems to be the "sweet spot"

- HEPA filters and diffuser configuration may allow for fewer ACH and improved air quality

    o The OR's with HEPA filters had lower particle counts than the one without; the configuration of the diffusers was so different in each room that we could not make any correlations

- Cost of additional air changes can be calculated for evaluation

    o It does cost more to provide more air changes- approximately $5000 per OR/year/5 ACH, but this is a small number relative to the overall revenue from surgery and the hospitals will typically continue using higher than required air change rates as a risk management measure

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CHAPTER 2

METHODOLOGY FOR ANALYZING ENVIRONMENTAL QUALITY INDICATORS (EQIs) IN A DYNAMIC

OPERATING ROOM ENVIRONMENT

Abstract

Innovative and potentially high risk medical procedures are performed in hospital operating

rooms across the country on a daily basis. As a result, there are detailed and stringent procedures in

place for routine clinical practices, such as handwashing and instrument sterilization, and for the HVAC

(heating, ventilation and air conditioning) systems, such as relative humidity and ventilation rates. In an

attempt to make operating rooms as clean as possible, operating room ventilation, which is measured in

air changes per hour (ACH), is 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 (SSI), 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 operating rooms under conditions currently being used in the

healthcare industry. The testing protocol was developed by an interdisciplinary team which included

medical clinicians, air quality experts, engineers and industrial hygienists experienced in operating room

proceedings. The process for the research testing included a "mock' surgical procedure that was

directed by a Board certified surgeon in real operating rooms. The procedure used industry standard

gowning and sterilization practices, and was supported by experienced operating room 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 operating room

conditions. The testing protocol developed was measurable and repeatable, and thus, provides an

effective method to measure air quality in operating rooms and potentially other critical spaces in a hospital environment.

Background

The healthcare industry is consistently faced with the dual challenge of improving the quality of care while simultaneously reducing costs. A recent study in the Journal of American Medicine reported the health care industry sustains $10 billion in annual costs related to infections acquired after admission. (Reference 1 JAMA) Similarly, the CDC reported that 1 in 20 patients admitted to hospitals will contract a hospital-acquired infection (Reference 2 CDC/ASTHO). Medical insurance companies and government payers have taken note of these costs and are reducing reimbursement for hospital acquired infections. Reductions in reimbursements put pressure on providers to reduce hospital acquired infections including surgical site infections while simultaneously reducing operating costs to remain financially sound.

Due to the many confounding variables and factors, it is not feasible to make a direct connection from poor air quality to surgical site infections (Reference 3 Memarazadeh). However, it is generally accepted that poor air quality and airborne contaminates can be a cause of increased rates of surgical site infections. Studies suggest that over a third of all hospital acquired infections could be a result of airborne transmissions (Reference 4 Kowalski). In another study reported in the American Journal of Infection Control, the authors concluded that the air in the operating room is considered a route for microbes to enter the surgical wound (Reference 5 Brigand).

The ventilation rates, as measured in air changes per hour, vary in the different state regulations and in actual practice. These air change rates are often "based on tradition rather than science" (Reference 6 English).   Therefore, there is notable variety in hospitals across the country with regards to air changes per hour, use of high-efficiency particulate air (HEPA) filters, UV or ozone systems and the overhead diffuser layouts.   There is often a sense of "more is better" and while this philosophy may not

always lead to cleaner operating rooms 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

increasing positive clinical outcomes.

We aimed to design a methodology for assessment of dynamic operating room quantifiable

Environmental Quality Indicators that offered measurable, repeatable and verifiable results. The

specific purposes of this methodology were to: 1) develop a reproducible testing model using a "mock"

surgical procedure that could be utilized for clinical assessment of clean spaces, and 2) evaluate

quantifiable EQIs with measurable criteria which were defined as microbial contaminants measured in

colony forming units CFU/ m3 and particle counts in particles/m3.

Means and Methods

Locations

Three different operating rooms in three different hospitals in two different states were chosen

for experimentation. The ORs in two hospitals were associated with academic medical schools (OR's A

and B), both had HEPA filtered air supplies to the rooms and were 638 and 554 square feet, respectively.

The third OR (OR C) was located in a private community hospital, had MERV 14 filters and was 505

square feet. Studies took place from the summer of 2015 to the spring of 2016.

Instrumentation Setup

In order to detect microbial contamination, the operating table and the back table, where the

surgical instruments are opened and prepared, were selected as the critical locations in the operating

rooms at which to measure the microbial contamination (Reference 7 Memarazadeh). Bioscience viable

surface air samplers (SAS180) were placed at both locations to detect the contaminants. Petri plates

with Tryptic Soy Agar (TSA) 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 1000 liters of air over a five and a half minute period of time. Each set of three samples were

run eight times for a total of twenty-four 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 colony forming units per cubic meter. Since there are no current

guidelines for airborne microbial sampling in operating rooms, sample collection procedures and data

analysis followed the recommendations set forth for the Pharmaceutical Industry by the United States

Pharmacopeia Society (USP 797).

Particle contamination was measured using a Climet Model CJ-750T 75 LPM counter or

Lighthouse World Wide Solutions (LWS) handheld 3016-IAQ particle meters. ISO 14644 standards were

utilized which required 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 microns in particles per cubic meter.

To verify that the operating rooms 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 grill using a TSI

Velocicak air velocity meter Model 9565. The pressure relationships with the adjacent spaces were also

monitored to verify compliance with the regulations using a Shortridge Digital Multimeter Model ADM –

860C. The temperature was monitored and held at consistent levels using the building automation

system.

Mock Surgery Procedure

In order 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 four minute increments during the one hour mock

surgical procedure to simulate as many actual operating room conditions as practical (Excerpt of script

in Figure 1). The research team consulted with two Board certified surgeons to develop the mock

procedure. The script simulates the actual steps undertaken by an operating room 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 (Figure 2).

Personnel

As this research involved different perspectives on the operating room 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 members of the health care profession to

provide the practical clinical input.   The same practicing surgeon led the mock procedure at all sites to

provide consistency. A practicing operating room 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, and

therefore an experienced healthcare 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 two 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. As there is no standard in

the current building codes related to airborne colony forming units or particle counts in an operating

rooms, USP and ISO standards were adapted to this application to compare the ORs and design a

method to test and develop quantifiable EQIs for healthcare spaces. The air sampling locations were

well defined and repeated exactly at each site (Figure 3).

Implementation

The testing was completed over a weekend so it did not impact the use of the operating rooms as it was essential to make sure the room was ready for use again on the following Monday morning. This required developing a process that could be completed in one 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 operating rooms were ready and safe for use after the testing.

Statistical Analysis

Skewness and kurtosis statistics were used to test the assumption of normality for microbial values. Levene's Test of Equality of Variances was used to test the assumption of homogeneity of variance. Given the meeting of statistical assumptions, one-way ANOVA were used for between-subjects comparisons. For continuous outcomes, Scheffe's test was used for pairwise comparisons in a post hoc fashion. Medians and interquartile ranges (IQR) were reported. An alpha value of .001 assumed statistical significance. All analyses were conducted using SPSS Version 21 (Armonk, NY: IBM Corp.).

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Results

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Air Velocity

The air velocity was measured at the face of one of the ceiling mounted diffusers, directly below at 6 inches above the surface of the operating table, at the back table and at one low-wall return grille (Figure 4). The mean air velocities at the face of the diffuser were consistent at the academic medical centers at 29 and 30 Ft/minute while it was 50 Ft/minute at the 3rd site. The results were similar at the operating table at 30.59 and 30.85 Ft/minute for the academic medical centers and different at the 3rd

site. The mean velocities at the back table were more consistent at the 3 sites with a range of 9.5 to 13.9 Ft/minute (Table 1).

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 .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 ASHRAE guidelines of 30 to 60%.

Microbial data

At 20 ACH, the microbial loads at the operating tables, in the sterile field, were comparable and had a range of 0 to 41 CFU/m3 with medians ranging from 3 to 22 CFU/m3 (OR A, 1-10 CFU/m3, median 3.0, IQR 2.5; OR B, 14-41 CFU/m3, median 22.0 and IQR 12.0; OR C, 0-13 CFU/m3, median 6.0 and IQR 4.0). The upper limit CFU/m3 counts place the ORs A, B and C into extrapolated USP ISO classes of 7, 8 and 8, respectively (Table 2). The air in the sterile filed in OR A had statistically significantly fewer microbes than the air in OR C, which had significantly fewer microbes than OR B (p<0.001).

At 20 ACH, the microbial loads at the back table, outside the sterile field, were also comparable and had a range from 2 to 51 CFU/m3 with medians ranging from 5 to 27 CFU/m3 (OR A, 16-51 CFU/m3, median 27.0, IQR 10.5; OR B, 10-24 CFU/m3, median 16.0, IQR 6.3; OR C, 2-15 CFU/m3, median 5.0, IQR 3.8). The upper limit CFU/m3 counts placed the ORs A, B and C into extrapolated USP ISO class 8 for all three ORs (Table 2) and the air at the back table in OR C had statistically significantly fewer microbes than the air in both OR A and B (p<.001). The air at the back table in OR B had significantly fewer microbes than the air in OR A (p<0.001). In one of the three 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/m3, back table median 27.0; p<0.001). However, in both OR B and OR C, the air in the sterile field as compared to the air at the back table was not significantly different (p=0.10 and p=0.35, respectively).

Particle Counts

At 20 ACH, the particle counts were consistent at the two sites with the HEPA filters mounted in the diffusers, OR A and OR B, with no significant differences at any of the four particle sizes, 0.3µ, 0.5µ, 1.0µ, 5.0µ (medians in particles/m3: 0.3µ = 15.90×10^4, 13.44×10^4, 13.44×10^4 (p=0.54 for A,B); 0.5µ = 8.51×10^4, 8.53×10^4 (p=0.67 for A,B); 1.0µ = 4.46×10^4, 6.01×10^4 (p=0.65 for A,B,C); 5.0µ = 2.6×10^3, 1.8×10^3 (p=0.18 for A,B,C), respectively). Additionally, the particle counts in the non-HEPA filtered OR C were also consistent with OR A and B at the 1.0µ and 5.0µ sizes with no statistical difference (medians in particles/m3 for OR C: 1.0µ = 6.06×10^4; 5.0µ = 2.4×10^3. However, at smaller particle sizes, 0.3µ and 0.5µ statistical analysis revealed significantly higher particle counts in the non-HEPA filtered OR C (medians in particles/m3 for OR C: 0.3µ = 11.14×10^6; 0.5µ = 91.22×10^4) as compared to ORs A and B (p<0.001). Applying ISO 14644 standards to the average 0.5µ particle count data in particles/m3 placed the 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 operating room 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 as well as assisting 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 exceeds a target quantifiable numerical level. These protocols are standardized across the industry and adhered to by successful manufactures. The development of these protocols was driven, in part by the ability to define a connection between airborne contamination and product end quality, as well as by the negative financial impact of contaminated pharmaceuticals or microchip defects (Reference 8 Wagner). The variation in state codes and practical applications for operating rooms, which ranges from 15 to 30 ACH and sometimes even higher, indicate the need to define appropriate, evidence based protocols and action levels for healthcare settings.

In this study, a method was designed to test the Environmental Quality Indicators in a working, dynamic, operating room suite. Air velocity and temperature, as well as microbial and particle contamination were able to be consistently and repeatedly measured in operating rooms at three different institutions during the mock procedures. This method can therefore be utilized 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, as well as aspects of staff workflow.

Although the connection between surgical site infections and airborne contaminants has not yet been 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. However, achieving zero contaminants in a healthcare setting or operating room, as is required in some cleanrooms, is not practical and is likely unnecessary. Therefore, determining the point of diminishing returns or a practical level of cleanliness for operating rooms and other healthcare settings is essential. In essence, what is clean enough and how will it be defined and measured?

This research suggests that the application of a performance basis, such as EQIs, may be more effective for operating rooms and other healthcare spaces. 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 healthcare 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 three 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 two operating rooms

with HEPA filters (OR A and B) predictably had lower particle counts. Additionally, one OR (OR C) had

not been used for surgery for several days prior to the EQI testing and therefore lower CFU/m3 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 healthcare spaces within a facility and across facilities to provide scientific data for establishing

benchmarks and appropriate numerical levels for environmental quality indicators.

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. Due to health

privacy laws and ethical considerations, we were not able to perform these experiments during patient

operations. However, the conditions of the mock procedure were very similar to that of a real

operation, and therefore, the data are likely able to be extrapolated.

Additionally, the layout of the three operating rooms was not exactly 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 geographical locations and

time of year. However, all of the sites were modern operating rooms that were properly maintained

and used the week before and the week after the testing for surgery.

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Conclusion

This interdisciplinary team developed and implemented protocols to measure quantifiable Environmental Quality Indicators (EQIs) for this study. The process employed proven techniques and benchmarks used in pharmaceutical and semiconductor industries to measure airborne contamination in these operating rooms and to compare them based on numerical classification schemes used in cleanrooms. This simulated surgical procedure and testing tool was implemented accurately at three different operating room testing sites. Meticulous, detailed scripting and testing protocols yielded predictable microbial and particle trends across sites, consistently classifying these ORs into numerical ISO classes extrapolated from cleanrooms. This application of employing quantifiable EQIs to operating room contamination control can be utilized in other healthcare spaces, as well as to address the efficacy of air change rates and velocity guidance, staff movement, room set up and other variables. Lastly, 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.

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

Figure 1 – Mock Surgical Procedure

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 three hospitals.

Figure 2 – Testing in Operating Room

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

electro cauterization device to simulate the particles generated in actual cases.

OPERATING ROOM TESTING LOCATIONS
Diagram of Particle Count Locations

Stationary particle at return

STERILE CORE

#1 RETURN

3 samples on surgical table in Sterile zone

3 samples on back table outside sterile zone

A

Surgeon's assistant

Surgeon

B

C

7'2"

Sterile zone

Back table RN

D

14'5"

E

6'1"

F

7'2

Particle counts A-I

G

H

6'1"

I

Remains in sterile field
Moves around/in out

Nurses station

Scrub tech

RETURN #2

Anesthesiologist

Circulating nurse

Second surgeon

HALLWAY

Unless indicated otherwise, all rooms have a ceiling height of 10'
Drawing not to scale

Figure 3 – Test Locations

While the layout of the operating rooms differed some at each facility, the same approach was used for testing locations based on this layout. The microbial samples were taken at the operating table/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.

Figure 4 – Anemometer to Measure Air Velocities

In addition to microbial contaminants and number of particles, the EQI testing process measured the

velocity of the air at different points in the room to understand the air flow patterns. The direction and

speed of the air over the sterile field and back table are also factors in proper air management to

provide clean conditions for surgery.

Tables

	20 Air Changes Per Hour											
	Velocity at Surgical Table Upper Supply (Feet per Minute)		Velocity at Surgical Table Lower Supply (Feet per Minute)		Velocity at Back Table (Feet per Minute)		Temperature at Surgical Table Upper Supply (Deg. F)		Temperature at Surgical Table Lower Supply (Deg. F)		Temperature at Back Table (Deg. F)	
	Mean	Std. Dev.	Mean	Std. Dev.	Mean	Std. Dev.	Mean	Std. Dev.	Mean	Std. Dev.	Mean	Std. Dev.
Site 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
Site 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
Site 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

Table 1 – Air Velocities and Temperatures at 20 ACH

	OR A			OR B			OR C		
MICROBIAL CFU/M^3									
	Median	Range	ISO	Median	Range	ISO	Median	Range	ISO
SF	3.0	1-10	7	22.0	14-41	8	6.0	0-13	8
BT	27.0	16-51	8	16.0	10-24	8	5.0	2-15	8
PARTICLES/m^3 0.5 ☐									
	Median	Average	ISO	Median	Average	ISO	Median	Average	ISO
	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

Table 2 – Microbial Data for Operating and Back Tables and 0.05 Micron Particle Data at 20 ACH

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Acknowledgements

CHAPTER 3

COST-BENEFIT ANALYSIS OF DIFFERENT AIR CHANGE RATES IN AN OPERATING ROOM ENVIRONMENT

Abstract

Lean measures within the healthcare industry are designed to control costs while maintaining high quality. Evidence-based information is paramount in order to guide professionals and to achieve optimum balance for best hospital practices. In this regard, hospital ventilation systems are important to insure clean air within sterile environments, but also require abundant resources to operate and maintain. The required ventilation rates for operating rooms have increased over the years with minimal data to suggest that more ventilation provides cleaner conditions. We hypothesized that a test of the Environmental Quality Indicators (EQI's) utilizing a mock surgical procedure would provide evidence that increased ventilation rates would not necessarily provide cleaner air conditions.

The purpose of this study was to evaluate the costs and benefits of different air change rates in an operating room environment. The operating costs were estimated for the different facilities based on actual energy usage, while the air quality was measured using environmental quality indicators. The cost and quality data provided a comparative basis to assist in defining the optimum air change rates for operating rooms. This information can guide policy makers who define the codes and the practical applications for the estimated 38,000 operating rooms in the US. (Reference 1 AHA)

Background

Energy consumption for buildings is the highest category in the United States with heating, ventilation and air-conditioning (HVAC) being the largest use (Figure 1). Hospital buildings, in particular, have one of the highest energy demands due to their stringent heating and air conditioning requirements, the significant amount of diagnostic and therapeutic equipment available, and the need for 24 hour availability. Within the hospital, the operating room suites are the most expensive to heat,

cool and ventilate (Reference 2 Montanya). This cost is associated with stringent need for climate control, as well as vigorous rates of air changes to help maintain sterile spaces.

Operating rooms have stringent requirements for the design, construction and operation of the space and the systems serving the area. These are necessary to protect the patients and staff with one of the primary goals being to provide a clean environment to help minimize the risk of surgical site infections (SSI's). In operating rooms, two primary methods to reduce airborne transmission of contaminants are through proper ventilation of the physical space and filtration of the air. Ventilation is accomplished by systematically changing the air in the operating room on a regular timetable. The "new" air is typically a mixture of fresh air (approximately 20%) from the outside environment and air recycled from the operating room space that has been filtered to remove particles and contaminants (approximately 80%). The introduction of large quantities of conditioned and filtered air helps to dilute the number of contaminants within the room and the proper placement of the supply and return air devices directs the contaminants away from the sterile field.

There are many factors that can impact infection rates in surgical patients. Operating room air quality is only part of a complex list of factors that can contribute to SSI's, but direct connections between air quality and surgical infections are difficult to prove (Reference 3 Memarazadeh). However, it is intuitive that "dirtier" air can contribute to infections in the operating room and there is ample evidence to suggest that the air can carry harmful pathogens (Reference 4 Kowalski and Reference 5 Schal).

The requirements for air changes in hospital operating rooms are primarily defined in the Guidelines for the Design and Construction of Healthcare Facilities (Reference 6 FGI) and ASHRAE 170 (American Society of Heating, Refrigeration and Air Conditioning Engineers) (Reference 7 ASHRAE). In the 2010 Edition of the Guidelines, these standards were combined which resulted in a significant increase in the number of air changes required in new operating rooms built in many states in the U.S.

The minimum requirements went from 15 to 20 air changes per hour (ACH) and from 3 to 4 of these air changes being fresh, outside air. While these are the minimum standards, in practice, most hospitals use 20 to 30 ACH for their operating rooms, despite minimal evidence to suggest that a greater number of air changes will provide cleaner air.

Air change rates also vary internationally (Figure 2). Different countries require different number of air changes per hour, and some use other standards, such as ISO. In spite of these significant variations in operating room ventilation rates, surgical site infection rates remain similar between these countries. Surgical infection rates averaged 1.9% in the United States, 2.2% in Europe, 1.6% in Germany, 1.4% in England, 1.6% in France, and 2.0% in Portugal (Reference 8 Yunzhou).

Given the variation in required air change rates in hospital operating rooms and the high energy costs of providing more air changes per hour, research in this field could help clarify the appropriate balance between the costs and benefits of different ventilation rates. We therefore hypothesized that a test of the Environmental Quality Indicators (EQI's) utilizing a mock surgical procedure that has been previously identified could provide measurable, repeatable and verifiable results for analysis of operating room air quality. (Reference 9 Gormley et al) This coupled with an analysis of the energy costs for different air change rates could provide the basis for a realistic cost-benefit analysis to provide guidance on hospital practices and code requirements.

Means and Methods

Environmental Quality Indicator Testing

This method of testing dynamic operating room EQI's was utilized at three different hospital operating rooms. A one hour scripted simulated medical procedure was enacted to mimic the dynamic conditions seen during actual surgery in an operating room. Air velocities at key locations in the rooms provided insight into the flow of the air used for ventilation to provide "clean" conditions for surgery.

The velocities were measured at the face of the supply grilles and the return grilles, as well as at two critical locations-the operating room table (sterile field) and at the back instrument table.

Three different operating rooms in three different hospitals in two different states were chosen for experimentation. The ORs in two hospitals were associated with academic medical schools (OR's A and B), both had HEPA filtered air supplied to the rooms and were 638 and 554 square feet, respectively. The third OR (OR C) was located in a private community hospital, had MERV 14 filters and was 505 square feet. The layout of the operating rooms was generally the same, but the actual number and location of the supply air diffusers varied along with the location of overhead lights and equipment booms. Studies took place from the summer of 2015 to the spring of 2016.

Bioscience viable surface air samplers (SAS180) were placed at both the surgical operating field and at the back instrument table to detect the contaminants. Petri plates with Tryptic Soy Agar (TSA) media were used in the samplers and were changed in regular cycles to collect microbial data during the entire mock procedure. 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 colony forming units per cubic meter. Particle contamination was measured using a Climet Model CJ-750T 75 LPM counter or Lighthouse World Wide Solutions (LWS) handheld 3016-IAQ particle meters. ISO 14644 standards were utilized which required 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 microns in particles per cubic meter.

Testing was performed at 15, 20 and 25 air changes per hour (ACH) during the mock surgical procedure. The air change rates were measured using standard HVAC test and balance hoods manufactured by Shortridge Model number 9565-P. In addition, the building automation systems (BAS) were used the set and monitor the ventilation rates and temperatures in the operating rooms. The measurements were taken at each supply and return grill in cubic feet per minute (CFM) and the air

change rates in ACH were calculated based on the actual size of each individual operating room (Table 1-sample OR air change calculation). While the layout of supply grilles varied some in each operating room, all three of them had two low wall returns grilles (Figure 3-picture of supply grilles).

Cost Analysis

The higher air change rates require a significant amount of additional air to be conditioned, filtered and supplied to the operating room. For example, in a typical 600 ft.² OR with a 10 foot ceiling 25 ACH requires 60,000 more total cubic feet of air per hour than 15 ACH. This increases the capital or construction costs as a result of incrementally larger fans, duct work and heating/cooling capacity required. It also significantly increases the operating or energy cost as a result of conditioning, filtering and moving the additional air.

This applied research project focused on the operating costs, which varied by hospital as result of the variations in the cost of energy and the type of systems in the different locations. The mechanical engineer on the research team worked with the facility managers at the 3 sites to estimate the cost for one air change per OR per year. The three primary elements included in the pricing are the fan power (supply and return), cooling (chillers, pumps and cooling tower fans) and the preheat/reheat/humidity control.

The cost per kilowatt hour (kW) for the energy was determined along with the number of kW per ton. With this information and the cost per therm, the estimated energy cost for 5 ACH per year per OR was developed (Table 2A & 2B- cost estimates).

Statistical Analysis

Skewness and kurtosis statistics were run on continuous distributions to test for the assumption of normality. All distributions in the study were assumed to be non-normal with skewness and kurtosis statistics above an absolute value of 2.0. Due to this violation of normality, only non-parametric statistics were used to answer research questions in this study. Kruskal-Wallis tests were used to assess

main effects when comparing three or more groups. In the event of a significant main effect, Mann-Whitney U tests were used in a post hoc fashion to explain pairwise differences. When comparing two groups on outcomes, Mann-Whitney U tests were used. Medians and interquartile ranges were reported to give context to all inferential findings. All analyses were conducted using SPSS Version 21 (Armonk, NY: IBM Corp.).

Results

Environmental Quality Indicators

Particles

The particle counts at Sites A and B were very close, but there was a nonsignificant difference, p=.08. At the same time, the relationship between average particle counts at the different air change rates stayed the same with 20 ACH better than 15 ACH, but 25 ACH being no better than 20 (Figure 4 – graph of particle counts at different air changes). Both of the sites had high-efficiency particulate air filters (HEPA). Site C did not have HEPA filters and the particle counts were significantly higher although the relationships at different air change rates were similar at 15 and 20 ACH , but not at 25 ACH. The particle counts were 10 times higher than the other sites without HEPA filters which indicate a benefit with these filters in spite of the higher costs.

The larger particles (1.0 and 5.0 µm) were significantly lower and much more consistent at all three sites which could indicate that the filters perform better on these sizes as opposed to the smaller ones. There are studies that suggest many viruses and bacteria are carried on squamous cells which are typically in this larger range. This could bring into question the benefits of using the more expensive HEPA filters if they are just removing very fine particles which may not be the primary source of surgical site infections.

The particle counts were compared to ISO classifications, which is used for the pharmaceutical and computer chip industries. All three sites were within ISO class 7 or 8 which might typically be used for a sub-sterile area in a pharmacy compounding facility.

Microbial Contaminants

The level of microbial contaminants were consistent at the two academic medical centers with a non-significant difference p=.21. There was a significant difference in the microbial levels between the two academic medical centers and the community hospital with a p-value of <.001. As with the particles, there was a measurable increase in the quality of the air from 15 to 20 ACH but it did not improve significantly from 20 to 25 ACH. At 15 ACH the Median was 17.000 and the Interquartile Range (IR) was 33.0, while at 20 ACH the Median was 11.000 and the IR was 15.0 which are very close to 25 ACH with a Median of 10.000 and IR of 12.5.

Surprisingly, the colony forming unit (CFU) count at Site C, which was a community hospital, was lower even though the particle count was higher. After further research, we found that the OR at Site C had not been used the day before the test and was lightly loaded even earlier that week. The OR's at Site A and B were used for full caseloads on Friday before the tests were done on Saturday. We theorized that the lack of clinical activity could have reduced the microbial load in the room with the absence of patients and staff. This is consistent with another study of microbiological contaminants in a new hospital before and after it was opened which showed no difference in the nosocomial infection rates from the old hospital. This suggested that it was the organisms generated from the activity in the hospital not the unoccupied space that contributed to the microbiological contaminants and resulting infection rates (Reference 10 Maki et al).

Although SSIs are the "third most common health care-associated and contribute to 13 to 17% of all such infections", there is no industry accepted method to for routine monitoring of airborne microbial contaminants. This research stated that "appropriate ventilation is critical for SSI prevention"

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but did not provide a conclusion as to the required number of air changes to effectively control this risk (Reference 11 Brigand et al).

Velocity

Our testing in all cases showed that the actual air velocity at the sterile field and back table varied significantly. In some cases, the velocity of the air ranged from high of 30 feet per minute (FPM) at the diffuser to a low of 3 FPM at the sterile field, while in most cases the velocity at the sterile field was a third of that at the ceiling level. It appears that the conditioned and filtered air is often flowing very slowly at the sterile field even though that is a key element in providing safe conditions for surgery (Figures 5 A and B air velocities at sterile field and back table). Our testing also indicated that the air flow is very low at the back table where the surgical instruments are opened and prepared. The velocities there averaged less than 15 FPM which would provide little flow of conditioned and filtered air.

Cost

The costs to provide ventilation to the three operating rooms varied based on location local utility rates in the type of HVAC system. Based on analysis of these factors, the estimated costs for five air changes per OR per year were developed for each of the three sites. They are listed below with additional detail in Tables 2A and 2B:

- Site A - $ 8,775 / 5 ACH/OR/year

- Site B - $ 4,870 / 5 ACH/OR/year

- Site C - $ 4,870 / 5 ACH/OR/year

Discussion

The common practice with operating room HVAC systems is to supply the air from ceiling mounted diffusers that directs the flow over the operating room table to low return grilles mounted in opposing corners of the room. The goal is provide the sterile field and surgical site with conditioned and

filtered air to minimize the risk of surgical site infections. The codes require minimum velocity 25 to 35 FPM at the face of the ceiling diffuser. All three sites met this requirement, however the velocity of the clean air at the sterile field had wide ranges and at the lows was close to or less than 10 FPM. A consistent and strong supply of clean air may not be reaching the patient area at all times.

In general, the back tables had higher particle counts and microbial contaminants than the sterile field. There were nearly twice as many microbial contaminants with Median of 10.000 at the sterile field and 18.000 at the back table. The IR's were similar with the sterile field at 25.5 and the back table at 25.5. The velocities were typically less than 5 FPM which provides little flow of clean air. The supply air diffusers are typically focused on the sterile field/operating table and dedicated supply air is not directed at the back table. This may not be practical as the table may be in different locations depending on the type of surgery. Given the fact that the instruments are opened and lying on the back table, this appears to be a potential risk for the introduction of foreign material into the surgical site

The number of particles and microbial contaminants varied significantly across the three sites. While there were consistent trends as noted before, there were also wide variances in the sites where one would have predicted similar results. For example, at the two academic medical centers with modern, new operating rooms utilizing HEPA filters the particle count averages were 220,000 particles per cubic meter at one location and 580,000 particles per cubic meter at the other similar operating room at the same air change rate. The microbial contaminants also varied significantly in a few cases and at one site the colony forming units were lower than other sites even though the particle counts were higher as a result of not having HEPA filters in the system. These significant differences in some of the data show the variations in operating room designs and functionality. Further testing will be required to establish reasonable and realistic levels of particles and microbial contaminants; however ISO classifications could be applied in operating room environments as it is done in other industries.

The use of ISO standards or environmental quality indicators to define the requirements for operating room air is another approach to be considered. While ventilation rates as measured in air changes per hour have been the standard for many years, the amount of air circulated through the room may not tell the whole story. Through better or different approaches for "air management" in the operating rooms, cleaner air could be delivered at key points, such as the back table and sterile field, at no more or maybe even less cost. By using environmental quality indicators, the cleanliness of the air and proper air flows could be monitored and maintained at the minimum air change rates required rather than a set standard.

In addition to the humanitarian and clinical reasons for providing proper ventilation in operating rooms in order to help reduce surgical site infections, in today's world there is also the practical need to manage the business risk for the healthcare provider. It appears that providing more air changes per hour is the safest approach as a national standard- ASHRAE 170 was 12 in 2008 and it has increased to 20 ACH while almost all hospitals in the US provide more than 20 with 25 being common in general ORs and up to 30 or 40 ACH in neuro or ortho rooms. There is little scientific evidence to support that increasing the ventilation rates to higher levels actually reduces surgical site infections and one study using a computational fluid dynamics (CFD) model concluded that " a lower percentage of particles hit the site in a case that has an ACH of 20 than one that has an ACH of 150". It suggested that the design of the ventilation system was potentially a more significant factor in proper ventilation than the number of air changes (Reference 12 Memarazadeh). This raises the question as to the appropriate number of air changes required to provide a safe environment for the patients at a reasonable cost without adding financial and legal risk for the facility. Can a hospital use the national standard of 20 ACH in lieu of higher rates without weakening their defense in the event of litigation related to a surgical site infection?

Conclusions

20 ACH appears to be the most cost-effective ventilation rate based on the three tested. In all cases, 25 ACH did not significantly improve the quality of air as compared to 20 ACH. In all cases, 20 ACH was better than 15 ACH, but more so at the two academic sites than at the third. The cost of higher air change rates can be a significant expense to the healthcare system when factored over the number of operating rooms in the US. While the cost differs at each facility, the average cost for the three sites was almost $ 6,171 per 5 ACH per year per OR. One of the participants in the study has 90 ORs and higher than typical energy costs, so their estimated system wide cost for 25 versus 20 ACH was over $500,000/ per year.

The question that remains unanswered is if 15 ACH is adequate. 15 ACH had significantly higher particle counts and microbial contaminants as compared to 20 ACH, but it does not necessarily translate to higher rates of SSIs. This was the requirement in many states before 2010 and it was 12 ACH before that. Is this improvement worth the cost? There is the potential for significant cost savings if one could demonstrate through the analysis of surgical site infections or other methods that the risk is no greater at 15 ACH than at the higher rates currently being used in hospitals in the US.

The use of environmental quality indicators for the operating room environment may be a better or even a supplemental standard for air change rates. These indicators, such as level of microbial contaminants, number of particles and velocity of the air at key points, could provide more accurate measurements of the actual quality of the air and the potential to minimize the risk of surgical site infections. As the hospitals face the dual challenge of improving quality while reducing costs, the use of measurable quality indicators may provide the tool to define the optimum ventilation rate from a cost-benefit standpoint.
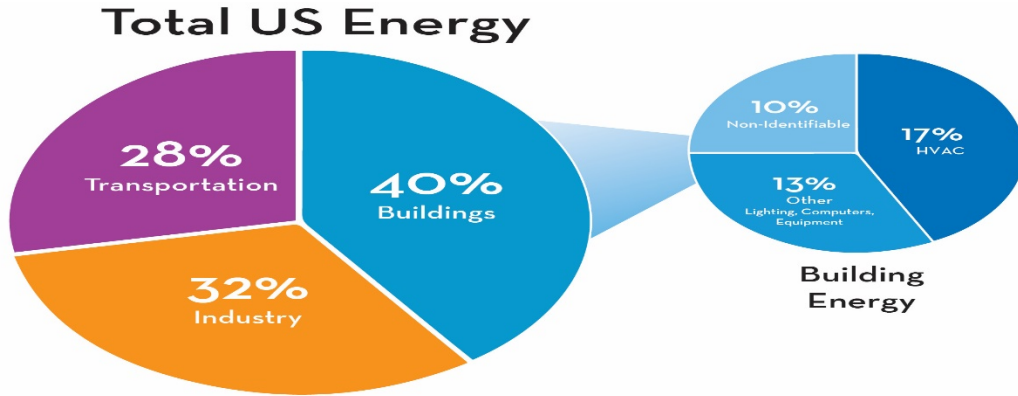
Total US Energy

Energy Use per Square Foot of Building Space
Source: Commercial Buildings Energy Consumption Survey

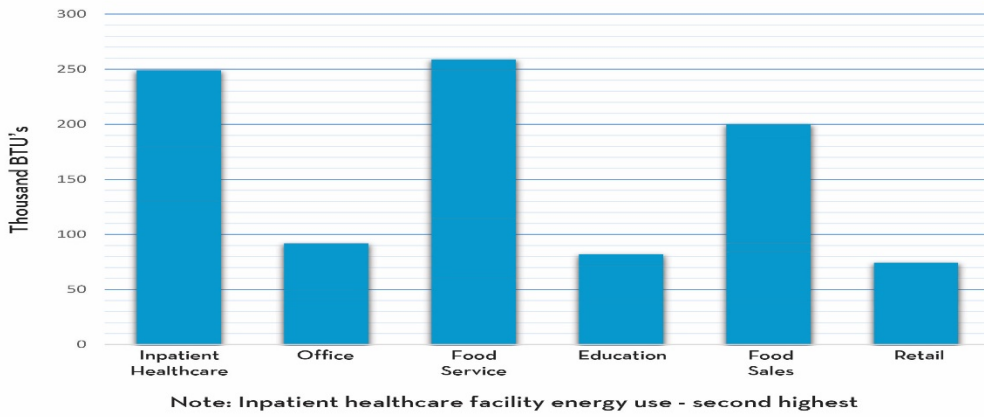Note: Inpatient healthcare facility energy use - second highest

Figure 1 – Energy Use per Square Foot of Building Space - Of the total energy use in the US, buildings comprises 40%. The largest portion of this cost is for the HVAC which is 17%. Inpatient healthcare is the second-largest energy use sector for facilities.

EUROPEAN OPERATING ROOM CLASSIFICATION PARAMETERS AND VENTILATION REQUIREMENTS

Operating Room Classification Parameters Limits

Standard, Airflow Distribution System	Particle Contamination		Recovery time, min	Microbiological Contamination		Total ACH
	At rest	In Activity particle/m^3		At rest cfu/m^3	In activity cfu/m^3	
French, undirectional	ISO 5	N/A	10	10	N/A	50 vol/h
Italian, not specified	ISO 5	N/A	N/A	N/A	N/A	15 vol/h
German, undirectional	N/A	3500	N/A	N/A	N/A	8,800 m^3/h
British, undirectional	N/A	N/A	N/A	N/A	10	11,900 m^3/h
British, turbulent	N/A	N/A	N/A	10	180	11,900 m^3/h

Figure 2 – European Operating Room Classification Parameters and Ventilation Requirements - The ventilation rates in other countries vary from each other and from the US standards. In several cases, the European standards employ not only air change rates but also microbial and particle levels.

Figure 3 – The operating rooms in this study used ceiling mounted supply diffusers providing conditioned and filtered air over the surgical area. Ceiling mounted equipment, such as booms and lights, can impact the flow of air and location of diffusers.
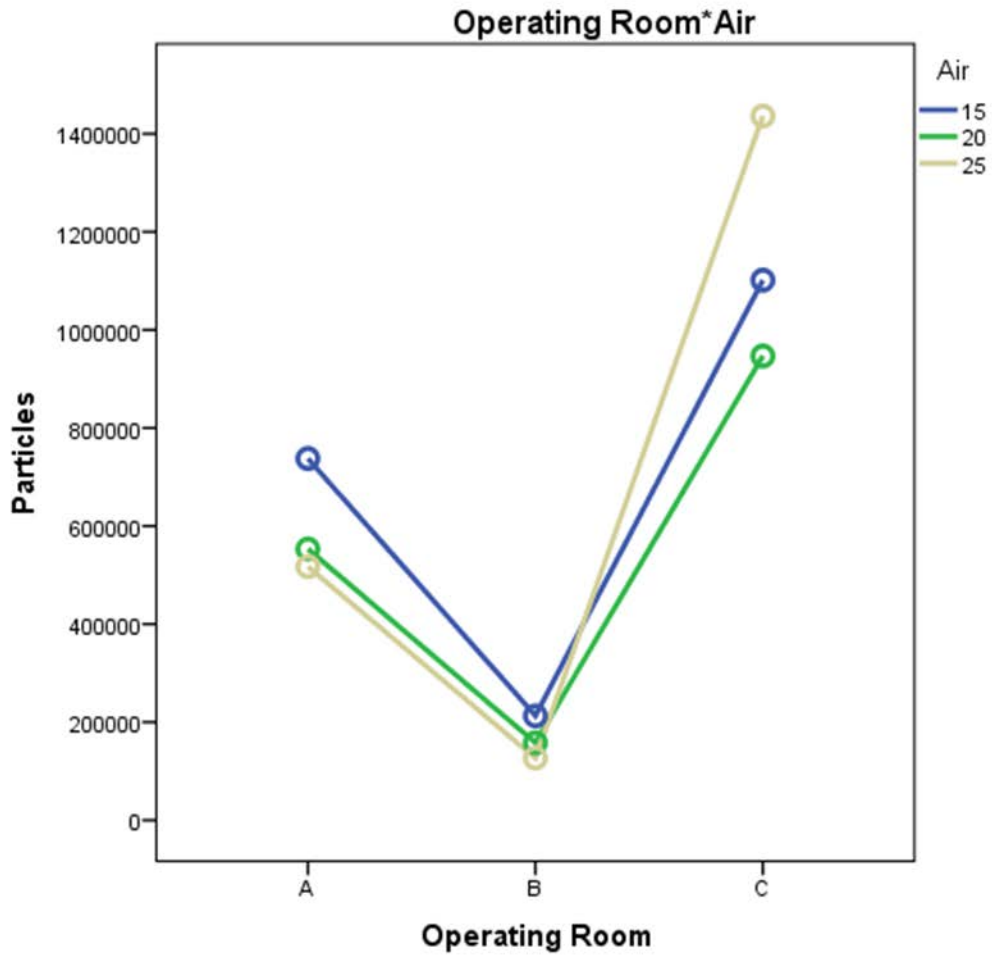
Figure 4 – In all cases, the particle levels at 20 ACH were lower than at 15 ACH. In both academic medical centers, the number of particles at 20 ACH and 25 ACH were very similar. At the community hospital, the number of particles was actually higher at 25 ACH that at 20 ACH.
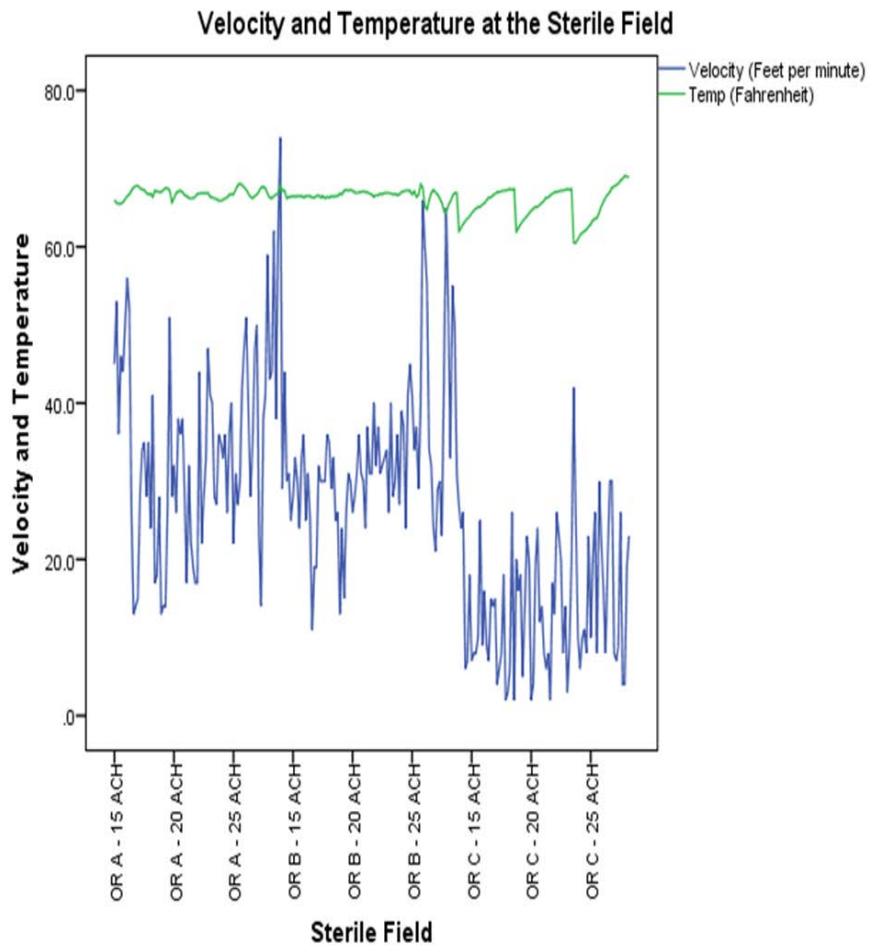
Figure 5A - The velocity of the air varied significantly at the sterile field and at the back table. In all cases, the velocity of the air was lower at the back table and in some cases was less than 10 FPM.
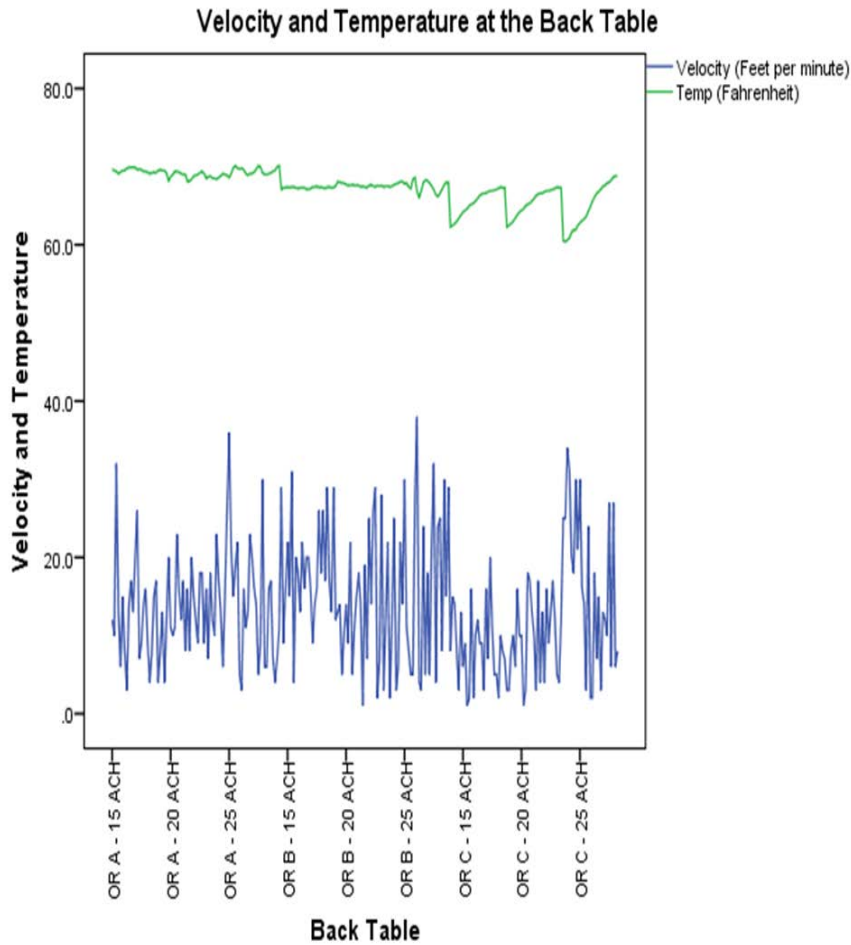
Figure 5B - The velocity of the air varied significantly at the sterile field and at the back table. In all cases,

the velocity of the air was lower at the back table and in some cases was less than 10 FPM.

Tables

27 x 27 operating room with 10 ft ceiling =7300 CF
20 ACH per hour so 20 x 7300 =146,000 CF/ hour or 2433 CFM
To determine the supply grille face velocity divide CFM by the square feet face of the grille. FGI Guidelines recommend 25 to 35 CFM/SF
Note: more supply than return is required to maintain positive pressure relative to adjacent spaces.

Table 1 – Sample OR Air Change Calculation

HVAC System or Component	Per 5 ACH per Year per OR
Fan Power (Supply & Return)	$3,880
Cooling	$2,585
Steam	$2,310
Total*	$8,775

Table 2A – Site A estimated utility operating cost per 5 ACH/yr/OR for 730 SF OR @ 22 ACH based upon

average mid-west utility rates with district energy chilled water and steam plant

HVAC System or Component	Per 5 ACH per Year per OR
Fan Power (Supply & Return)	$3,880
Cooling (Chillers, Pumps, Tower Fans)	$225
Pre Heat/Reheat/Humid. (Reheat Pumping)	$765
Total*	$4,870

Table 2B – Site B estimated utility operating cost per 5 ACH/yr/OR for 730 SF OR @ 22 ACH based upon

average mid-west utility rates with onsite chilled water and steam plant

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Acknowledgements

CHAPTER 4

CONSTRUCTION MANAGEMENT OF HEALTHCARE PROJECTS

• Book on related topic of healthcare construction

• Published by McGraw-Hill in 2013

• Co-written by Thomas C. Gormley

• Forwards provided by Facilities Guidelines Inst., International Building Code Council and

  American Society of Healthcare Engineering

A complete, practical guide to managing healthcare facility construction projects. Filled with

best practices and the latest industry trends, *Construction Management of Healthcare Projects* describes

the unique construction requirements of hospitals, including building components, specialized functions,

codes, and regulations. Detailed case studies offer invaluable insight into the real-world application fo

the concepts presented. This authoritative resource provides in-depth information on how to safely and

successfully deliver high-quality healthcare construction projects on time and within budget. Coverage

includes:

• Regulations and codes impacting hospitals

• Planning and predesign

• Project budgeting

• Business planning and pro formas

• Healthcare project financing

• Traditional delivery methods for healthcare projects

• Modern project delivery methods and alternate approaches

• The challenges of additions and renovations

• Mechanical and electrical systems in hospitals

• Medical technology and information systems

- Safety and infection control

- Commissioning of healthcare projects

- Occupying the project

- The future of healthcare construction

CHAPTER 5

SUMMARY

Overview

This research project, completed as part of my PhD requirements, has been an incredible learning experience. The research involved both healthcare and engineering to explore how the designed indoor environment can potentially contribute to improving clinical outcomes. This work required learning about operating room practices from scrubbing to prepare for surgery through to using surgical tools. On the engineering side, I learned how the HVAC system is designed, built and operated to control the air quantity and quality controls to provide a comfortable and safe environment for surgery.

Through collaboration, team developed the concept of Environmental Quality Indicators (EQI's) which is a measure of the overall air quality considering all of these factors. These are: temperature, relative humidity, particle load, number of microbial contaminants, ventilation rates, pressurization and airflow. The multi-disciplined team included a Board certified surgeon to provide clinical input, an air quality expert to guide the testing procedures, a mechanical engineer to provide design input and an HVAC testing specialist to take the measurements. With their help, I learned how to measure these important indicators in a dynamic operating room condition. I was able to organize and find funding for the testing at three different hospitals to compare the air quality at different ventilation rates. Working with a PhD statistician, I learned how to analyze a significant amount of data we had gathered at the three sites with the four different ventilation rates that were tested. From this analysis, the results of varying the air change rates could be effectively defined.

Executing the mock surgical procedures in the three different operating rooms was the most interesting and allowed us to take measurements under dynamic, surgery like conditions. The only key element missing was the patient and this was a conscious decision. The approvals required to test in an

operating room during live procedures were going to be difficult, if not impossible to obtain. Not having

an actual patient in the room also gave us much more freedom to test in different ways and at critical

locations. We used a steak to simulate surgery using an electro cauterization tool, called a Bovie, and

other surgical tools. The mock surgical team scrubbed, dressed out and followed standard operating

room cleaning, gowning procedures and instrument preparation.

Working with the energy managers at each of the three facilities, we were able to estimate the

cost of different air change rates. We found that five air changes per hour is equivalent to approximately

$5000 per year per operating room. For large systems with multiple operating rooms, this could amount

to savings in the hundreds of thousands. However, relative to the overall revenues generated by

surgeries this is a very small number. Providing air changes at rates of 25 ACH, when the code only

requires 20 ACH, will probably be perceived as a reasonable investment to minimize the risk of surgical

site infections caused by airborne contaminants. There is however, a point of diminishing returns where

additional air changes are unnecessary and just a waste of money. Hopefully, this research will help

confirm that ventilation rates greater than 25 ACH are not adding value in a typical operating room.

Given the different approaches to maintaining air quality used by other countries and in other

industries, the question remains as to whether requiring minimum air changes per hour is the best

metric. The requirements for minimum air quality may be better expressed as a combination of the

multiple factors impacting cleanliness and particle control. As mentioned before, these are:

temperature, relative humidity, particle load, number of microbial contaminants, pressurization and

airflow which are addressed by the environmental quality indicator concept.

There were several limitations to this research project that should be identified. These items

were evaluated, but could not be changed.

- The OR's were not the same size and had different configurations for the supply air grilles

- One OR was in a community hospital and the other two were in academic centers which showed different conditions

- The tests were taken at different times of the year in different cities which could have changed the outdoor air conditions

- Funding was limited so only three sites could be done

Conclusions

There were several conclusions that came from the research project. One of the original thesis ideas was incorrect as I thought 15 ACH would be just as good as 20 ACH. This is not correct. 20 ACH is significantly cleaner than 15 ACH, however 25 ACH is not significantly cleaner than 20 ACH. The air flow at back table is lower than expected and could add risk as the surgical instruments are opened there and could be exposed to air borne contaminants. The potential cost savings could be hundreds of thousands of dollars for large system to reduce air change rates from 25 to 20 ACH, however the savings are small relative to overall revenue compared to perceived risk of impacting SSI's

Recommendations for Research

Throughout the project, questions rose where additional research could be valuable. We identified the list below as the best opportunities.

- Utilize EQI air testing protocol for other rooms in healthcare facilities to verify cost-benefits for code required minimums i.e. patient rooms

- Obtain surgical site infection data and compare those results to different air change rates and air quality indicators in operating rooms

- Develop for application in the industry a comprehensive air quality metric using multiple indicators to provide a better view of air quality than just air change rates

APPENDIX –EXAMPLES OF MICROBIAL TEST RESULTS

Prism Environmental Health and Safety Solutions, Inc. PO Box 1702

Discovery Bay, California 94505

Attn: Jennifer Wagner

Project: OR Research Project-Vanderbilt (Sample F)

Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 11/07/2015

Date Received: 11/11/2015

Date Analyzed: 11/20/2015

Date Reported: 11/20/2015

Project ID: 15029369

CLIENT SAMPLE #: 18

Sample Location: 15-1 SF F

Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2

Lab Sample #: 15029369-001

Positive Hole: 401

Positive Hole Corrected Result: 35 CFU/m3

Air Volume: 1000 (L)

MRL: 1

Organism Name:	Raw Count	CFU/m^3	% Total	Reservoirs
Coag-negative *Staphylococcus* species	10	1	30	Human
Micrococcus species	23	2	70	Human
	33	3	~100%	

CLIENT SAMPLE #: 24

Sample Location: 15-2 SF F

Lab Sample #: 15029369-002

Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2

Positive Hole: 401

Positive Hole Corrected Result: 62 CFU/m3

Air Volume: 1000 (L)

MRL: 1

Organism Name:	Raw Count	CFU/m^3	% Total	Reservoirs
Coag-negative *Staphylococcus* species	23	23	40	Human
Micrococcus species	34	34	60	Human
	57	57	~100%	

CLIENT SAMPLE #: 30

Sample Location: 15-3 SF F

Lab Sample #:

15029369-003

Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2

Positive Hole: 401

Positive Hole Corrected Result: 28 CFU/m3

Air Volume: 1000 (L)

MRL: 1

Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2

Positive Hole: **401**

Positive Hole Corrected Result: **28 CFU/m^3**

Air Volume: **1000 (L)**

MRL: **1**

Organism Name:	Raw Count	CFU/m³	% Total	Reservoirs
Coag-negative *Staphylococcus* species	11	11	41	Human
Micrococcus species	16	16	59	Human
	27	27	~100%	

CLIENT SAMPLE #: 36

Sample Location: 15-4 SF F

Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2

Lab Sample #: 15029369-004

Positive Hole: **401**

Positive Hole Corrected Result: **50 CFU/m³**

Air Volume: **1000 (L)**

MRL: **1**

Organism Name:	Raw Count	CFU/m³	% Total	Reservoirs
Bacillus species	7	7	15	Environment
Coag-negative *Staphylococcus* species	10	10	21	Human
Micrococcus species	30	30	64	Human
	47	47	~100%	

CLIENT SAMPLE #: 42

Sample Location: 15-5 SF F

Lab Sample #: 15029369-005

Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2

Positive Hole: **401**

Positive Hole Corrected Result: **66 CFU/m³**

Air Volume: **1000 (L)**

MRL: **1**

Organism Name:	Raw Count	CFU/m³	% Total	Reservoirs
Bacillus species	3	3	5	Environment
Coag-negative *Staphylococcus* species	23	23	38	Human
Micrococcus species	35	35	57	Human
	61	61	~100%	

CLIENT SAMPLE #: 48

Sample Location: 15-6 SF F

Lab Sample #: 15029369-006

Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2

Positive Hole: **401**

Positive Hole Corrected Result: **29 CFU/m³**

Air Volume: **1000 (L)**

MRL: **1**

Organism Name:	Raw Count	CFU/m³	% Total	Reservoirs
Coag-negative *Staphylococcus* species	11	11	39	Human
Micrococcus species	17	17	61	Human
	28	28	~100%	

CLIENT SAMPLE #: 54

Sample Location: 15-7 SF F

Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2

Lab Sample #:   15029369-007

Positive Hole: **401**

Positive Hole Corrected Result: **75 CFU/m³**

Air Volume: **1000 (L)**

MRL: **1**

Organism Name:	Raw Count	CFU/m^3	% Total	Reservoirs
Bacillus species	13	13	19	Environment
Coag-negative *Staphylococcus* species	36	36	53	Human
Coryneform bacteria group/Corynebacterium group	1	1	1	Human/ Environment
Micrococcus species	18	18	26	Human
	68	68	~100%	

CLIENT SAMPLE #: 60

Sample Location: 15-8 SF F

Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2

Lab Sample #:   15029369-008

Positive Hole: **401**

Positive Hole Corrected Result: **41 CFU/m^3**

Air Volume: **1000 (L)**

MRL: **1**

Organism Name:	Raw Count	CFU/m^3	% Total	Reservoirs
Bacillus species	3	3	8	Environment
Coag-negative *Staphylococcus* species	14	14	36	Human
Micrococcus species	22	22	56	Human
	39	39	~100%	

CLIENT SAMPLE #: 66

Sample Location: 20-1 SF F

Lab Sample #: 15029369-009

Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2

Positive Hole: **401**

Positive Hole Corrected Result: **23 CFU/m^3**

Air Volume: **1000 (L)**

MRL: **1**

Organism Name:	Raw Count	CFU/m^3	% Total	Reservoirs
Coag-negative *Staphylococcus* species	15	15	68	Human
Coryneform bacteria group/Corynebacterium group	1	1	5	Human/ Environment
Micrococcus species	6	6	27	Human
	22	22	~100%	

CLIENT SAMPLE #: 72

Sample Location: 20-2 SF F

Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2

Lab Sample #:   15029369-010

Positive Hole: **401**

Positive Hole Corrected Result: **19 CFU/m^3**

Air Volume: **1000 (L)**

MRL: **1**

Organism Name:	Raw Count	CFU/m^3	% Total	Reservoirs
Coag-negative *Staphylococcus* species	10	10	56	Human
Micrococcus species	8	8	44	Human
	18	18	~100%	

CLIENT SAMPLE #: 78

Sample Location: 20-3 SF F

Lab Sample #: 15029369-011

Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2

Positive Hole: **401**

Positive Hole Corrected Result: **14 CFU/m^3**

Air Volume: **1000 (L)**

MRL: **1**

Organism Name:	Raw Count	CFU/m^3	% Total	Reservoirs
Bacillus species	1	1	7	Environment
Coag-negative *Staphylococcus* species	4	4	29	Human
Micrococcus species	9	9	64	Human
	14	14	~100%	

CLIENT SAMPLE #: 84

Sample Location: 20-4 SF F

Lab Sample #: 15029369-012

Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2

Positive Hole: **401**

Positive Hole Corrected Result: **19 CFU/m^3**

Air Volume: **1000 (L)**

MRL: **1**

Organism Name:	Raw Count	CFU/m^3	% Total	Reservoirs
Coag-negative *Staphylococcus* species	11	11	61	Human
Micrococcus species	7	7	39	Human
	18	18	~100%	

CLIENT SAMPLE #: 90

Sample Location: 20-5 SF F

Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2

Lab Sample #:   15029369-013

Positive Hole: **401**

Positive Hole Corrected Result: **14 CFU/m^3**

Air Volume: **1000 (L)**

MRL: **1**

Organism Name:	Raw Count	CFU/m^3	% Total	Reservoirs
Coag-negative *Staphylococcus* species	6	6	43	Human
Micrococcus species	8	8	57	Human
	14	14	~100%	

CLIENT SAMPLE #: 96

Sample Location: 20-6 SF F

Lab Sample #: 15029369-014

Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2

Positive Hole: **401**

Positive Hole Corrected Result: **16 CFU/m^3**

Air Volume: **1000 (L)**

MRL: **1**

Organism Name:	Raw Count	CFU/m^3	% Total	Reservoirs
Coag-negative *Staphylococcus* species	9	9	56	Human
Micrococcus species	7	7	44	Human
	16	16	~100%	

CLIENT SAMPLE #: 102

Sample Location: 20-7 SF F

Lab Sample #: 15029369-015

Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2

Positive Hole: **401**

Positive Hole Corrected Result: **27 CFU/m^3**

Air Volume: **1000 (L)**

MRL: **1**

Organism Name:	Raw Count	CFU/m^3	% Total	Reservoirs
Coag-negative *Staphylococcus* species	16	16	62	Human
Micrococcus species	10	10	38	Human
	26	26	~100%	

CLIENT SAMPLE #: 108

Sample Location: 20-8 SF F

Lab Sample #: 15029369-016

Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2

Positive Hole: **401**

Positive Hole Corrected Result: **No Growth**

Air Volume: **1000 (L)**

MRL: **1**

Comments: No impaction marks detected on sample. No bacteria detected

CLIENT SAMPLE #: 114

Sample Location: 25-1 SF F

Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2

Lab Sample #:   15029369-017

Positive Hole: **401**

Positive Hole Corrected Result: **11 CFU/m^3**

Air Volume: **1000 (L)**

MRL: **1**

Organism Name:	Raw Count	CFU/m^3	% Total	Reservoirs
Bacillus species	2	2	18	Environment
Coag-negative *Staphylococcus* species	6	6	55	Human
Micrococcus species	3	3	27	Human
	11	11	~100%	

CLIENT SAMPLE #: 120

Sample Location: 25-2 SF F

Lab Sample #: 15029369-018

Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2

Positive Hole: **401**

Positive Hole Corrected Result: **18 CFU/m^3**

Air Volume: **1000 (L)**

MRL: **1**

Organism Name:	Raw Count	CFU/m^3	% Total	Reservoirs
Bacillus species	2	2	12	Environment
Coag-negative *Staphylococcus* species	11	11	65	Human
Micrococcus species	4	4	24	Human
	17	17	~100%	

CLIENT SAMPLE #: 126

Sample Location: 25-3 SF F

Lab Sample #: 15029369-019

Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2

Positive Hole: **401**

Positive Hole Corrected Result: **9 CFU/m^3**

Air Volume: **1000 (L)**

MRL: **1**

Organism Name:	Raw Count	CFU/m^3	% Total	Reservoirs
Coag-negative *Staphylococcus* species	4	4	44	Human
Micrococcus species	5	5	56	Human
	9	9	~100%	

CLIENT SAMPLE #: 132

Sample Location: 25-4 SF F

Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2

Lab Sample #:   15029369-020

Positive Hole: **401**

Positive Hole Corrected Result: **13 CFU/m^3**

Air Volume: **1000 (L)**

MRL: **1**

Organism Name:	Raw Count	CFU/m^3	% Total	Reservoirs
Coag-negative *Staphylococcus* species	9	9	69	Human
Micrococcus species	4	4	31	Human
	13	13	~100%	

CLIENT SAMPLE #: 138

Sample Location: 25-5 SF F

Lab Sample #: 15029369-021

Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2

Positive Hole: **401**

Positive Hole Corrected Result: **10 CFU/m^3**

Air Volume: **1000 (L)**

MRL: **1**

Organism Name:	Raw Count	CFU/m^3	% Total	Reservoirs
Coag-negative *Staphylococcus* species	5	5	50	Human
Coryneform bacteria group/Corynebacterium group	2	2	20	Human/ Environment
Micrococcus species	3	3	30	Human
	10	10	~100%	

CLIENT SAMPLE #: 144

Sample Location: 25-6 SF F

Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2

Lab Sample #: 15029369-022

Positive Hole: **401**

Positive Hole Corrected Result: **13 CFU/m^3**

Air Volume: **1000 (L)**

Organism Name:	Raw Count	CFU/m^3	% Total	Reservoirs
Coag-negative *Staphylococcus* species	9	9	69	Human
Micrococcus species	4	4	31	Human
	13	13	~100%	

CLIENT SAMPLE #: 150

Sample Location: 25-7 SF F

Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2

Lab Sample #:   15029369-023

Positive Hole: **401**

Positive Hole Corrected Result: **7 CFU/m^3**

Air Volume: **1000 (L)**

MRL: **1**

Organism Name:	Raw Count	CFU/m^3	% Total	Reservoirs
Coag-negative *Staphylococcus* species	3	3	43	Human
Micrococcus species	4	4	57	Human
	7	7	~100%	

CLIENT SAMPLE #: 156

Sample Location: 25-8 SF F

Lab Sample #:

15029369-024

Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2

Positive Hole: **401**

Positive Hole Corrected Result: **19 CFU/m^3**

Air Volume: **1000 (L)**

MRL: **1**

Organism Name:	Raw Count	CFU/m^3	% Total	Reservoirs
Coag-negative *Staphylococcus* species	11	11	61	Human
Micrococcus species	7	7	39	Human
	18	18	~100%	