Pilot study of directional airflow and containment of airborne particles in the size of *Mycobacterium tuberculosis* in an operating room

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Background: Containment of airborne microorganisms to prevent transmission in a positively pressured operating room (OR) is challenging. Occupational transmission of *Mycobacterium tuberculosis* (*M tuberculosis*) to perioperative personnel has occurred, but protection of the surgical site is of equal importance. High-efficiency particulate air (HEPA) filters can mitigate occupational exposure and improve air quality. Smoke plumes and submicron particulates were released to simulate aerobiology of *M tuberculosis* and assess impact and efficacy of particle removal in an OR suite using different HEPA filtration units and configurations.

Objectives: My objectives were to compare the impact of freestanding HEPA filter units, which are currently more commonly deployed inside the OR, with a novel portable anteroom system (PAS)-HEPA combination unit (PAS-HEPA) placed outside the OR and assess the efficiency of removal of particulates from an OR.

Methods: Smoke plume and submicron particles were generated inside an OR. Plume behavior was observed during deployment of 3 different configurations of HEPA units. Two of these involved different models of freestanding HEPA filtration units inside the OR, and the third was the PAS-HEPA unit located outside the OR. The concentration of submicron airborne particles was quantified for each configuration of freestanding HEPA and PAS-HEPA units. In addition to measurement of submicron airborne particulates, a high concentration of these was generated in the OR, and time for removal was quantified.

Results: Observations of released plumes, using the PAS-HEPA unit revealed a downward evacuation, away and toward the main entry door from the sterile field. By contrast, when portable freestanding HEPA units were placed inside the OR, plumes moved vertically upward and directly into the breathing zone of where the surgical team would be stationed during a procedure. The PAS-HEPA unit, working in tandem with the OR heating, ventilation, and air conditioning system, was confirmed to have removed over 94% of an initial release of at least 500,000 submicron particles/ft^3 within 20 minutes after release.

Conclusion: This pilot study clearly indicates that avoiding the use of freestanding HEPA filters inside an OR during a surgical procedure is prudent and consistent with Centers for Disease Control and Prevention guidelines. A PAS-HEPA unit is effective in removing submicron particles and will enhance safety of care of a patient with an airborne infection requiring surgery. (Am J Infect Control 2008;36:260-7.)

Preventing secondary transmission of *Mycobacterium tuberculosis* to perioperative personnel from patients with suspected or confirmed active tuberculosis (TB) disease who require urgent surgery or are discovered intra- or postoperatively presents a significant challenge in a positive-pressure environment such as an operating room (OR). Although there are no documented cases of occupationally acquired infection or disease among perioperative personnel from a case of pulmonary or laryngeal TB, Hutton et al identified tuberculin skin test conversion in 4 of 5 OR personnel after incision, drainage, and irrigation of a cutaneous hip abscess.[1] Others have also reported high risk of tuberculin skin test conversions among personnel after caring for patients with similar sites of extrapulmonary TB.[2-4]

Airborne infectious agents such as *M tuberculosis* are difficult to contain in most ORs that are designed to generally operate in positive air pressure. *M tuberculosis* was chosen for simulation in this study because it causes the prototype, obligate airborne disease.[5] Patients with TB in the OR may be encountered more often in lieu of recent changes in epidemiologic trends in the United States. For example, the rate of decline in annual incidence of TB in the United States has slowed significantly since 2000.[6] Second, the proportion of TB cases among foreign-born persons has increased

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each year since 1993.[6] Third, support for public health programs to identify and treat TB in the community is declining commensurate with public policy makers who are responding to a drop in incidence after the peak in early 1990s. Therefore, despite this decline in the United States, occupational exposure of health care personnel to TB remains not only a problem in the United States but also worldwide.[7] Finally, the emergence of extensively drug-resistant (XDR) TB may necessitate more use of surgical intervention and has prompted the Centers for Disease Control and Prevention (CDC) to state, "... to prevent the spread of XDR TB, renewed vigilance is needed through drug susceptibility testing, case reporting, specialized care, infection control, and expanded capacity for outbreak detection and response ..."[8]

Of similar difficulty is admission of immunocompromised patients who need a protective environment because of their underlying susceptibility but have coincident airborne infection such as TB or varicella zoster virus. The same goal as protection from TB in the OR applies, specifically protection of the patient while preventing exposure of others to the airborne pathogen. Environmental controls to assist with this goal have been described elsewhere.[9]

Data regarding the communicability of those with pulmonary disease who require lung resection is inconclusive; however, surgery remains a viable option for this most common site of TB disease. Surgery may be even more probable for those with protracted illness caused by strains that are either multidrug-resistant TB or the more recent extensively drug-resistant TB (XDR-TB).[10,11] Furthermore, Wan et al and others have documented that exhaled gas from a high proportion of patients with pulmonary TB receiving mechanical ventilation was polymerase chain reaction positive for *M tuberculosis* even with filtration.[12] This suggests that those at risk of occupational exposure after care of the surgical patient with pulmonary TB may include anesthesia and postanesthesia care personnel.[13]

Protection of personnel against occupational exposure is essential; however, protection of the patient against surgical site infection is a standard goal of perioperative personnel.[14-16] Air in an OR can contain microorganisms, dust, aerosol, lint, skin squamous epithelial cells, and respiratory droplets. Work practices followed by surgical personnel along with appropriately functioning heating, ventilation, and air conditioning (HVAC) system are therefore aimed at protecting the surgical site.[17-19] Therefore, the challenge in the OR during care of someone with an airborne disease is protection of the operative site and perioperative personnel.

This investigation utilized noninfectious materials to simulate the behavior of droplet nuclei particles containing *M tuberculosis* in an OR environment and also assessed the potential impact of airborne particle containment strategies on the safety of the surgical patient and perioperative personnel. Visible smoke plume release is a standard tool used to determine direction of airflow in critical environments such as an airborne infection isolation room.[20] Therefore, it was used for qualitative assessment of the impact of freestanding high-efficiency particulate air (HEPA) units located inside an OR compared with a novel portable anteroom system (PAS)-HEPA unit located outside the OR. Quantitative measurement of submicron particles to compare impact of different HEPA units (phase 1) was followed by release of high concentration of particles (phase 2) to determine the removal efficiency of PAS-HEPA.

MATERIALS AND METHODS

Smoke plume and submicron particle generator

Smoke plume was generated using a Borozin Gun (E. Vernon Hill, Inc., Benicia, CA) that creates a plume from zinc sterate. Poly-alpha olefin (Emery 3004; Air Techniques Intl, Owings Mills, MD), a colorless, odorless liquid, was used to create submicron particles using a Laskin Nozzle Generator (Air Techniques Intl). This device produces particles with a mean diameter of 0.5 μm (range, 0.1-1.0 μm) from the liquid poly-alpha olefin.

Sound level monitoring equipment

Sound level monitoring was performed utilizing a Digital-Display Sound level meter (Model 33-2055; RadioShack, Fort Worth, TX)

Freestanding HEPA units

Two different models of freestanding HEPA filtration units were utilized. A Microcon MAP-800M (Biological Controls, Inc., Eatontown, NJ) and a HEPA-CARE Model HC800F (Abatement Technologies, Inc., Suwanee, GA) were deployed inside the OR immediately adjacent to the surgical table as shown in Fig 1. The MAP-800M is equipped with a variable speed control fan that draws air into the filter chamber through the top, first passing through a polyester prefilter then down through a 99.97% HEPA filter before being discharged out the lower panel grilles located on all 4 sides of the device. For this study, the speed control was set on "High," which provides filtration at a rate of 675 cubic feet/min (cfm). The HC800F also has variable speed control that was similarly set to "High," providing approximately 750 cfm. It, however, draws air in through a side panel grille, a prefilter, and then through a final 99.97% HEPA filter before being discharged via a single top and side exhaust grille configuration. Filter media in both units were installed and tested to assure correct positioning based on manufacturer's specifications.

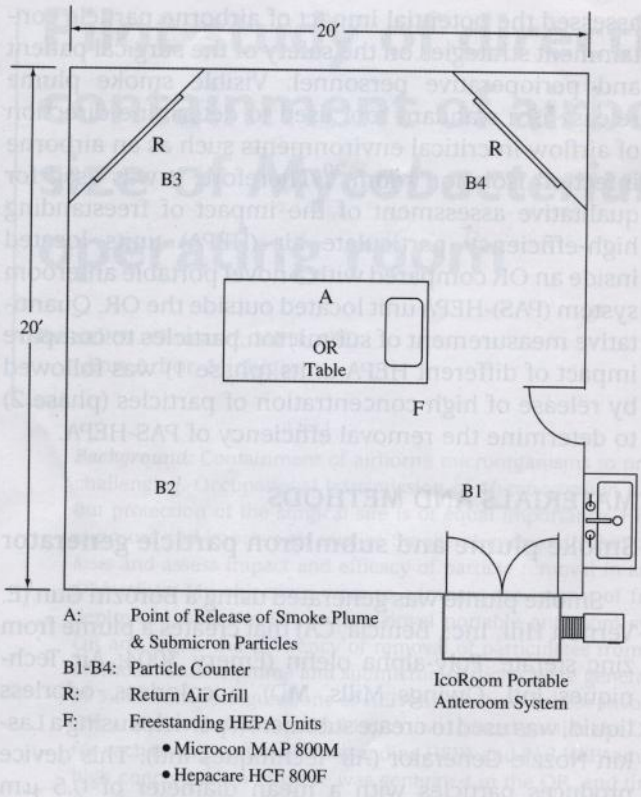

Fig 1. Configuration of operating room and location of sampling locations and equipment.

PAS-HEPA combination unit

The IcoRoom (Mintie Technologies, Inc., Los Angeles, CA) was designed as a temporary solution to be used only for specific clinical purposes. The IcoRoom consists of 3 major components, a 6-mm-thick woven thermoplastic polymer anteroom envelope, adjustable in height from 7 feet to 10 feet 6 inches with a 12-inch diameter exhaust side port, and a portable collapsible metal frame with an overall footprint of 34 inches × 61 inches. This footprint is designed so as not to obstruct corridor passage when deployed. The NFPA Life Safety Code requirements mandate that corridors must be not less than 96 inches wide in an OR setting, and, therefore, when deployed, the IcoRoom occupies less than one third of the minimum corridor width. A negative-pressure machine with a footprint of 34 inches × 20 inches, equipped with a single prepoly filter, and a final 99.99% HEPA filter is attached to the exhaust side port. Airflow direction out of the anteroom is horizontal and is achieved through one end of a flexible duct being fed through a dual configuration side port with the opposing end being attached to the intake manifold on the HEPA filtration unit. Two negative pressure machines were used for this study. In phase 1, an Omni*AIRE* 660V (Omnitec Design, Inc., Lynnwood, WA) with an airflow of 150 to 600 cfm and polytreated prefilter and final 99.97% HEPA filter was used. In phase 2, an OMNI*AIRE* 2000V (Omnitec Design, Inc.) that draws air at a speed of 300 to 1900 cfm equipped with a presized 40% polytreated prefilter and a final 99.97% HEPA filter housed in a metal frame was used. A flange (door collar), which is part of the IcoRoom envelope, is secured to the OR door by use of Velcro sealing tape around the door frame of the main OR entry door. The IcoRoom is equipped with zippered access doors on all 4 sides of the anteroom envelope for versatility. The side panels adjacent to the OR door are used for passage of the patient, personnel, and equipment into and out of the OR.

Environmental measurements and study site setup

Airborne particles in the size of 0.5 to 1.0 μm were quantified as particle concentration/ft^3 with an aerosol measurement photometer. Sound pressure or noise levels generated by the freestanding and PAS-HEPA units after activations were recorded in decibels (dB) with a sound level meter.

The placement of the air particle sampling locations, freestanding HEPA, and the PAS-HEPA units is illustrated in Fig 1. Particle counts were collected in the OR at locations designated as B1 to B4 in Fig 1. Particle count samples in the unoccupied OR were collected for a period of 1 minute at a rate of 1 ft^3/minute (cfm) beginning at time zero separated by 5-minute intervals for a total sampling time of up to 20 minutes. Parameters and sample times were duplicated in sequence for the 2 freestanding HEPA devices and, last, the PAS-HEPA unit.

The freestanding HEPA filtration units were each placed at a distance of 1 foot from the head of the OR table on the side nearest to the main entry door (see Fig 1). The size of the OR used was 20 ft × 20 ft × 10 ft with a total of 4000 cubic feet. An array of supply air diffusers are located immediately above the OR table, and there are 2 return air diffusers, which occupy a total of 2 square feet located at the inboard corners of the room. On the days of this investigation, the supply air was delivered at a flow of 1731 cfm with a total return or exhaust of 872 cfm. Air exchanges for the OR were 26 air changes/hour. The OR used was 1 of 16 in the surgical suite, had undergone recent terminal cleaning, and was certified as ready for use by the OR supervisor.

Data were collected in 2 separate phases on 2 different days. The first phase was limited to qualitative observation of smoke plume release and sampling of concentration of submicron particles and noise pressure levels following deployment of the 2 freestanding HEPA and

Table 1. Comparison of air particle counts in an operating room with deployment of different HEPA filtration devices

Test conditions	Particle count sample location*	Particle count, sample 1 (5 minutes)	Particle count, sample 2 (10 minutes)	Particle count, sample 3 (15 minutes)	Particle count, average
Unoccupied OR, no HEPA device deployed					
Normal	B1	25,417	26,202	27,841	26,486
	B2	21,825	22,039	22,404	22,089
	B3	21,944	22,798	24,205	22,982
	B4	22,038	21,743	22,512	22,098
	Total average				23,046
HEPA unit A† inside OR					
	B1	16,048	16,311	16,839	16,399
	B2	18,405	18,624	18,126	18,385
	B3	19,276	19,660	19,358	19,431
	B4	17,794	17,609	17,298	17,567
	Total average				17,944
HEPA unit B‡ inside OR					
	B1	16,969	17,766	17,312	17,349
	B2	20,104	20,318	20,538	20,320
	B3	20,595	22,312	24,250	22,386
	B4	20,861	22,355	21,667	21,628
	Total average				20,183
Anteroom-HEPA combination§ outside OR					
	B1	23,732	24,098	25,797	24,542
	B2	23,550	23,520	23,640	23,570
	B3	25,786	27,034	26,234	26,351
	B4	24,684	26,811	27,616	26,371
	Total average				25,087

*Locations B1-B4 are illustrated in Fig 1.
†Microcon MAP 800M (Biological Controls, Inc., Eatontown, NJ).
‡HEPACARE HCF 800F (Abatement Technologies, Inc., Suwanne, GA).
§IcoRoom (Mintie Technologies, Inc., Los Angeles, CA).

the PAS-HEPA units. All particle counts were measured with only 1 device deployed. The negative air machine attached to the PAS-HEPA unit during phase 1 was set at 600 cfm. During phase 2, the submicron particles were released in the OR, and measurement of clearance of particles was limited to the use of the PAS-HEPA unit with the flow rate setting at 1600 cfm.

RESULTS

Phase 1

Smoke plumes were released several times, for a total of at least 10 cycles for each configuration, from the middle of the OR table (see Fig 1). For each freestanding HEPA unit (MAP-800M and HC-800F) deployed inside the OR, the smoke plume was not captured by the air-filtration device. Instead, it traveled vertically upward from the OR table into the breathing zone of personnel who would normally be around the table during a surgical procedure. By contrast, when the PAS-HEPA was deployed, the smoke plumes were pulled down, away from the OR table and toward the floor and in the direction of the main door, which was kept closed.

Particle counts during phase 1 are provided in Table 1. Overall average of particle counts taken at the sampling locations in the OR was reduced slightly during deployment of the freestanding MAP-800M unit (approximately 22% compared with baseline readings). Following 15 minutes of continuous operation, the particle concentration did not change significantly at any of the sampling locations. The HC-800F unit reduced average particle concentration compared with baseline (unoccupied OR) by 12%, and, likewise, there was similarly no significant reduction in particle concentration after 15 minutes of continued operation.

Particle counts for the PAS-HEPA unit concentration increased by 8% compared with baseline, and no significant change was found after 15 minutes of continual operation. According to the certified safety technologist who measured particle counts for this investigation (verbal personal communication, Bruce Mack), the gradient increase in concentration of particulates over the course of this phase of the investigation was likely due to interference from residual smoke plume released from each preceding deployment of the various HEPA devices.

Noise levels were recorded during phase 1 at a distance of approximately 3 feet from freestanding HEPA units, MAP 800M and HC-800F. Readings were taken at 1 and 5 minutes during continuous operation inside the OR. Baseline sound levels with no freestanding HEPA unit inside the OR were 45 dB and 47 dB at

minute 1 and minute 5. With the freestanding HEPA MAP-800M unit, the noise level recordings were raised to 69 and 68 dB, respectively. For the HC-800F unit, sound levels at both 1 and 5 minutes were 65 dB. Sound levels with the PAS-HEPA unit outside the main OR door were essentially the same as baseline, 48 and 49 dB at 1 minute and 5 minutes, respectively.

Phase 2

The results of the particle release in this phase are illustrated in Fig 2. The average particle count at locations B1 to B4 at baseline (prior to particle generation) was 6468 particles/ft^3. A measured concentration of at least 500,000 particles/ft^3 was released, and the PAS-HEPA unit was activated. Sampling was conducted and accomplished 5, 10, and 20 minutes thereafter. By 20 minutes, over 94% (average concentration = 28,034p/ft^3) of the submicron particles were cleared from the OR. Of note, particle concentration at sampling locations B3 and B4 (see Fig 1) were consistently 25% and 50% lower, respectively, than location B1 at 5, 10, and 20 minutes. This mirrored the qualitative observation of the smoke plume seen in phase 1, ie, plume was pulled down and toward the main OR door. The lower gradient in concentration nearest the door suggests that the PAS-HEPA was drawing the particles away from the OR table toward the door. Air supply and exhaust fan controls for the OR were not changed or reset during deployment of the PAS-HEPA unit thus allowing the OR HVAC system to function as designed and intended.

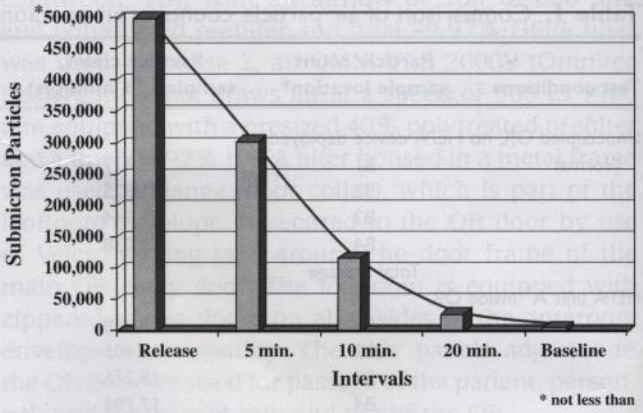

Fig 2. Efficiency of removal of submicron particles (particles/ft^3) from operating room with portable anteroom-HEPA unit device.

DISCUSSION

This pilot investigation offers some insight into comparative effectiveness of various containment strategies when a patient with an airborne infection is encountered. Specifically, in phase 1 the smoke plumes with freestanding HEPA units inside the OR caused an unanticipated disruption of normal patterns of airflow in the OR by traveling vertically up into the breathing zones of surgical personnel. This suggests that there may be an increased potential for occupational exposure to an airborne infectious agent and possibly unwanted introduction of contaminants into the patient's surgical site. Also background noise levels generated from any freestanding device located adjacent to the surgical table inside the OR would further inhibit communication among the surgical team if allowed to operate during a procedure. These observations reinforce recommendations from the CDC that, if used, a freestanding HEPA unit inside the OR should be limited only to those specific intervals at which aerosols containing *M tuberculosis* might more likely be generated—intubation and extubation.[9] Appropriate respiratory protection should also be worn by personnel during these activities. An additional matter of potential concern is interference from noise generated by the HEPA unit inside the OR. Others have also identified this potential limitation for an occupied patient care room.[21]

The PAS-HEPA unit deployed outside the main OR door in this study effectively cleared a high concentration of submicron particles in a short period of time (refer to Fig 2). The concentration and size of particles generated in phase 2 represented a significant challenge to the HVAC system. Availability of the OR used was limited, so a comparative challenge with no supplemental air-filtration device could be accomplished. However, despite formulas that indicate estimated time needed for clearance of small particles in guidelines,[9,20] the data in Table 1 did not demonstrate a significant drop in concentration of particles in the OR even after 15 minutes. Therefore, under the natural conditions in the OR used, supplemental HEPA filtration using the PAS-HEPA unit appeared optimal for removal of airborne contaminants. The behavior of particles generated in this phase is a simulation and may or may not be predictive of aerobiology of *M tuberculosis*. However, the PAS-HEPA unit also offers unique flexibility because it can be deployed at any point in the schedule of surgical cases, obviating a need to hold and delay these types of cases until the end of the day.[20] Other potential advantages include more rapid removal of contaminants in the OR after completion of the case and additional protection of surgical personnel during terminal room cleaning and disinfection. It also can be moved with the patient to a private room for postoperative care and recovery. Application to other high-risk procedures such as bronchoscopy, if an airborne infection isolation room is not available, is another example of its flexibility.[22]

Table 2. Synopsis of CDC guidelines on management of TB in the OR

2003 CDC Guidelines for environmental infection control[9]	2005 CDC TB Guidelines[20]
Administrative controls	
• If possible, schedule infectious TB patients as the last surgical cases of the day to maximize the time available for removal of airborne contamination. • Intubate the patient in either the AIIR or the operating room; if intubating the patient in the operating room, do not allow the doors to open until 99% of the airborne contaminants are removed. • Extubate and allow the patient to recover in an AIIR. • If the patient has to be extubated in the operating room, allow adequate time for air changes/hour (ACH) to clean 99% of airborne particles from the air because extubation is a cough-producing procedure.	• When possible, postpone nonurgent surgical procedures on patients with suspected or confirmed TB disease until the patient is determined to be noninfectious or determined to not have TB disease. • Procedures should be scheduled for patients with suspected or confirmed TB disease when a minimum number of HCWs and other patients are present in the surgical suite and at the end of the day to maximize the time available for removal of airborne contamination. • Postoperative recovery of a patient with suspected or confirmed TB disease should be in an AIIR in any location where the patient is recovering. If an AIIR or comparable room is not available for surgery or postoperative recovery, air-cleaning technologies (eg, HEPA filtration and UVGI) can be used to increase the number of equivalent ACH.
Environmental controls	

• When anesthetizing a patient with confirmed or suspected TB, place a bacterial filter between the anesthesia circuit and patient's airway to prevent contamination of anesthesia equipment or discharge of tubercle bacilli into the ambient air.
• Use portable, industrial-grade HEPA filters temporarily for supplemental air cleaning.
• During intubation and extubation for infectious TB patients who require surgery:
  ○ Position the units appropriately so that all room air passes through the filter; obtain engineering consultation to determine the appropriate placement of the unit.
  ○ Switch the portable unit off during the surgical procedure.
• Provide fresh air as per ventilation standards for operating rooms; portable units do not meet the requirements for the number of fresh ACH.
	• Ventilation in the OR should be designed to provide a sterile environment in the surgical field while preventing contaminated air from flowing to other areas in the health care setting.
	• A bacterial filter should be placed on the patient's endotracheal tube (or at the expiratory side of the breathing circuit of a ventilator or anesthesia machine, if used)
	• If a surgical suite or an OR has an anteroom, the anteroom should be either (1) positive pressure compared with both the corridor and the suite or OR (with filtered supply air) or (2) negative pressure compared with both the corridor and the suite or OR.
	• Using additional air-cleaning technologies (eg, ultraviolet germidical irradiation) should be considered to increase the equivalent ACH. Air-cleaning systems can be placed in the room or in surrounding areas to minimize contamination of the surroundings after the procedure.

AIIR, airborne infection isolation room; *UVGI*, ultraviolet germicidal irradiation.

There have been 2 comprehensive guidelines published by the CDC that include recommendations to assist with preventing transmission during care of TB in the OR.[9,20] Aspects of administrative and environmental controls that relate to this study are summarized in Table 2. Surgical personnel need to be aware that the 2003 CDC Environmental Infection Control Guidelines are slightly more direct that the freestanding HEPA unit, if deployed inside the OR, be turned off during the procedure.[9] The 2005 CDC TB Guidelines did expand on the need to protect the patient's surgical site and recommend consideration of an anteroom for surgery on a person with active TB disease.[20] This study's findings offer supportive evidence that is consistent with recommendations in these guidelines.

Rutala et al and others have demonstrated that freestanding HEPA units can clear a nonventilated aerosol chamber, which was approximately one third the size of the OR in this study, of submicron particles in a range of 5 to 31 minutes.[23] Measurements of particles in phase 1 of this pilot study did not replicate these prior results. However, the OR was not as well sealed as an aerosol chamber, the HVAC system was running throughout, the volume of the room in this study was much greater, and there was additional interference from smoke plume releases. All of these variables are contributing factors that might explain differences.

There are several limitations in this study. The study was conducted in a single OR on 2 separate days. Smoke and submicron particles were used to simulate the aerobiologic characteristics of an obligate airborne pathogen. More direct evidence on comparative efficacy of environmental containment that would be available with use of an actual infectious agent or a viable surrogate microbe such as other, nontuberculous *Mycobacteria* was not used. Next, even though the sizes of particles used in this study are smaller than those measured for *M tuberculosis*, other studies have not shown a direct correlation between particle simulation investigations and occupational TB outbreaks or clusters involving OR personnel. Similarly, correlation between intraoperative particle counts and subsequent risk of surgical site infection has not been well described. There are, however, more recent investigations that encourage better air quality to lessen infection risk.[17,19,24] Last, this is a pilot investigation whose goal was to determine which HEPA filtration technology was best suited for use in positively pressured ORs. Impact of this technology on occupational transmission of TB was not assessed.

Predicting and mitigating risk of cross transmission of TB in health care settings remains an unknown variable. Aspects relevant to both administrative and environmental controls have been identified as primary weaknesses in prevention of transmission of TB in health care facilities.[25-27] Of concern, recent assessment of the function of airborne infection isolation rooms at a large number of facilities revealed that recommended environmental parameters, eg, negative pressure and air exchanges per hour, are not being correctly maintained.[28]

CONCLUSION

Smoke plume and particulates were used to simulate the aerobiology of airborne agents such as *M tuberculosis* in an OR environment. A novel PAS-HEPA unit was an effective environmental control for containment of plume and submicron particles in the OR in this study. Results obtained are consistent with the strategies outlined in the CDC guidelines and reinforce need to avoid operation of a freestanding HEPA unit inside the OR during a surgical procedure. The PAS-HEPA unit also offers additional flexibility for a variety of patient care needs. Further investigation is needed to reproduce findings in this pilot study. However, prior experience with airborne pathogens indicates continued need for risk assessment and preparedness rather than reactionary steps to manage the sudden appearance of an airborne infection.

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