Operating Room Ventilation Systems

Assessing Ventilation Concepts for Aseptic Performance and Compliance with U.S. Healthcare Codes and Standards

Background

Over 60 years of clinical evidence supports the correlation between airborne contamination and surgical site infection. In 2017, approximately 1.2 million arthroplasties were performed annually in the United States. That number is expected to increase to 3.8 million by the year 2030. The incidence of periprosthetic joint infection is perceived to be low (<2.5%); however, the personal and fiscal consequences are significant. At the same time, the use of implantable biomedical devices continues to grow with virtually all surgical professions engaged in the use of implants which have been shown to significantly increase the risk of interoperative contamination and infection.

In 2017, based on a growing body of evidence demonstrating that conventional ventilation is not as effective in protecting patients from surgical infection as originally thought, the World Health Organization and Centers for Disease Control and Prevention retracted previous recommendations for use of conventional Laminar Air Flow ventilation for infection sensitive procedures such as joint arthroplasty.[1, 2]

While little innovation has occurred in operating room ventilation since the 1960s, alternatives to conventional ventilation are emerging. Providers have two options: 1) continue to install conventional ventilation despite a growing body of evidence and global health authority recommendations against its use for certain procedures or 2) explore alternative ventilation concepts.

Purpose

Medical technology standards are rarely written with an eye toward innovation, but rather address the current state of technology. The purpose of this document is to: 1) outline U.S. requirements for operating room ventilation systems and 2) an approach to evaluation of alternative ventilation concepts for compliance with U.S. codes and standards.

Definitions

Colony Forming Unit (CFU) - is a unit commonly used to estimate the concentration of microorganisms in a test sample. The number of visible colonies (CFU) present on an agar plate can be multiplied by the dilution factor to provide a CFU/ml result.

Multiple Diffuser Array (MDA) – a grouping of supply air diffusers separated by non-air delivery materials,

e.g., monolithic ceiling, ceiling supporting grid, access panels, boom mounts, medical gas or power outlets/hose connections, or lights.

Unidirectional Airflow – air that flows in a straight, unimpeded path. It is defined as the controlled airflow through the entire cross-section of a clean zone with a steady velocity and parallel streamlines.

Turbulent Mixed Airflow – non-unidirectional airflow. Air moves in an unpredictable manner as dictated by pressure and temperature differences. Air molecules are constantly colliding creating contamination of the air as particles are transported around the room before leaving via the return grille.

Overview of Operating Room Ventilation Codes, Standards and Requirements

ANSI/ASHRAE/ASHE Standard 170-2017 Ventilation of Health Care Facilities

The purpose of ANSI/ASHRAE/ASHE Standard 170[3] is to set forth design requirements that provide for environmental control for comfort, asepsis, and odor in healthcare facilities. Standard 170 states that air handling and distribution systems are required to provide healthcare facilities with not only a comfortable environment, but with ventilation to dilute and remove contaminants, provide conditioned air, and assist in controlling airborne infection.

The standard sets forth minimum requirements intended for adoption by code enforcement agencies. It is updated every four years in concert with publication of Facilities Guidelines Institute (FGI) guidance. Section 6 addresses filtration and cleaning requirements. Section 7 addresses ventilation design parameters. Table 1, below, outlines the requirements of sections 6 and 7.

Additionally, sections 4 and 6 of Standard 170 specifically address the potential use of *alternative* air distribution and ventilation as follows:

- Section 4.4 states "*the provisions of this standard are not intended to prevent the use of any material, method of construction, design or building system not specifically prescribed herein, provided that such construction, design or building system has been approved by the agency having jurisdiction as meeting the intent of this standard*."
- Section 6.7.2(b) states that "*surgeons may require alternate air distribution systems for some specialized surgeries. Such systems shall be deemed acceptable if they meet the requirements of the section.*"

Section 7 states that because the standard sets forth minimum requirements that in light of the diversity and differing susceptibilities of the patient population, meeting the standards does not *assure* protection from airborne transmission of contagions.

TABLE 1
ANSI/ASHRAE/ASHE 170 (2017)
Requirements for Operating Room Ventilation

Section and Requirement	Specifications
6.4 Filtration Minimum Filter Efficiencies	Filter Bank No. 1 – MERV 7 Filter Bank No. 2 – MERV 14
6.7.2 Supply Air Outlets Cleaning	(a) Surfaces of air distribution systems shall be suitable for cleaning. (b) The supply diffusers in ORs shall be designed and installed for internal cleaning.
7.1 and 7.4.1 General Design Parameters for Operating Rooms	

Pressure Relationships to adjacent rooms Minimum outdoor ACH Minimum total ACH Relative humidity Temperature	ORs shall be maintained at positive pressure with respect to adjoining rooms at all times. 4 ACH 20 ACH 20-60 68-75F; Each room shall have individual temperature control
7.4.1 Airflow and Coverage	(a) The airflow shall be unidirectional downwards and the average velocity of the diffusers shall be 25-35cfm/ft^2 The airflow shall be concentrated to provide an airflow pattern over the patient and surgical team. (b) The coverage area of the primary supply diffuser shall extend a minimum of 12 inches beyond the footprint of the surgical table on each side. Additional supply diffusers shall be permitted inside the room, outside of the primary array, to supply additional ventilation to the OR to achieve environmental requirements for temperature, humidity, and air exchange rates.

Facilities Guidelines Institute: Guidelines for Design and Construction of Hospitals 2018

FGI sets forth requirements for design and construction of hospitals.[4] Where operating room ventilation is concerned, FGI defers to ANSI/ASHRAE/ASHE 170. FGI does not impose additional requirements beyond ASHRAE 170.

The Joint Commission (TJC) Environment of Care Standard EC.02.01.01/EC.02.05.01

TJC also defers to ASHRAE 170 for operating room ventilation standards. TJC Standard EC.02.05.01[5] addresses broadly the safety and security of people, equipment, and other material. TJC recognizes that airborne contamination is a significant source of health care-associated infection (HAI).

Operating room ventilation is addressed in EC.02.05.01 (Utility Systems), Item 15: The section states, *"In critical areas designed to control airborne contamination, the ventilation system provides appropriate pressure relationships, air-exchange rates, filtration efficiencies, temperature and humidity.*" For new and existing facilities or altered, renovated, or modernized portions of existing systems, heating, cooling, and ventilation must be in accordance with ASHRAE 170 or state requirements if more stringent. Non-compliance occurs when the ventilation system is unable to provide appropriate pressure relationships, air-exchange rates, and filtration efficiencies.

TJC additionally requires healthcare institutions to identify safety and security risks associated with the environment of care. Risks are identified from internal sources such as ongoing monitoring of the environment, results of root cause analyses, results of annual proactive risk assessments of high-risk processes and from credible external sources such as Sentinel Event Alerts. This leaves determination of the appropriate operating room ventilation system up to the organization based upon risk and compliance with ASHRAE 170.

Discussion

Current State of Operating Room Ventilation

Findings from the literature point to three consistent principles that are recommended for operating room ventilation systems across the facility:

1. Unidirectional airflow should be maintained within the surgical field, back instrument table location(s) and periphery of the room where case carts, imaging equipment or back tables where instruments and implants are prepared for the case are located.[6]
2. Supply and return ventilation quantities should produce consistent patterns (unidirectional airflow moves from clean to less clean zones) in each operating room consistently.[7]
3. Microbial contamination levels should not exceed 10 CFU/m^3 at rest or in procedures within critical aseptic zones which include the surgical field, back instrument table location(s) and periphery of the room. [8]

A multicenter trial examining the impact of HVAC design on surgical site infection rates is cost prohibitive and unlikely to ever be conducted. Comparing systems can be challenging as operating and procedure rooms lack a consistent approach to supply air delivery. Conventional ventilation typically consists of a general rectangular configuration in the room centered over the patient table. In contrast to emerging ventilation concepts, there is no air delivery in the room periphery.

Recent observations of a recently constructed operating room air delivery performance indicate disparities in consistent temperature, relative humidity, and unidirectional airflow. This situation creates a potential safety concern for both staff and patients. Figure 1 demonstrates observed lack of unidirectional flow over the surgical table including reverse unidirectional in the periphery of the room. Figure 2 demonstrates desired unidirectional airflow pattern over the surgical table and no unidirectional reversing in the room periphery. Table 2 lists typical code compliance disparities. Studies using the air sampling and culturing method prescribed by US Pharmacopeia (USP) 797 demonstrate that these compliance disparities result in elevated bacterial contamination levels.[9-17]

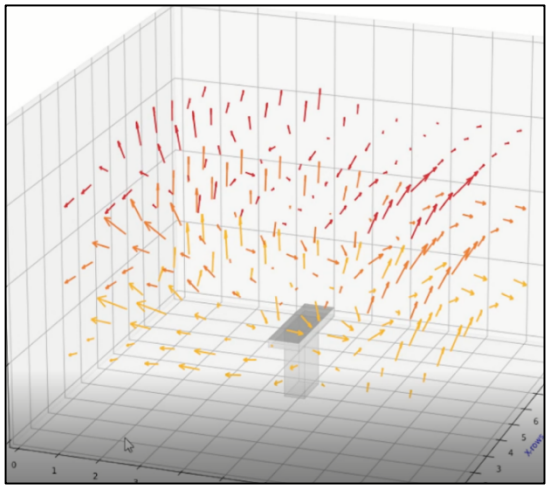

Fig. 1: ASHRAE 170-2017 Compliant Operating Room 3D Airflow Map via ISO 14644-1 Bi-Directional Ultrasonic Anemometer. **Unidirectional airflow is not present** in the sterile field.

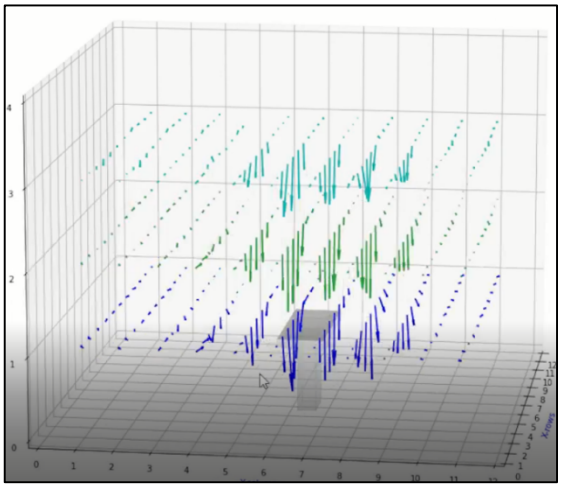

Fig. 2: 3D Unidirectional Airflow Mapping of Operating Room via ISO 14644-1 Bi-Directional Ultrasonic Anemometer. **Unidirectional airflow is present** in the sterile field.

TABLE 2
Current State: Operating Room Supply Air Systems Code Compliance Disparities*

Location	Conditions Measured or Assay Results
Over the surgical or procedure table	• Non-unidirectional airflow pattern • Transversal of diffuser array at 90 deg. F table turn • Up to 30% blockage of air • Room temps below 68 def. F • Relative humidity > 60% • Viable Bacteria CFU/m3 > 10 (in activity) • Viable Bacteria CFU/m3 > 10 (at rest)
Room periphery	• No diffusers, only passive airflow from center array • Reverse unidirectional airflow patterns • Room temps below 68 deg. F • Relative humidity > 60% • Viable Bacteria CFU/m3 > 20 (in activity) • Viable Bacteria CFU/m3 > 20 (at rest)

*OnSite-LLC regularly conducts operating room dynamic or in-procedure contamination risk assessments in which these are common findings.

Supplemental Assessment

Airborne Microbial Measurement for Room Aseptic Performance

Organizations are encouraged to research what is appropriate for the safety of the institution's surgical patient population. For example, patients undergoing joint replacement, neuro or cardiovascular procedures are greater risk of surgical site infection. The number of personnel in the room, duration of the procedure and use of biomedical implants all increase risk of infection from airborne microbial contamination.

While engineering controls provide insights into the functioning of the system, only an airborne microbial risk assessment can determine the efficacy of the HVAC system in protecting surgical patients, instruments, and implants from airborne contamination. Organizations may want to consider requiring operating room ventilation system vendors to provide microbial risk assessment data as a condition of consideration for OR construction or renovation projects and post-installation microbial measurement prior to acceptance.

As noted above, U.S. standards for operating room ventilation are based on engineering controls. The standards do not set forth bacterial or asepsis performance requirements. In contrast, movement is taking place in the European Union to set performance-based standards. While an EU-wide standard is in development, the following countries have established performance-based standards:

- French standard NFS 90-351 *Clean rooms and related controlled environments in medical establishments*, sets thresholds of 10 CFU/m^3 at rest. [18]
- British standard HTM 03-01:2007 sets thresholds of 10 CFU/m^3 turbulent (periphery of the room) at rest and 10 CFU/m^3 unidirectional (over surgical table) in activity.[19]
- Swedish Standards Institute Teknisk Specification SIS-TS 39 and Dutch Standard RL8 ≤10 CFU/m^3 for procedures utilizing implants. A mean value of ≤5 CFU/m^3 should be targeted to ensure that a level of ≤10 CFU/m^3 is maintained.[20]

The U.S. Pharmacopeia (USP) standard 797 sets forth standard air sampling and culturing methods. A standard operating room microbial risk assessment would include measurement of microbial load (CFU/m^3) during live and/or mock procedures.[21] Typical assessments include measurements taken at three locations: 1) the surgical field, 2) instrument table location(s) and 3) in the periphery where case carts and back tables are prepared with instruments and implants before the case begins. Studies undertaken in unoccupied rooms "at rest" do not present a reliable assessment of microbial exposure or potential risk to staff and personnel.

Key Publications Linking Environmental Performance to SSIs

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