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Major Article

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

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Air quality in operating rooms
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Environmental quality indicator (EQI)

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

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

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

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

BACKGROUND

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

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

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

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

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

The ventilation rates, in ACH, vary in different state regulations and in actual practice. These air change rates are often "based on tradition rather than science."[7] Therefore, there is notable variety in hospitals across the country regarding ACH, use of high-efficiency particulate air (HEPA) filters, ultraviolet or ozone systems, overhead diffuser layouts, and routine heating, ventilation, and air conditioning (HVAC) system maintenance. We found that the different indicators varied significantly during the 3 tests. For example, the air velocity at the sterile field varied from 41.99-116.09 m/s. This is similar to results from a study that showed the indoor air quality of different active ORs varied from month to month. Another similarity in the studies was that the particle count increased in direct relationship to the number of people in the room.[8]

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

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

MATERIALS AND METHODS

Locations

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

Instrumentation setup

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

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

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

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