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RESEARCH ARTICLE

Operating Room Improvements Based on Environmental Quality Index Risk Prediction can help Reduce Surgical Site Infections

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ABSTRACT

Importance: The role of the operating room (OR) airborne environment in the incidence of surgical site infections (SSI) has ranked behind patient and perioperative team-related factors associated with risk for SSI. Emerging evidence demonstrates that the design and performance of the OR environment impacts the airborne microbiome both within the sterile field and at tables where instruments and implants are exposed. However, the correlation between OR air quality and the risk of SSI continues to be challenged.

Objective: To determine if improving the asepsis of the airborne environment in ORs contributes to reduced SSI rates.

Design: The performance of air delivery systems in fourteen operating rooms was evaluated using the Environmental Quality Indicator (EQI) risk picture method to identify potential improvements to airflow management that reduce airborne contamination and operating costs. SSI rates for colon and abdominal hysterectomy procedures were tracked in these ORs for 39 months before and after improvements were implemented. SSI rates were also tracked for the same time frame for six control ORs in which no improvements were made. Airborne microbial data was collected.

Setting: Twenty ORs in an academic medical center, Midwest USA. A convenience sample of all surgical patients, de-identified, was used in the twenty ORs studied.

Results: SSI rate was reduced from 8.4% to 5.7% (p=.0039) in ORs in which improvements were implemented. Reduction of SSI rate in control ORs was not significant (p=.76). Fewer airborne microbes were detected in areas of OR with improvements (p<.0001).

Conclusion: Areas for environmental quality improvement in ORs was identified and mapped by relative risk of contamination. Implementation of these improvements resulted in decreased microbial contamination and contributed to significant reduction in surgical site infection.

Keywords: Surgical site infection, SSI, Environmental Quality Indicators, EQI, Risk, Contamination, Operating Room

Background

Surgical site infections (SSIs) are estimated to occur in 2-4 % of surgical procedures totaling approximately 160k infections per year[1]. These infections extend the average length of stay by 9.7 days, cost approximately $100,000 each[2], for an estimated 3.3 billion dollars per year[3], and result in an additional 1 million patients days per year[4]. Readmissions result in the use of additional resources such as, antibiotics, wound debridements, prosthetic removals, as well as additional rehabilitation. Numerous guidelines designed to reduce SSI have been implemented by the Center for Disease Control and Prevention (CDC)[5], World Health Organization (WHO)[6], US Dept of Health and Human Services[7], Association of Professionals in Infection Control (APIC)[8], Association of peri-Operative Registered Nurses (AORN)[9], the American College of Surgeons (ACS)[10] and others. These guidelines include hand and forearm antisepsis, prophylactic antimicrobial use, antiseptic bathing, maintenance of normothermia, adherence to proper sterilization techniques and device reprocessing, and environmental cleaning and disinfection. The contribution of the airborne environment to SSI prevention is currently addressed through dilution with air changes, effective filtration, positive pressurization, supply air velocity, temperature, and humidity ranges, primarily by the Healthcare Infection Control Practices Advisory Committee (HICPAC) guidelines[11] and the American Society of Heating, Refrigeration and Air conditioning Engineers (ASHRAE)[12]. None of these recommendations include periodic monitoring of the airborne environmental quality or evaluation of the environmental microzones within the operating room, e.g., sterile field or back instrument tables.

It is generally accepted that the contributors to SSI are multifactorial[13] and therefore, no single change will eliminate all SSIs. According to the Agency for Healthcare Research and Quality (AHRQ) the use of interventions to improve the safety culture, data tracking, checklists, and evidence-based bundles reduced the incidence of SSI by 16% from 2010 to 2015[14]. Interestingly, while aseptic design of the OR is becoming increasingly accepted, interventions to date do not include a more optimal utilization of the physical environment to prevent airborne transmission of contamination. This is likely because studying the connection between airborne microbiological contamination and surgical site infections has historically been expensive and time consuming.[15,16,17]

Furthermore, the guidelines for air distribution in ORs are based on minimal scientific evidence and are prescriptive as opposed to performance based. For example, ASHRAE 170 recommends the use of unidirectional, downward flow of filtered air over the sterile field, with the array extending 12 inches beyond the footprint of the surgical bed, and with allowance for 30 percent hard lid, non-air delivery space.[12] The current guidelines also recommend a minimum air change per hour (ACH) rate which is subject to individual state adoption, with some remaining at 15, while others recommend 20 to 40 ACH. While these minimum guidelines allow for variation in design and operation, they are also conducive to variation in performance.

There is evidence that an aseptically designed OR in which there are minimal blockages to downward air flow, four low wall returns, and dedicated air delivery over the back instrument table, will have superior contamination control and may be able to run at a lower ACH.[18,19] The differences in the layout of the ceiling mounted supply air diffusers can also impact the distribution of the conditioned and filtered air, and therefore the air quality and contamination control. This is very important at critical areas of the OR, such as the sterile field and back instrument table, where the clean air is needed to help provide sterile conditions for invasive procedures.

Additional environmental qualities specified by regulation include temperature and humidity ranges (20-23°C and 20-60%), and supply air velocity (30fpm).[12] Optimal aseptic performance of the operating room requires all parameters, such as ACH, temperature, humidity, and supply diffuser velocity, to be within acceptable ranges. Optimal performance also requires the effective control of the protective filtered air supply by minimizing blockages to supply and ensuring return grilles are open to allow the air to leave the space. Based on the design and performance of the room, a unique risk map of the space can be created, indicating, based on environmental quality indicators, areas within the OR that are at increased risk of contamination.[18-23] When one or more environmental conditions are out of optimal range, the risk of environmental contamination increases. This risk map can be used to better understand how the room is performing, where higher and lower risk areas are within the room, and how to optimize the aseptic performance of the OR.

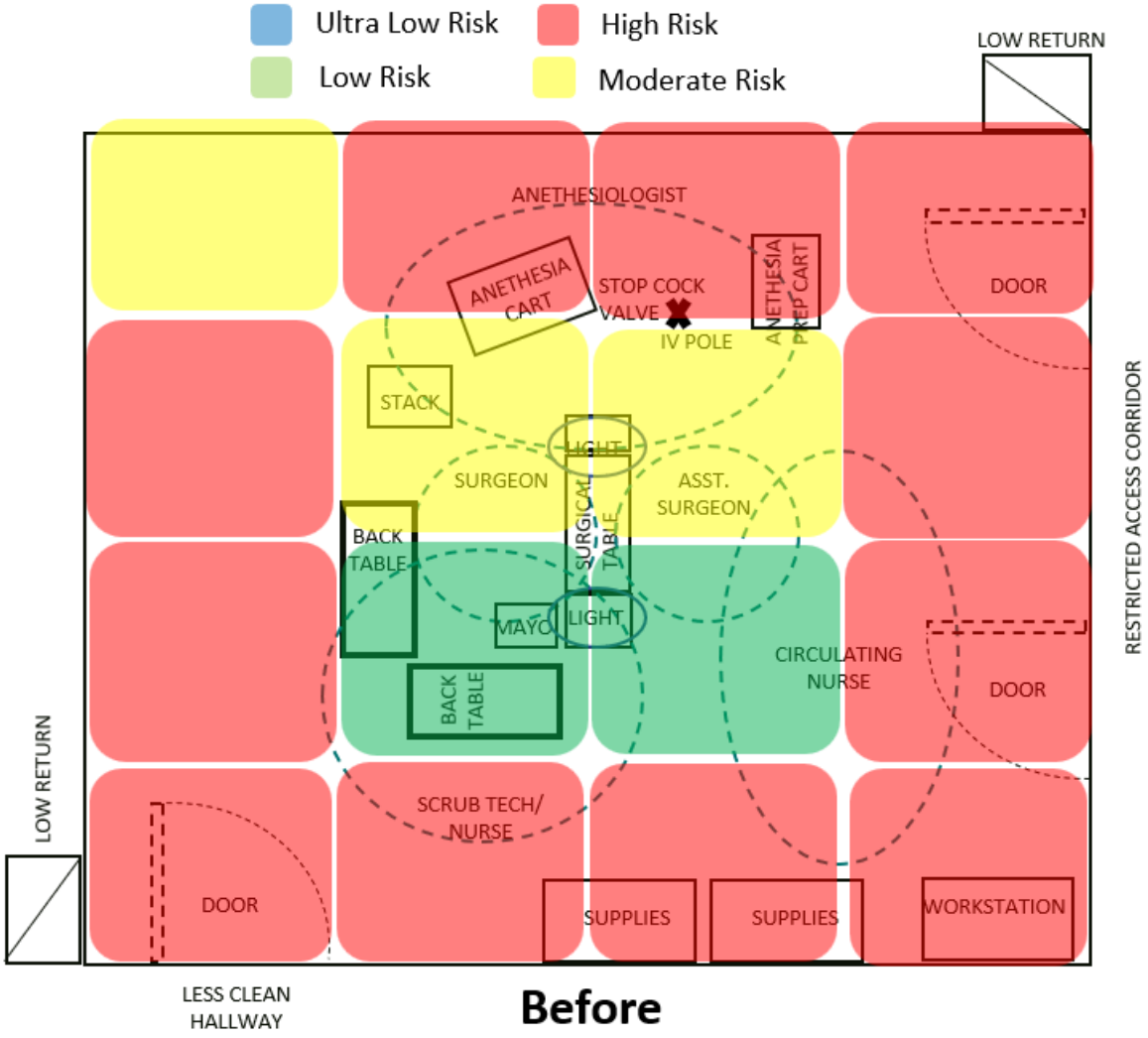
The risk map was used to inform the infection prevention and quality management staff of lower and higher risk areas within each OR so they could optimize the aseptic performance of the room and

monitor the EQIs to ensure continued optimization. Additionally, minimal, physical improvements to these ORs were made. SSIs were tracked before and after improvements were made and the reduction in SSIs was compared to ORs in which no environmental improvements were made. Implementation of clinical improvements was universally applied to all ORs.

We hypothesized that 1) implementation of environmental improvements, intended to establish lower risk, in an OR, would yield a cleaner environment, 2) these evidence-based improvements would contribute to a significant reduction in SSI, and 3) that optimization of the aseptic OR environment would result in lower operational and clinical cost.

Methods and Materials

Risk Mapping – Risk mapping of the ORs was accomplished by measuring the Environmental Quality Indicators (EQI) within each room[20] and applying them to the EQI risk predicting algorithm (patent pending) (Figure 1).



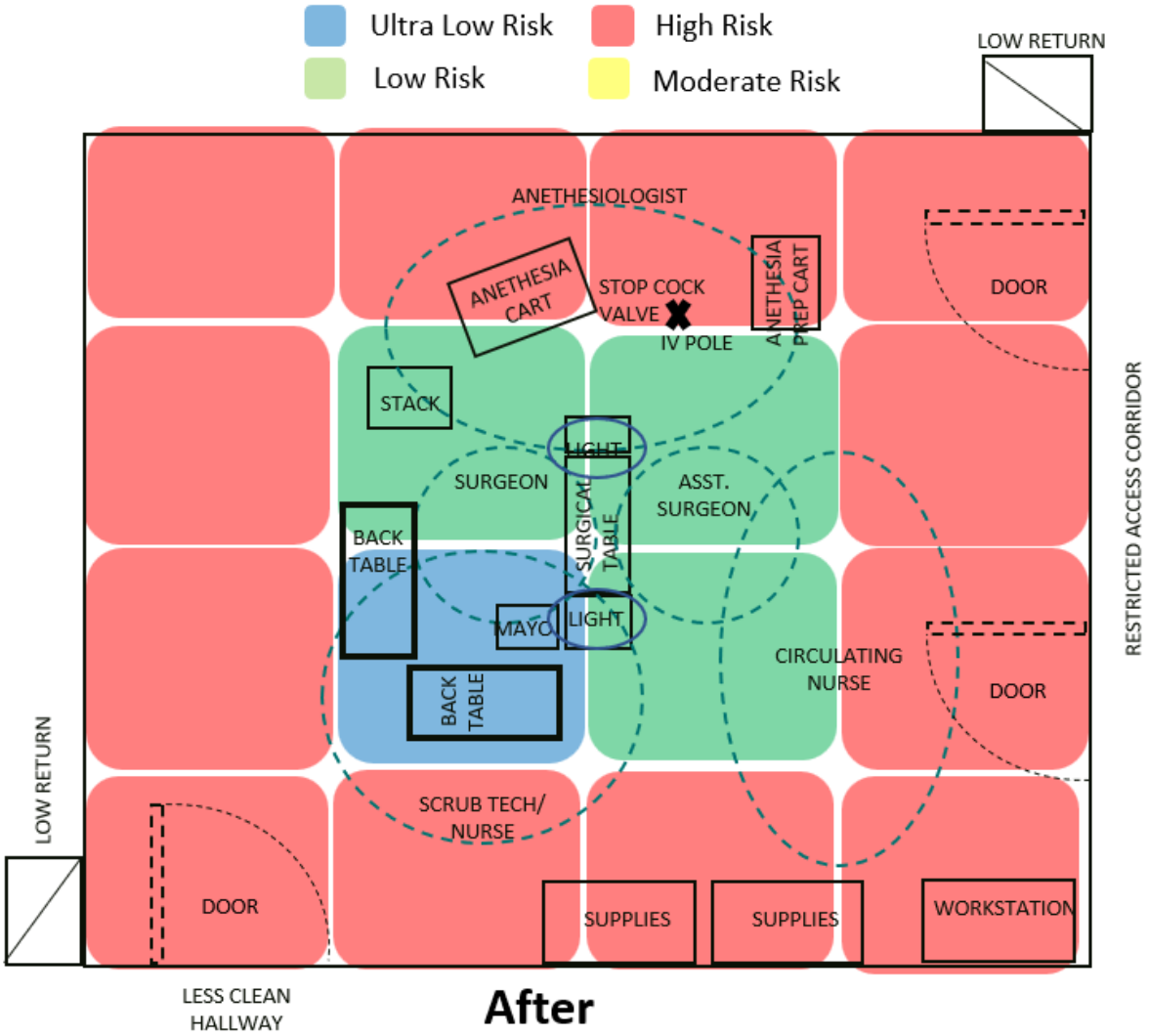


Figure 1: Before and After Improvements - Risk map of OR showing areas of greater risk of microbial contamination in red, moderate risk in yellow, low risk in green, and ultra-low risk in blue. In this example, a concerted effort was made to direct all available supply air over the surgical bed and location of the back instrument tables, both in preparation and in-procedure locations.

Environmental Improvement Implementation – Environmental improvements implemented include reconfiguration of the air distribution to improve air velocity at the sterile field and at the back instrument tables, increased relative humidity from 20-35%, real time monitoring of the temperature, pressure and humidity levels, reduction of overall air change rates by 5 ACPH, and staff education on the role of the environment in the potential transmission of contaminants. (All staff were educated equally, and all staff worked in both control ORs, and improved ORs, equally). Additionally, the ORs were ISO 14644-1 particle counted (in static conditions) to maintain an ISO classification of 6.

Clinical Data Harvesting – The infection preventionist used the Cerner (Kansas City, MO) electronic medical records system for surgical patients to abstract SSI case data and create a "line list" of cases under review. Isolates were reviewed and cases were screened by ICD10. Reports were generated that include SSI organism, depth, symptom onset date, culture date, operating room, surgeon. Colon, and abdominal hysterectomy SSI cases were reported to NHSN.

Clinical Statistical Analysis – Statistical analysis of the clinical infection data included Chi-square analysis to compare two groups of data, ratios of SSI to total surgeries before and after implementation of environmental improvements in

ORs in which improvements were made, and ratios of SSI to total surgeries before and after the latest date of implementation, August 1, 2017, for control ORs. The rationale being that all clinical improvements had also been implemented by August 1, 2017, thereby choosing the most conservative approach to analyzing the control group data. A total of 1,788 surgeries and 119 SSIs were analyzed with 43 SSI out of 511 surgeries in the control ORs with no environmental improvements, and 89 SSIs out of 1,277 total surgeries in ORs in which environmental improvements were made.

Microbial Statistical Analysis – Skewness and kurtosis statistical analysis 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. Because of this violation of normality, only nonparametric statistics were used to answer research questions in this study. Kruskal-Wallis tests were used to assess main effects when comparing ≥3 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 2 groups on outcomes, Mann-Whitney *U* tests were used. Medians and interquartile ranges (IQRs) were reported to give context to all inferential findings. When assumptions of normality and homogeneity of variances were met, means and SDs were used. All analyses were conducted using SPSS Version 21 (IBM, Armonk, NY).

OR Environmental Improvement Process - Fourteen ORs at an academic medical center were risk mapped based on their environmental quality indicators. In these ORs, the map was used to inform the infection prevention and quality management staff of lower and higher risk areas within each OR so they could optimize the aseptic performance of the room and monitor the EQIs to ensure continued optimization. Addition of an in-ceiling diffuser was installed above the location of the 'back instrument table' and blockages to air returns were removed, resulting in a reduction of air change rates from 26 to 21 ACH. Six ORs (controls) at the same medical center were not mapped and no environmental alterations were made. Surgical site infections were tracked before and after the improvements were implemented in the 14 modified ORs from April 2015 to July 2018 (40 months). SSIs were tracked for the same time duration, Aril 2015 to July 2018 in the 6 ORs that had no environmental modifications. Implementation of clinical improvements was universally applied to all 20 ORs, and the repeatability of the abdominal hysterectomy, and colon surgeries were accounted for and posed little variation among surgical teams.

Validation of risk map in one OR with microbiological sampling - In one of the modified ORs, the EQI method of dynamic, simulated surgical procedure testing[20] was used to measure the airborne microbial contamination between a back instrument table located under the added supply air array (BT 1), and a back table outside the footprint of the supply air (BT 2). All EQI parameters were also measured and maintained as per the EQI method.[20]

Compilation of previous EQI study data into prediction database –

The EQI method includes gowning, gloving, prepping and passing of instruments, movement of light booms, electrocautery, door openings, and traffic. Over 35,000 measurements were collected both inside the sterile field and outside the sterile field. These Environmental Quality Indicators (EQI) were collected during eighty procedures, and include over 5,000 data points for humidity, and temperature inside the sterile field at the face of the supply grille, at the surgical table, and at the back instrument table; over 5,000 data points for supply air velocity at the face of the grille, at the surgical table, and at the back instrument table; over 22,000 particle counts for 0.3, 0.5, 1.0, 5.0 and 10.0 micron size particles in the ISO 14644-1 (24) 9-point grid within the OR, at the back instrument table, and in the return grille; and over 3,000 microbial colony forming unit (CFU) counts within the sterile field, and at the back instrument table outside the sterile field. These data points were entered into a database, correlations determined, and an algorithm developed (patent pending).

Cost outcome analysis - Energy calculations were based upon ~ 20 ACPH for a 550 SF operating room that included electrical energy from fans, pumps, cooling systems, thermal energy for preheating, terminal unit reheating, and steam humidification. The energy model also included the appropriate seasonal utilization hours for cooling, heating, economizer, and dehumidification/sub cooling modes of operation. The number of SSIs averted following implementation of improvements was determined by using a Shapiro-Wilk normality test of the Optimized room data prior to environmental improvements with GraphPadPrism8 (Graph-Pad Software, LaJolla, CA). The data was determined to be a normal distribution. A linear best fit line was established using Microsoft Excel (Microsoft Office 10, Redmond, WA). This line was

then extrapolated to determine the possible number of SSIs that would have occurred if no environmental improvements were made by year. Then the actual by year was subtracted from the potential (if no environmental improvements) by year to determine the difference.

Results

Surgical Site Infections – In the four ORs with a 'change date' of January 1, 2016, SSIs dropped from 12.4% (12 SSI/98 surgeries) to 4.7% (15 SSI/319 surgeries) following environmental improvements. In the two ORs with a 'change date' of April 1,2016, SSIs increased from 10% (1 SSI/10 surgeries) to 10.5% (4 SSI/38 surgeries). In the eight ORs with 'change date' August 1, 2017, SSIs dropped from 7.8% (43 SSI/551 surgeries) to 5.4% (14 SSI/261 surgeries). Collectively, the decrease in SSIs in all modified ORs following environmental improvement was 8.4 to 5.7 percent and the SSI ratio reduction was statistically significant at p=0.039 (significance at p<0.05) (Figure 2 and Table 1). In control ORs, the SSIs dropped from 8.6 to 7.9 percent after August 1, 2017, however, the ratios of SSI to surgery before and after August 1, 2017, were not significantly different, p=0.76. The overall percent of SSIs in control ORs for the duration of the study was 8.4.

Microbiological Contamination – The colony forming units per cubic meter (CFU/m3) collected at BT1 were significantly fewer than the CFU/m3 collected at BT2, p<0.0001 (significance at p<0.0001) (Figure 3).

Percent SSI in Control ORs versus Improved ORs before and after Environmental Improvements

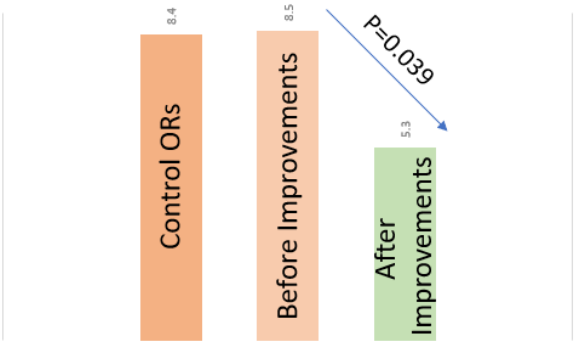


Figure 2: The percent SSI in control ORs as compared to the percent SSI in modified ORs before and after improvements. The reduction in SSI in improved ORs was statistically significant at p=.039. Control ORs did not show significant reduction in SSI.

Table 1:

Operating Room	Improvement Date	#SSI/ #Surgeries	Proportion SSI	#SSI/ #Surgeries before Improvement	Proportion SSI before Improvement	#SSI/ #Surgeries after Improvement	Proportion SSI after Improvement
Control 1	NA	8/63	0.13	NA	NA	NA	NA
Control 2	NA	14/82	0.17	NA	NA	NA	NA
Control 3	NA	4/27	0.15	NA	NA	NA	NA
Control 4	NA	2/30	0.07	NA	NA	NA	NA
Control 5	NA	6/179	0.03	NA	NA	NA	NA
Control 6	NA	9/130	0.07	NA	NA	NA	NA
Optimized 1	Jan 2016	NA	NA	3/8	0.38	0/11	0
Optimized 2	Jan 2016	NA	NA	1/16	0.06	3/49	0.06
Optimized 3	Jan 2016	NA	NA	6/70	0.09	6/171	0.04
Optimized 4	Jan 2016	NA	NA	2/4	0.5	2/18	0.11
Optimized 5	April 2016	NA	NA	1/7	0.14	2/24	0.08
Optimized 6	April 2016	NA	NA	0/3	0	2/9	0.22
Optimized 7	Aug 2017	NA	NA	7/133	0.05	2/83	0.02
Optimized 8	Aug 2017	NA	NA	3/104	0.03	2/55	0.04
Optimized 9	Aug 2017	NA	NA	5/33	0.15	1/7	0.14

Optimized 10	Aug 2017	NA	NA	1/29	0.03	0/1	0
Optimized 11	Aug 2017	NA	NA	13/139	0.09	5/61	0.08
Optimized 12	Aug 2017	NA	NA	13/108	0.12	3/40	0.08
Optimized 13	Aug 2017	NA	NA	1/3	0.3	0/4	0
Optimized 14	Aug 2017	NA	NA	0/2	0	1/10	0.1
					p=0.039		
	%SSI	43/511	8.4%	56/659	8.5%	29/543	5.3%

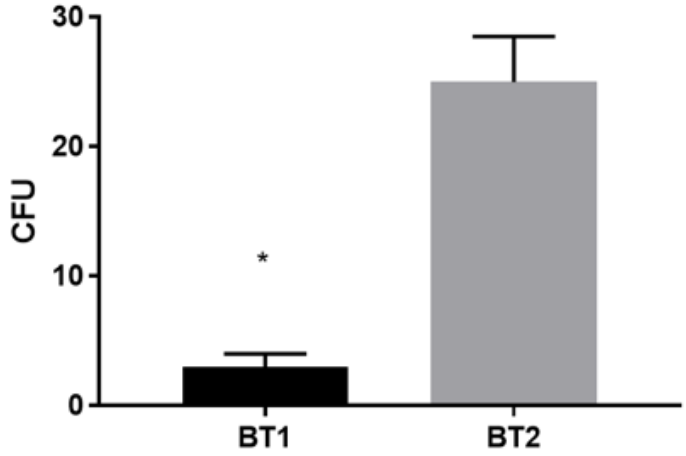


Figure 3: The quantity of microbial colony forming units was statistically significantly ($p<.001$) less at a back instrument table located beneath unidirectional downward supply of filtered air than at a back instrument table located outside of the supply air grid, without dedicated clean air.

Cost Outcomes - The average air change rate per OR before the EQI modifications was approximately 29. After the EQI modification the average air change rate was 24. This resulted in a 5 ACPH rate reduction per OR. The model was validated by the local utility provider[18] and a national healthcare engineering firm. Energy calculations were based upon a facility located in Department of Energy Climate Zone 5 with approximately 22 air changes per hour (ACPH) for an average 550 square foot (SF) operating room that included electrical energy from fans, pumps, cooling systems, thermal energy for preheating and terminal unit reheating, and steam humidification. The model also included the appropriate seasonal utilization hours for cooling, heating, economizer, and dehumidification/sub cooling modes of operation. The energy cost savings, using the hospital's city thermal utilities provider rates for steam and chilled water coupled with the electrical utility provider demand and usage aggregated rate of electricity for the fourteen (14) ORs over a three-year period was $422,856 (Table 2). Additionally, it was extrapolated that 42 SSIs were averted by the implementation of improvements, and at an estimated 35k per SSI for this particular type, this amounted to an overall cost saving of $1.470,000 in the improved ORs.

Table 2:

Building Utility Service Type & Climate Zone	**Annual Energy Savings per 5 ACPH Reduction***	**Annual Savings for all EQI Modified Operating Rooms (x 14)**
City Thermal Utilities Climate Zone 5	**$10,068**	**$140,952**
Campus Thermal Climate Zone 4	**$7,052**	**$98,728**
Self-Generated Thermal Climate Zone 4	**$5,218**	**$73,052**

Discussion

Analyzing room environmental conditions and empirical operating data to predict the risk for microbial contamination in the operating room can help reduce surgical site infections. SSIs occur when bacteria, often normal human flora, access the open surgical wound and proliferate. These bacteria are opportunistic pathogens and under the right conditions can result in infection, especially in higher risk patients with comorbidities that can reduce the body's ability to fight infection. They can enter the wound on contaminated surgical instruments, implantable items or doctor's hands, or they can be carried through the air on shed skin cells or other particles and be deposited into the wound or onto items that contact the wound.[25-28]

The majority of contamination in the operating room (OR) comes from the people in the space, the doctors, nurses, scrub techs, residents, sales reps and observers.[13] Each human sheds approximately 30 thousand squams per minute amounting to nearly 2 million cells per one hour surgery per person. There are many ways to establish procedural based asepsis in the OR including, proper gowning and scrubbing techniques, sterile implants and instruments, patient prep, prophylactic antibiotics and maintaining normothermia, among others. Sometimes, these clinical interventions alone are not effective at significantly reducing SSIs. Additionally, current code compliant environmental parameters discussed above are also essential to maintaining asepsis during procedure times.[12] However, these environmental control methods are only prescribed with relationship to the sterile field leaving unprotected areas of the OR with uncontrolled, fluctuating, environmental parameters in zones with little or no air flow and increased risk for contamination. Furthermore, these prescribed design and construction environmental guidelines are minimum standards and don't address the performance of the operating room during procedure when the patient is in the room and susceptible to contamination. Lastly, medical equipment, light booms and the surgical team can impede the protective flow of air within the sterile field producing eddies and currents that entrain contamination from outside the sterile field, bringing contamination into the field. Thus, a more wholistic approach to analyzing and controlling environmental parameters is necessary to point to or even predict, in near real time, the increase in risk of microbial contamination in the sterile field and outside the sterile field where instruments and implants are located and susceptible.

In order to understand the relationship between the OR environment and the risk for microbial contamination, we compiled data collected using the EQI method for analyzing environmental quality indicators in a dynamic operating room environment.[20] The method has been used to study the environmental quality during dynamic, simulated, one-hour long, scripted and repeatable, surgical procedures.[18,19,22,23]

Due to strong statistical power, significance of correlated data and repeatable findings, the EQI measurements can be used to establish likelihood or predict the risk of increased microbial CFU contamination both inside and outside the demarcated sterile field. This ability to predict risk of increased microbial contamination by sub sterile zones, allows the surgical team to adapt their processes and procedures to optimize asepsis by procedure type and room configuration. Implementation of the environmental quality improvements occurs by consciously avoiding areas with increased risk, re-configuring the OR to optimize aseptic design, maintaining proper EQIs, limiting traffic and door openings, and other procedure specific environmental interventions. In this study, implementation of evidence based, risk mapped, environmental quality improvements, resulted in a decrease of microbiological contamination and contributed to a statistically significant reduction in surgical site infections as compared to a matched set of control ORs. Lastly, the predicted prevention of over 40 SSIs is estimated to have resulted in a cost saving of approximately 1.5 million following the environmental improvement implementation.

CONCLUSIONS

This study demonstrated the efficacy of this environmental risk predicting model in helping to reduce surgical site infections. Environmental quality indicators were measured, and improvements based on these EQI risk predictors, were implemented. Modifications included location of back instrument tables, addition of in-ceiling diffusers, increased accessibility of return air grilles, and reduction of air exchange rates. Additionally, all EQI parameters were monitored and maintained within appropriate ranges. These implemented environmental improvements helped to significantly reduce the SSI rate as compared to the control ORs in which no environmental improvements were made. The environmental improvements also resulted in significantly less airborne microbial contamination, bolstering evidence for a connection between decreased airborne bacteria and

decreased SSI rates. Additionally, improvements intended to control the airborne environment can also decrease both operational cost and the cost associated with treating SSIs. Although clinical improvements alone, did result in a decrease in percent of SSIs in the control ORs, it was not statistically significant. The addition of environmental quality improvements to clinical improvement bundles, resulted in a statistically significant reduction in SSIs. The addition of evidence based environmental improvements, identified with microbial contamination level risk prediction should be considered as part of a bundled approach to SSI reduction.

Limitations

The study was limited to a single academic medical center's 14 improved ORs and 6 control ORs over a period of four years. The SSI study was retrospective and therefore the researchers did not have the ability to design the study from the start, or the ability to choose the ORs that were altered versus those that were not altered. Improvements were made to three groups of ORs, with 'change dates' of January 1, 2016, April 1, 2016, and August 1, 2017. Only two types of surgery were tracked and approximately 25% of the organisms causing the SSI were not identified, rendering it impossible to quantify how many SSIs were due to specific organisms. Clinical improvements including adoption of improved wound ostomy practices and the Enhanced Recovery After Surgery (ERAS) best practice bundles were also implemented in the same time frame as the environmental improvements, however, identical clinical improvements were implemented in all ORs studied, both modified ORs and control ORs. However, SSIs did not significantly decrease in control ORs even with implementation of the same interventions. The staff were aware of, and educated on, the environmental modifications that were implemented. The airborne microbial culture study was limited to one of the improved ORs. Submission of this study for publication was delayed while waiting for permission to publish which was granted.

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