Air Contamination and SSI Risk in Implant Procedures

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Disclosures

Speaker provides clinical consulting services to Aerobiotix.
Learning Objectives

1. Explain why there is an increased risk of SSI from air contamination with implants.

2. List surgical procedure types that involve implants, and potential associated SSI.

3. Discuss methods of measuring air quality in ORs and compounding pharmacies.

4. List standard measures for ensuring safe OR air quality.

5. Describe adjunctive measures for improving OR air quality for implant procedures.
Adherence of bacteria to the surface of implants is promoted by a biofilm called:

A. Renal calyx
B. Glycocalyx
C. Miralax
Potential for Surgical Wound Contamination From OR Air

Courtesy Maureen Spencer, Clinical Consultant
Increased Risk of SSI in Implant Procedures From Contaminated Air

- Procedures involving an implant pose the greatest risk of infection from the smallest inoculum.¹
- A foreign body such as an implant can reduce the number of organisms needed to cause an infection by a factor of 100,000.²
- Organisms, typically skin flora, are dispersed in the operating room on squamous epithelial cells that can settle in the open incision and adhere to the implant.³
Air contamination and SSI: A proven relationship

Nearly a century of peer-reviewed literature supports the relationship between airborne pathogen levels and SSI. 4-6

**Key SSI Risk Factors**

- Number of people in the room
- Number of door openings
- Facility risk factors
- Length of procedure time
- Instrument tray exposure
- Procedural type

**Figure.** Schematic of airborne pathogen environmental cycle.
Elevated OR air bacterial level causes increased infection rates

A prospective randomized multicenter study shows that joint replacements in rooms with over 50 CFU bacteria were 2.6 times as likely to have postoperative infection than those with 10-20 CFU.7

As airborne bacterial levels increase, infection rates increase. The relationship is linear.

SSI RATE INCREASES LINEARLY WITH AIRBORNE BACTERIAL LEVELS

Adapted from OM Ludwell et al. 1992
Surgical Disciplines Placing Implants

- Breast
- Plastics
- Orthopedic
- Spine
- General – hernia mesh
- OB-GYN – pelvic floor mesh
- Cardiac – pacemakers, stents, valves, IADs . .
Just how small of an inoculum is required to cause an implant infection:

A. 100 CFU  
B. 150 CFU  
C. 50 CFU
PJI (prosthetic joint infection)

- 2.18% of hip and knee implants become infected.\(^8\)
- A cost range for a single case of PJI using a one-way sensitivity analysis of $389,307 to $474,004.\(^9\)
- PJI is associated with a mortality rate of between 2 – 7%.\(^10\)
- Experts report that the five-year survival rate of patients with PJI is worse than with most cancers.\(^11\)

Figure: Historical and projected number of infected THA, TKA, and total (THA + TKA) procedures in the United States.\(^8\)
Hernia mesh (implant) infections

- Implanted mesh infection following incisional hernia repair has been reported at around 6-10%.
- Preoperative administration of single-dose cefazolin for prosthetic hernia repairs does not markedly decrease the risk of wound infection.
- The outcome of patients treated for chronic mesh infection is unsatisfactory with high risk of recurrent herniation and development of further chronic abdominal wall sepsis.\textsuperscript{12}
Cardiac implant infections

- Cardiac implants: pacemakers, implantable cardioverter defibrillators, or ICDs, and implanted heart rhythm monitors called loop recorders.
- Despite improvements in cardiovascular implantable electronic device (CIED) design, application of timely infection control practices, and administration of antibiotic prophylaxis at the time of device placement, CIED infections continue to occur and can be life-threatening.
- Pocket infection, bloodstream infection, endocarditis.¹³
Spine implant infections

- SSI after lower back fusion increases the total cost of care more than four times.
- The more invasive techniques, such as fusion with instrumentation, have the higher the rate of SSI.\textsuperscript{14}
- Adherence of bacteria to the surface of implants is promoted by a polysaccharide biofilm called glycocalyx that acts as barrier against host defense mechanisms and antibiotics.\textsuperscript{15}
Plastic surgery infections

- Clean cases that are complicated with an implant such as breast augmentation, have an increased risk of SSI.\textsuperscript{16}
- The SSI rate following breast cancer reconstructive surgery is relatively high (range, 6.3\%-28\%), based on a few reports in the literature.\textsuperscript{17}
- There is an increased surgical site infection rate in breast surgery without implants, compared to other clean cases.\textsuperscript{59}
SSI from respiratory aerosols

• A physician colonized intra-nasally with *S. aureus* exhibited a 40-fold increased airborne dispersal after acquiring an upper respiratory rhinovirus infection, becoming thus a ‘cloud adult’.\(^{18}\)

• Outbreaks of SSI caused by other organisms such as MRSA and *Staph aureus* have been associated with viral upper respiratory tract infection in a phenomenon of airborne dispersal of *Staphylococcus aureus* called the "cloud" phenomenon.\(^{19}\)
What is the reason for this increased shedding of *Staph aureus* during a cold?

A. Increased nose touching transfers *S aureus*

B. Swelling of nasal turbinates increases aerosols

C. Rhino virus transforms during flu season to *S aureus*
SSI from Bacteria Laden Skin Scales

- Eight infections occurred after modified radical mastectomies in a tertiary-care hospital. Group A streptococci (GAS) was isolated from the patients.

- This outbreak of GAS infection is believed to have occurred by airborne transmission, from scales of skin from colonized surgeon, shed and aerosolized, inoculating the operative field and leading to the infections.\(^{33}\)
Impact of SSI in General

• SSIs are the most common type of hospital-acquired infection, accounting for 20% of all HAI.\textsuperscript{20}
• Patients with SSI have 2- to 11-fold increased risk of mortality.\textsuperscript{21}
• SSIs are the most costly of all HAI. With an annual estimated overall cost of $3 to $5 billion in the U.S.\textsuperscript{22}
• As many as 60% of SSIs are considered to be preventable.\textsuperscript{23}
• 45 million inpatient surgical procedures performed annually in US.\textsuperscript{24}
• Medicare no longer reimburses most SSIs.\textsuperscript{25}
OR Air Quality:
How clean is clean enough?

Air Scrubber Filter

Exhaust Vent
Surface culture

Air Scrubber Filter
After 1 Month in OR

O.R. Ventilation Fan
OR Air Quality: How clean is clean enough?

- Bacterial levels as high as 150 colony forming units (CFU)/m³ have been documented in ORs. Despite the risk of infection, there is no requirement for bacterial testing or particulate counts in US ORs.⁶

- Air exchanges and positive air pressure are easily defeated by door openings and room traffic. Contamination arises largely from room personnel.

- Whyte and team showed that the incidence of joint SSI progressively declines as air contamination is reduced.⁷

Figure 1. Representation of Typical EU/WHO air quality guidelines. Source: Charkowska (2008).
OR Air Quality:
How clean is clean enough?

Is typical O.R. air quality adequate for today’s O.R. environment?

• More procedures per day and faster turnovers increase biological load in the O.R.
• More personnel, activity and technology in the O.R.
• Increased use of implants, particularly in orthopedics which have a higher risk for SSI
• Older and more acute patient populations
• Antibiotic resistant organisms
• More revision procedures
Compounding Pharmacies

- Unlike operating rooms, the pharmaceutical and computer industries enforce stringent air quality standard on their manufacturing processes.
- Currently no air quality standard (bacteria and particle limits) nor standard methodology for testing OR air quality, as there are in compounding pharmacies.
- Compounding pharmacies prepare sterile solutions to be introduced into the sterile vascular system. In OR, the majority of procedures involve entering a sterile organ space through an incision, which remains open to the OR air.
Compounding pharmacies must comply with International Standards Organization (ISO) class 5 standards for air quality.26
Required testing methods and schedule per USP 797 for compounding pharmacies

<table>
<thead>
<tr>
<th>Test Parameter</th>
<th>Class</th>
<th>Maximum Time Interval</th>
<th>Test Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Particle Count Test</td>
<td>&lt;= ISO 5</td>
<td>6 Months</td>
<td>ISO 14644-1 Annex A</td>
</tr>
<tr>
<td></td>
<td>&gt; ISO 5</td>
<td>12 Months</td>
<td></td>
</tr>
<tr>
<td>Air Pressure Difference</td>
<td>All Classes</td>
<td>12 Months</td>
<td>ISO 14644-1 Annex B5</td>
</tr>
<tr>
<td>Airflow</td>
<td>All Classes</td>
<td>12 Months</td>
<td>ISO 14644-1 Annex B4</td>
</tr>
</tbody>
</table>

Compounding pharmacies must comply with International Standards Organization (ISO) class 5 standards for air quality.\textsuperscript{26}
Minimizing OR Air Contamination
Standard Measures

1. Engineering air controls – dilution, filtration, pressurization and disinfection (AORN, CDC, ANSI/ASHE, ASHRAE standard 170-2008)\(^{27}\)
   - Filtration: MERV (minimum efficiency rating value) 13-14 required for OR, HEPA = 17
   - Pressurization: air pressure (positive)
   - Dilution: air changes (20/hour)

2. Temperature and Humidity

3. Traffic control in OR – AORN, CDC\(^{28,29}\)

4. Hair clipping outside OR - AORN
# Minimizing OR Air Contamination

**ASHRAE 170-2008**

## TABLE 6-1  Minimum Filter Efficiencies

<table>
<thead>
<tr>
<th>Space Designation (According to Function)</th>
<th>Filter Bank Number 1 (MERV)(^a)</th>
<th>Filter Bank Number 2 (MERV)(^a)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class B and C surgery; inpatient and ambulatory diagnostic and therapeutic radiology; inpatient delivery and recovery spaces</td>
<td>7</td>
<td>14</td>
</tr>
<tr>
<td>Inpatient care, treatment, and diagnosis, and those spaces providing direct service or clean supplies and clean processing (except as noted below); AII (rooms)</td>
<td>7</td>
<td>14</td>
</tr>
<tr>
<td><strong>Protective environment (PE) rooms</strong></td>
<td>7</td>
<td>HEPA(^c,d)</td>
</tr>
<tr>
<td>Laboratories; Class A surgery and associated semi-restricted spaces</td>
<td>13(^b)</td>
<td>N/R*</td>
</tr>
<tr>
<td>Administrative; bulk storage; soiled holding spaces; food preparation spaces; and laundries</td>
<td>7</td>
<td>N/R*</td>
</tr>
<tr>
<td>All other outpatient spaces</td>
<td>7</td>
<td>N/R*</td>
</tr>
<tr>
<td>Skilled nursing facilities</td>
<td>7</td>
<td>N/R*</td>
</tr>
<tr>
<td>Psychiatric hospitals</td>
<td>2</td>
<td>N/R*</td>
</tr>
</tbody>
</table>

\(^a\)N/R = no requirement


Note b: Additional prefilters may be used to reduce maintenance for filters with efficiencies higher than MERV 7.

Note c: As an alternative, MERV-14 rated filters may be used in Filter Bank No. 2 if a tertiary terminal HEPA filter is provided for these spaces.

Note d: High-Efficiency Particulate Air (HEPA) filters are those filters that remove at least 99.97% of 0.3 micron-sized particles at the rated flow in accordance with the testing methods of IEST RP-CC001.3 (see Informative Annex B, Bibliography).
Minimizing OR Air Contamination
Temperature and Humidity

Humidity: 20% to 60%
- Aids in controlling microbial growth,
- Supports the shelf life and product integrity of sterile supplies,
- Controlling relative humidity (RH) can reduce transmission of certain airborne infectious organisms, including some strains of influenza

Temperature: 68 to 75°F
- Location of lights can increase room temperature and also be an obstacle to the desired airflow pattern,
- Patient hypothermia can contribute to increased risk of SSI.
Some bacteria are psychrophilic (prefer cold), some are thermophilic (prefer hot temperatures), and many are mesophilic (prefer normal temperature ranges). What category do most pathogenic bacteria fall into?

A. Thermophilic (hot)
B. Psychrophilic (cold)
C. Mesophilic (moderate normal)
Minimizing OR Air Contamination
Airflow Systems for ORs

1. **Turbulent flow:** Airborne contaminants are controlled with dilution. This increases the effectiveness of air exchange and distribution, but can speed up microbial dispersion.

2. **Unidirectional-flow ("laminar airflow or LAF"):** Air travels in parallel lines and contaminants are carried away at the same velocity as the airflow towards the exhaust outlets. This system is designed to ensure airborne particles pass the operating area.

3. **Laminar air-flow systems with HEPA filters (Ultra Clean air):** is often used for orthopaedic and other implant surgery.

4. **Mixed-flow:** Unidirectional airflow regimes are only used to protect critical zones (e.g. the area surrounding the operating field).

There is **no consensus** on the best airflow system for ORs.
Common Operating Room Airflow Pattern

Laminar Supply Diffusers above surgical area
HEPA filtration
Supply air washes down over patient and away to corners of OR
Common Operating Room Airflow Pattern

Typically 2 or 3 low returns in the corners of OR on opposite sides
Current systems, including laminar flow and positive pressure systems, do not deactivate pathogens, just displace pathogens. These pathogens are continuously being shed within the OR setting and contribute to the airborne pathogen concentration.
Minimizing Air Contamination
AORN Standards Surgical Attire

Full coverage of hair and skin is required for all members of the surgical team due to:

• On average, individuals shed more than 10 million particles from their skin every day.
• Approximately 10% of skin squames carry viable microorganisms.
• It is estimated that individuals shed approximately 1 million microorganisms from their bodies each day.\textsuperscript{31}
Minimizing Air Contamination
AORN Standards Surgical Attire

(a) Scanning electron micrograph of skin scales nearly ready to be detached from the skin surface. (b) Scanning electron micrograph of skin scales sampled from the air.$^{32}$
Minimizing Air Contamination
AORN Standards Surgical Attire

Masks do not filter all particulates from the air inhaled and exhaled by the wearer. They do not form a complete seal against the face.\textsuperscript{32}
Minimizing Air Contamination
AORN Standards Surgical Attire

A mask wet with exhaled moisture has increased resistance to airflow, is less efficient at filtering bacteria and has increased venting.\textsuperscript{34}

Current guidelines recommend that a new surgical mask is used for each surgical case and should be changed when wet.\textsuperscript{35}
Smoke Plume and OR Air Quality

- In the operating room (OR), smoke plume is generated by laser and electro-surgery.

- Smoke plume has been demonstrated to pose health risks to both surgical personal and patients including:
  - upper respiratory irritation
  - human papilloma virus (HPV) infection
  - surgical infection
  - metastatic melanoma.\textsuperscript{36,37}
Minimizing Air Contamination From Smoke Plume

- One research team estimates that exposure to the mutagenic potency of surgical smoke generated by cautery/burning of 1 gram of tissue was comparable to smoking 3 cigarettes for lasers and 6 cigarettes for electrocautery.\textsuperscript{38} Another study validated that electrocautery smoke presents greater danger than laser plume, and even cigarette smoke.\textsuperscript{39}

- AORN AND NIOSH support the use of smoke evacuators to eliminate smoke plume and the associated risks for surgical teams, however, compliance is not universal.\textsuperscript{40, 41}

- The smoke evacuation device must be placed near the site of smoke generation (within two inches) in order to provide protection for patients and OR personnel.\textsuperscript{42}
Minimizing Air Contamination From Smoke Plume

There are two categories of technology designed to remove smoke plume from OR environments.

- Smoke evacuator systems that vacuum the smoke at the surgical site through an air filter.

- New-to-market category systems that combine high efficiency particulate air (HEPA) and UV-C disinfection of all air throughout the operating room, for the duration of a case. This type of system has recently been shown to be effective at removing both airborne bacteria and surgical plume.43
The Original “Smoke Plume” in 1919

A FLU MASK MODIFIED FOR A SMOKE
Popular Science, May 1919
OR Air Quality and Human Factors

What do you mean "left leg"?
Human Factors Affecting OR Air Quality

- Coughing, talking
- Skin shedding
- People moving in and out of room causing convective flows spreading bacteria
- Heater Cooler exhaust
Human Factors Affecting OR Air Quality

• Not using smoke evacuators with laser and electrocautery
• Hair clipping
• Disconnecting forced air warmer before turning blower off
In one year, the average person will shed more than how many pounds of dead skin:

A. 0.5 pounds
B. 3 pounds
C. 8 pounds
Human Factors Affecting OR Air Quality

In a teaching hospital at the end of a case:

1. The Surgeon leaves the room and the Resident, PA or NP closes the incision.
2. At the same time the following activities are creating air turbulence which could result in contaminants settling on operative site:
   • Circulating nurse counts sponges
   • Scrub tech prepares instruments for CSP
   • Anesthesia moves in and out of the room
   • Instrument vendor rep moves out of the room
   • Students and visitors move out of the room

Courtesy Maureen Spencer, Clinical Consultant
OR Air Quality and Product Design

"Okay, the motorized rocking chair could use an emergency off switch."
Prolonged Outbreak of *Mycobacterium chimaera* Infection After Open-Chest Heart Surgery

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**Background.** Invasive *Mycobacterium chimaera* infections were diagnosed in 2012 in 2 heart surgery patients on extracorporeal circulation. We launched an outbreak investigation to identify the source and extent of the potential outbreak and to implement preventive measures.

**Methods.** We collected water samples from operating theaters, intensive care units, and wards, including air samples from operating theaters. *Mycobacterium chimaera* strains were characterized by randomly amplified polymorphic DNA polymerase chain reaction (RAPD-PCR). Case detection was performed based on archived histopathology samples and *M. chimaera* isolates since 2006, and the patient population at risk was prospectively surveyed.

**Results.** We identified 6 male patients aged between 49 and 64 years with prosthetic valve endocarditis or vascular graft infection due to *M. chimaera*, which became clinically manifest with a latency of between 1.5 and 3.6 years after surgery. *Mycobacterium chimaera* was isolated from cardiac tissue specimens, blood cultures, or other biopsy specimens. We were able also to culture *M. chimaera* from water circuits of heater-cooler units connected to the cardiopulmonary bypass, and air samples collected when the units were in use. RAPD-PCR demonstrated identical patterns among *M. chimaera* strains from heater-cooler unit water circuits and air samples, and strains in 2 patient clusters.

**Conclusions.** The epidemiological and microbiological features of this prolonged outbreak provided evidence for the airborne transmission of *M. chimaera* from contaminated heater-cooler unit water tanks to patients during open-heart surgery.

**Keywords.** outbreak; *Mycobacterium chimaera*; nontuberculous mycobacteria; open-chest heart surgery; infection control.
Product Design Affecting OR Air Quality
*Mycobacterium chimaera* Outbreak

- Heater-cooler devices are used during cardiothoracic surgery to warm or cool patients. They include tanks that provide temperature-controlled water to external heat exchangers or to warming/cooling blankets through closed water circuits.
- The source for the airborne transmission of *M. chimaera* in these outbreaks has been determined to be contaminated water tanks in the heater cooler units during open-heart surgery.
- Investigators determined that Stockert 3T heater-cooler units were contaminated during manufacturing.45
Product Design Affecting OR Air Quality

*Mycobacterium chimaera* Outbreak

- *M. chimaera* was found in air samples from the operating room when the HCUs were running.
- Spray from the heater cooler fan contaminated the operating field and implants.
- Water droplets containing NTM bacteria may remain suspended in the air, which increases the chance of contaminating the patient’s open surgical cavity and sterile implant such as a heart valve.
Product Design Affecting OR Air Quality

*Mycobacterium chimaera* Outbreak

- Since 2013, over 100 cases of *Mycobacterium chimaera* prosthetic valve endocarditis and disseminated disease were notified in Europe and the USA, linked to contaminated heater-cooler units (HCUs) used during cardiac surgery.
- The majority of cases have occurred after valvular surgery or aortic graft surgery and nearly half have resulted in death.
- Two cases have been reportedly associated with left ventricular assist devices (LVADs).\(^{46,47}\)
Product Design Affecting OR Air Quality

*Mycobacterium chimaera* Outbreak

FDA Guidance includes: **DO NOT** use tap water to rinse, fill, refill

- Direct and/or channel the heater-cooler’s exhaust vent(s) away
- Establish regular cleaning, disinfection and maintenance schedules
- Consider performing environmental, air, and water sampling when contamination suspected.\(^{48}\)
Consequently . . . . Are adjunctive measures indicated to improve the quality of OR air?
Supporting Adjunctive Technology

- “As a supplemental air-cleaning measure, ultraviolet germicidal irradiation (UVGI) is effective in reducing the transmission of airborne bacterial and viral infections in hospitals.”
  - CDC Guidelines for Environmental Infection Control in Health-Care Facilities

- “Recirculating HEPA filter units used for infection control without heating or cooling coils are acceptable (for use in operating rooms).”
  - ASHRAE/AIA Guidelines for Patient Care Construction.
Adjunctive Measures to Reduce Air Contamination in ORs

Technological innovations for reducing air contamination in the operating room most commonly fall in the categories of filtration and disinfection:

1. Filtration
   - Surgical helmet systems
   - Laminar Flow
   - Ultraclean ventilation
   - Ultraclean air applied to surgical site

2. Disinfection with UV-C

3. Filtration PLUS Disinfection: Novel air scrubbing technology (UV-C disinfection plus HEPA)
Surgical Helmet Systems (Filtration)

• The current positive-pressure surgical helmet systems (SHS) have been found to be ineffective in some studies and associated with increased risk of SSI in others.49-51

• This is felt to be due to positive pressure inside the suit which could carry air and particles via the unsealed area around the surgeon's cuff into the operative field.

• Alternatively the older negative-pressure Charnley-type body exhaust suits (BES) were reported to be effective in reducing contamination of the surgical field.52
Laminar Flow Systems (Filtration)

Laminar flow was originally recommended in order to maintain a flow of clean air during surgical cases. However, been found to be ineffective and in some cases can increase risk of SSI, because it can potentially force dirty air into the wound, instruments, implants and personnel.\textsuperscript{49-51}
Ultra clean air (Filtration)

- Ultra clean air = combining laminar airflow (LAF) and high-efficiency particulate air filters (HEPA).
- When used (not required) HEPA is effective in filtering particulates from OR air.
- Though LAF as mentioned has been shown in multiple studies to increase SSI risk.\textsuperscript{53}
- Currently there is no consensus in the scientific community with regard to the need to use unidirectional airflow in prosthetic ortho surgery, since no prospective studies comparing air quality with SSI rates are available.\textsuperscript{54}
Drying your hands with paper towels decreases bacterial counts on hands by 45-60%, while using a hand dryer instead can increase the bacteria on your hands by how much:

A. 10%
B. 100%
C. 255%
Novel HEPA Air Delivery System for Surgery Site (Filtration)

Delivering HEPA-filtered clean air immediately adjacent to the surgery site, creating an airflow layer directly over the surgical wound to repel bacteria.
Ultraviolet (UV-C) Germicidal Irradiation

Ultraviolet germicidal products are common and have been used in hospitals for decades. The effectiveness of UV-C in eliminating microorganisms in air, water, on surfaces and instruments/devices is well established.\textsuperscript{6}
Ultraviolet Germicidal Irradiation

The most efficient way to inactivate airborne pathogens is to apply C-wavelength ultraviolet (UV-C) radiation, which disrupts the DNA of microorganisms. The germicidal ability of UVC is well known and documented.\textsuperscript{56}
Novel UV-C Air Disinfection System
(UV Disinfection with Air circulating Fans and a Ceiling Light)
Novel Air Scrubbing Technology
(UV-C Disinfection plus HEPA Filtration)

- Shown in peer-reviewed studies to reduce air bacteria levels in operating rooms by 50-60%. 43,55,58
- Uses a proprietary ultraviolet technology combined with HEPA filtration to eliminate particulates and microorganisms.
Conclusions

1. Current methods of providing OR air quality are limited to positive air pressure, 20 air changes per hour, long sleeves, traffic control and HEPA filtration in some ORs.

2. Infection risk from contaminated OR air has been demonstrated most recently during the *M. chimera* outbreak associated with heater cooler devices.
Conclusions

3. Surgical helmet systems, laminar flow, ultraclean ventilation have shown limited value and in some cases have reported to increase SSI risk.

4. Air scrubbing technology (UV + HEPA) can serve as an adjunct for improving air quality for ORs where implant procedures are performed.
THANK YOU!!

AFTER THAT FIRST PERSON IN THE OFFICE SNEEZES

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References

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