



Developing the Case for Implementation of Operating Room Air Decontamination Technology for Orthopedic Surgery

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Over the last decade, considerable effort and investment has been made in decontamination of the patient environment however, almost all of this focus has been on hard surfaces. Despite evidence of the contribution of contaminated air to healthcare-associated infections (HAIs) and the symbiotic relationship between contaminated air and bioburden on surfaces, hospital air quality has not been a high priority from a risk mitigation perspective.¹ This is likely due to a combination of factors including: the technical difficulty of measuring the airborne bioburden; the absence of technological innovation in the air decontamination space; and the ongoing debate about the relative contribution of contaminated air to HAI. With a growing body of evidence correlating aerosolized bacteria and HAI (and surgical site infections (SSIs) in particular), along with the advent of air decontamination technologies that make reduction in airborne bioburden both technically and economically feasible, institutions should have increasing reason to revisit air quality management beginning with the operating room (OR).

Nowhere is the risk to patients of airborne bioburden greater than in the operating room. The recent outbreaks of *Mycobacterium chimaera* from contaminated heater cooler devices occurred despite proper OR ventilation. The transmission of invasive infection to these patients highlights both the potential for airborne contaminants to cause SSIs and the limitations of current approaches to mitigating airborne transmission.² This paper focuses on how the evidence-based legal standard of care can be used to help support adoption of new technologies proven

to reduce airborne pathogens in the quest to reduce SSIs and why airborne bioburden in the OR merits greater attention. We have chosen to focus on SSIs in orthopedic surgery where procedural volume is high and rapidly growing and where the clinical and economic consequences of infection are significant.

The Contribution of Contaminated Air to SSI

As early as 1971, Brachman estimated that airborne transmission was responsible for 10 percent to 20 percent of all endemic hospital-acquired infections.³ Where SSI in particular is concerned, evidence of the relationship between airborne pathogen levels in the OR and surgical site infection (SSI) continues to emerge:

- Kundsinn concluded that airborne transmission accounted for 20 percent to 24 percent of post-operative wound infections.⁴
- Researchers at the University of Glasgow analyzed the relationship between the number of bacteria washed from the wound at the end of an operation to both the number of bacteria in the OR air and those on the patient's skin at the wound site. They concluded that the most important and consistent route of surgical wound contamination was airborne.⁵
- Infection rates in joint replacement surgery have been correlated with airborne concentrations of bacteria near the wound.⁶
- Dharan and Pittet found that the risk of contaminated air to SSI increases as airborne microbial counts exceed 36 to 150 colony-forming units (CFUs) per m3 of sampled air.⁷

The discovery of *Mycobacterium chimaera* infections among cardiac surgery patients in 2015-16 were found to be epidemiologically linked to aerosolized bacteria from heater-cooler units contaminated during the manufacturing process.⁸ More than 250,000 heart bypass procedures using heater-cooler machines are performed in the U.S. each year. It was estimated that approximately 60 percent of these patients were exposed to contaminated devices. These infections occurred despite adherence to current OR air ventilation standards. Moreover, air sampling studies may actually underestimate the risk of airborne bacteria, as many airborne organisms are difficult to culture and therefore may go undetected.⁹ The *Mycobacterium* species falls into this category.

Contaminated Air and Prosthetic Joint Infection

Our focus on SSIs (prosthetic joint infections [PJI] in particular) is based upon evidence that surgeries involving implants have significantly higher rates of HAIs along with predictions of explosive growth in hip and knee replacement surgeries as the US population ages. PJIs are also among the most economically and clinically consequential HAIs. The volume of procedures with prosthetic joint implants is expected to exceed 3.8 million annually by 2030 as a result of the aging population.¹⁰ Studies by Parisi, et al. concluded that the cost of a single PJI could reach nearly \$500,000 when personal liabilities and consequential damages, such as lost wages and productivity, are included with basic healthcare costs.¹¹ As of FY 2018, total hip/knee arthroplasty SSIs are subject to additional penalties under the CMS Readmission Reduction Program. The mortality rate for PJI is also high at 2 percent to 7 percent with a five-year survival rate worse than with many cancers.¹²⁻¹³ While the incidence rate for PJI is low (<2.5 percent),¹⁴ given the projected rate of growth in procedural volume alone, the aggregate number of PJIs could reach close to 1 million infections by 2030.

There is considerable evidence of a close correlation between infections in joint replacement surgery and airborne bacteria. A prospective randomized multicenter study showed that joint replacement procedures performed in rooms with over 50 CFU/m3 airborne bacterial forming units were 2.6 times more likely to have postoperative SSIs than those done in cleaner air with 20 CFU/m.¹⁵ PJI has also been correlated with concentrations of bacteria near the wound.¹⁶ Airborne particles including dust, textile fibers, skin scales, and respiratory aerosols loaded with viable microorganisms (including

Staphylococcus aureus) are released from surgical team members and patients into the surrounding OR air and settle onto surgical instruments and into operative incisions.¹⁷⁻²³ Most of the organisms that cause SSIs are shed from skin or are attached to particulate matter of less than 5 microns in size. These particles become transiently airborne and float on air currents before implanting in the wound.²⁴⁻²⁵

The Changing Legal Environment

This is an exciting time in healthcare with innovations in medical technology that have the potential to greatly improve patient outcomes and reduce the cost of care. However, advancing change in healthcare, be it product, practice or people, can be challenging. Clinicians can be reticent to be agents of change due to political and organizational challenges, lack of resources, fear of failure and/or malpractice. While clinicians may think there is security in adhering to clinical practice guidelines, problems may arise when those guidelines conflict with evolving standards of care. Absence of a requirement in clinical guidelines or standards may not be an adequate legal defense for failure to prevent an SSI if the larger body of evidence suggests otherwise.

Clinical practice guidelines (CPGs) and evidence-based medicine (EBM) are not the same in the eyes of the court. CPGs can be defined as systematically developed statements to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances.²⁶ CPGs are a combination of contemporary belief and customary practice. All too often it is believed that a failure to adhere to CPGs is equivalent to a failure to meet the standard of care when in fact, following guidelines that are outdated (as they frequently are even on the date of publication) or "guidance" written for the benefit of the author, may prove detrimental to both patient and practitioner. For example, while the CDC issued a revision to the *Guideline for Prevention of Surgical Site Infection* in 2017, the recommendations are not inclusive of certain practices that have become widespread in the prevention of SSI. While these practices are not included in the guideline on the basis that they do not meet the threshold for quality and/or quantity of evidence, the overall body of evidence available to the field led to widespread adoption of these practices and the related technologies. Even though these practices and technologies are not recommended in the guideline, they are the de-facto standard of care.

In contrast, evidence-based medicine (EBM) is the conscientious, explicit and

judicious use of current best evidence²⁷ integrating the best research with clinical expertise and patient values.²⁸ More simply, EBM is focused on treating the individual patient based upon that patient's unique health state and diagnosis, individual risks and the benefits of potential interventions.²⁹ To meet the evidence-based standard, clinicians are urged to keep informed with respect to new evidence from patient-centered clinical research even if this invalidates previously accepted guidance in an effort to yield more powerful, accurate, safer and more cost-effective outcomes. Some courts have been moving toward utilizing an evidence-based standard of care because historical customary practice may not necessarily be reasonable or reflect the most recent advancements in medical care or technology.

At least a part of the legal rationale behind the movement toward an EBM standard of care is based upon the fact that malpractice standards change because of advancements in technology and not changes in the law itself. The issue then becomes whether reasonable care equates to what most medical professionals actually do or what is reasonable to expect given the state of medical knowledge at the time of treatment. It is important to keep in mind that both malpractice standards and evidence-based medicine include a "duty to stay abreast." This means that there is an obligation to be aware of evolving practices in medical care and to make appropriate use of new scientific knowledge in medicine as it emerges.³⁰

Clinicians contemplating adoption of new evidence-based products, practices, or technologies, but reluctant to move beyond clinical guidelines may want to investigate *Nowatske v. Osterloh* where the court ruled that should medical practice fail to keep pace with developments and advances in medical science, adherence to custom might constitute a failure to exercise reasonable care.³¹ It also stated that if what passes for customary or usual care lags behind developments in medical science, such care might be negligent, despite its customary nature.³² Some case law implies that if the relevant practice, product or technology was found acceptable by a reputable subset of the profession it would not be regarded as improper even if few clinicians had adopted it at that time.³³ This finding lends support to early adoption of technologies that do not place patients at additional risk and credence to the value of smaller, well designed and executed studies. This finding should encourage manufacturers, product developers and healthcare institutions to pursue smaller studies when large randomized control trials (RCTs) are not feasible.

Air Quality in the OR and Malpractice for Orthopedic Surgery

With respect to HAIs, medical malpractice cases generally focus upon whether the infection was preventable and/or whether the infection was properly and/or promptly treated. In their evaluation of the merits of a medical malpractice case based upon a patient acquiring a healthcare-associated infection, courts may look at the availability of evidence-based technology which could have prevented the infection with minimal risk, cost, and training in determining whether the standard of care was breached.

In the Pennsylvania case of *DiMeo v. St. Agnes Hospital*,³⁴ Annette DiMeo underwent a left total knee replacement that subsequently developed into an infected hematoma and progressed into an infected septic knee. Among the plaintiff's causes of action was an allegation for failure to take adequate precautions to prevent operating room infections. The jury awarded DiMeo \$1,200,000 in damages. In the New York case of *Lugo v. Klein*,³⁵ Lugo underwent knee surgery and subsequently developed a staph infection. He alleged negligence in failure to keep the wound sterile, failure to recognize infection as well as failure to warn of risks of infection resulting from the procedure. Jury awarded Lugo \$401,000 for pain and suffering.

Interestingly, in the Illinois case of *Goldby v. Orthopedic & Spine Surgery Associates*,³⁶ the plaintiff's allegations were based upon failure to properly diagnose and treat an infection following a right forearm injury, but also included negligence based upon closing a dirty wound. While it was not specifically alleged that the wound became dirty because of the OR conditions, this certainly paves the way for future claims asserting negligence based upon a failure to properly disinfect and/or inspect the operative field. A settlement was reached in favor of the plaintiff in the amount of \$1.75 million. Allegations in other orthopedic prosthetic joint infections have included failure to properly disinfect the OR and surgical instruments (*Dechico v. Hudson Valley Hospital*)³⁷ and failure to inspect the operative field and clean surgical instruments (*Phillips v. Baker*).³⁸

It is suspected that these cases are just the tip of the iceberg in orthopedic SSI litigation, as most malpractice cases are settled long before they get to court and many come with nondisclosure orders preventing release of information related to the case. Thus, it is not possible to estimate the actual number of SSI claims, claims alleging injury due to contamination of the OR and/or contamination of the wound, or average costs to healthcare institutions to defend SSI-related litigation.

Typically, when hospitals settle out of court the awards are far greater than those that go to trial and are likely, on average, far greater than the awards mentioned above.

Beyond the orthopedic realm, but related to the aerosolization of bacteria, more than 10 lawsuits have been filed against the manufacturer of the heater-cooler device found to be the source of *M. chimaera*. One suit is based on the patient's allegations that the device contributed to a potentially fatal chest incision infection.³⁹

Air Decontamination Technology: An Evidence Based Solution

Airborne pathogens are a known risk factor for SSIs. Particulate counts and bacterial colony forming units (CFUs) are key indicators of air quality utilized in critical environments. Yet, published data on airborne levels in operating rooms indicates that OR air is often no cleaner than the air in other units.⁴⁰ More than 90 percent of bacteria contaminating clean wounds come from the ambient air and a substantial part of these bacteria contaminate the wound directly during clean-wound surgery.⁴¹

Precautions such as scrubbing and gowning, special skin prep procedures for both patients and clinicians, protocols to restrict access and movement in the OR, between case and terminal disinfection, surgical irrigants, antimicrobial sutures and special postoperative dressings are just a few of the interventions directed at reducing the incidence of SSI. Reduction of air contamination in the OR is accomplished primarily through a combination of filtration, dilution, pressurization and traffic-related limitations. OR staff must ensure that temperature and humidity are controlled and that air handling systems receive preventative maintenance. These standards are largely architectural in nature and have been in-place for decades. Moreover, with some of these standards, most notably the required number of air changes per hour, there is no real agreement on whether they are sufficient. It is also widely accepted that risk mitigation strategies aimed at maintaining air quality in the OR, such as limiting traffic and door openings, can be only marginally enforced and therefore may also be of questionable effectiveness.

To supplement traditional methodologies, a variety of new technologies such as those utilizing ultraviolet (UV) disinfection have been developed to reduce airborne contamination. There is published data available which demonstrates that technology utilizing UV and recirculation can further reduce viable airborne particle concentrations in the OR setting.⁴² The CDC, in *Guidelines for Environmental Infection*

Control in Health-Care Facilities, states that "as a supplemental air-cleaning measure, ultraviolet germicidal irradiation is effective in reducing the transmission of airborne bacterial and viral infections in hospitals."⁴³ Further paving the way for adoption, the American College of Governmental Industrial Hygienists (ACGIH) states that airborne infections can be prevented or reduced by maximizing removal rates of airborne infectious aerosols through dilution ventilation and use of air cleaners.⁴⁴

While there are no OR air quality standards in the U.S., as of this writing, the World Health Organization (WHO) has established limitations for microbial contamination in ORs of <50 CFU/m³ and <10 CFU/m³ for orthopedic, cardiac, and transplant ORs.⁴⁵ A number of EU states are also implementing air quality standards for the OR and other areas where patients are at high-risk risk for infection.⁴⁶

In light of the evidence and global movement toward air quality standards in the OR, infection preventionists may want to consider adoption of air quality technologies as a supplemental evidence-based solution for reduction of SSI. Where practices and processes are reliable and consistent with policy, technology solutions should be considered as an additional means of mitigating the risk.

In cases where SSI rates are elevated, an audit should be conducted to identify if airborne contamination could have been a contributing factor. The audit should also include the costs of treating infections, the financial consequences of any legal action, all costs related to penalties and incentives under the Affordable Care Act such as value-based purchasing, inpatient quality reporting, hospital acquired conditions and postoperative readmissions and penalties under the Deficit Reduction Act for conditions that were not present on admission. This information can contribute to value analysis and bolster the foundation for implementation of evidence-based improvements and adoption of new technologies.

Clinicians may want to consider the resources offered by medical technology companies as many employ clinical experts who are prepared to assist in performing assessments and audits. Companies are also often willing to assist with small studies that can be used in value analysis and provide an evidence-based, institutionally relevant foundation for adoption of innovative, new technological improvements.

While there is a host of factors in OR environment and practice that can contribute to SSI, there is a growing body of evidence which suggests that air quality

merits heightened attention on the part of the infection prevention community. For prevention of PJI in particular where procedural volume is high and growing and the clinical and economic costs of infection are also high, supplemental strategies that can further reduce infection risk should be on every IP's radar. Recent innovation in air decontamination technologies make significant reduction in airborne bioburden in the OR, for the first time, both technically and economically feasible offering a new asset in the quest to eliminate SSI and meet the evidence-based standard of care. 

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