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Quantification of bacterial shedding from the respiratory tract of health care workers wearing PAPRs and other types of Air-Purifying Respirators on sterile conditions in a simulated Operating Rooms (ORs)

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ABSTRACT

Quantification of bacterial shedding from the respiratory tract of health care workers wearing PAPRs and other types of Air-Purifying Respirators on sterile conditions in a simulated Operating Rooms (ORs)

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The role of powered air-purifying respirators (PAPRs) in healthcare settings during infectious diseases outbreaks or use with highly contagious pathogens (e.g., SARS, HINI, and Ebola, etc.) has attracted much interest based on their many beneficial features. A common practice to minimize airborne contaminant exposure among healthcare workers has been using surgical masks (SMs) or N95 filtering facepiece respirators (FFRs). However, SMs have been shown to offer minimal respiratory protection. N95 filtering facepiece respirators (FFRs) have been shown to provide better protection than SMs; however, they have been found uncomfortable to use for prolonged periods. In current PAPR designs, exhaled air from the wearer is not filtered before release to the environment. This design suggests a potential for biocontamination if used in an operating room sterile field condition. The objective of this research is to evaluate the effect of bacterial shedding from the respiratory tract of healthcare workers wearing PAPRs and half-mask respirators on sterile conditions in operating rooms (ORs).

Firstly, a pilot study was conducted in a laboratory setting to determine the appropriate sampling methodology to use in the sterile field setting. Both passive sampling (settle plate method) and active sampling (Andersen cascade impactor sampler and SKC Bio sampler impinger) were evaluated. Settling plates were used for a sampling period of 45 minutes, and both

active sampling methods were used for 15 minutes. During sampling, two subjects, each donning an elastomeric half-mask, performed activities such as reading the rainbow passages and rotating around a simulated patient manikin while sampling was being done. The results suggest that active sampling with the use of Andersen N6 single-stage cascade impactor collected more colony-forming units when compared to the settling plates of the SKC Bio sampler.

After the pilot study, a randomized, simulated workplace study was conducted to compare the bacterial shedding from respiratory tracts of 9 teams of 2 participants, each wearing six different types of respiratory protection devices (RPD), including an FDA approved surgical mask (SM), and five different NIOSH certified respirators. The NIOSH certified devices were two N95 filtering facepiece respirators (FFR), one with and one without an exhalation valve, an elastomeric half facepiece respirator (EHMR) equipped with an exhalation valve, and two PAPRs, one having an assigned protection factor (APF) of 25 and one with an APF of 1000. Sterile field contamination resulting from the use of the FDA-approved surgical mask was used as a baseline for comparison with the NIOSH-certified devices. Contamination was determined by active biological sampling using ' 'sheep's blood agar plates. Collected samples were incubated, and the resulting bacterial colony-forming units (CFU) were counted. The primary outcome was expressed as concentration, the number of CFU/m^3. Poisson regression analyses were used to evaluate the concentration of CFU/m^3 resulting from the use of the surgical mask as compared to the other RPDs. A Bonferroni pairwise comparison was used to estimate the difference between the respirators. The study was conducted between February and March 2021 at the WV Simulation Training & Education for Patient Safety laboratory at Ruby Memorial Hospital, Morgantown, WV. Two identical simulated OR rooms were used. Each had a volume dimension of 13.'5' x 13.'5' x '8' with an air exchange rate (AER) of 25 per hour. 18 participants

grouped into nine teams of two completed the study. The data analysis found that the bacterial contamination produced by a pair of subjects wearing the N95 FFR without exhalation valves, the PAPR with APF=25, and the PAPR with APF=1000 was not significantly different than the contamination resulting from wearing the SM. The bacterial contamination resulting from using the N95 FFR with exhalation valve and EHMR with exhalation valve was found to be significantly higher than the bacterial contamination resulting from wearing the SM.

Table of Contents

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List of Figures

List of Tables

List of Abbreviations and Nomenclatures

ACH **Air Change per Hour**

AER **Air Exchange Rate**

AORN **Association of peri-Operative Registered Nurses**

APF **Assigned Protection Factor**

B-PAPR **Bullard EVA Powered Air Purifying Respirator**

CDC **Center for Disease Control**

CFM **Cubic Feet per Minute**

CFU **Colony Forming Unit**

EHMR **Elastomeric Half Mask Rsepirator**

FDA **Food and Drug Administation**

FFR **Filtering Facepiece Respirator**

GM **Geometric Mean**

GSD **Geometric Standard Deviation**

HCW **Healthcare Worker**

NIOSH **National Institute of Occupational Safety and Health**

OR **Operating Room**

PAPR **Powered Air Purifying Respirator**

RPD **Respiratory Protection Device**

SM **Surgical Mask**

V-PAPR **Versaflo Powered Air Purifying Respirator**

Chapter 1: Introduction

1.1. Background

In healthcare settings, a common practice to minimize airborne contaminant exposure among healthcare workers is to use surgical masks or N95 filtering facepiece respirators (FFRs). Various studies have shown surgical masks offer minimal respiratory protection, and while N95 filtering facepiece respirators offer better respiratory protection, they are not as comfortable to use (Davidson et al., 2013). Surgical masks are classified as a medical device, not a respirator. Therefore, surgical masks need to be approved by the Food and Drug Administration (FDA) (FDA, 2018).

N95 FFRs are negative pressure devices. All such devices are associated with elevated breathing resistance. Their disadvantages include requiring an initial and periodic fit testing, the possibility of being compromised by an improper fit (e.g., because of facial hair), poor tolerance by users due to breathing resistance, and heat and moisture build-up, the high cost of stocking different types and sizes, and the potential for contamination due to exposed face and neck (Roberts, 2014).

The effect of exhaled moisture upon the breathing resistance of FFR has been mentioned anecdotally (Mardimae et al., 2006) (Bailar *et al.*, 2006); (Weiss et al., 2007); (Roberge et al., 2010); (Khaw et al., 2008), but scientific data are lacking to either establish or refute this claim. The presumption is that exhaled moisture clogs the voids in the fibrous filtration media (primarily by condensation), thereby increasing the breathing resistance (Mardimae et al., 2006; Roberge et al., 2010). A survey entitled """Prevalence of Respiratory Protective Devices in USS Healthcare Facilities""", conducted in 2014 found that NIOSH-certified N95 FFRs were the most widely used

respiratory protection device (RPD) in healthcare environments, followed by powered air-purifying respirators (PAPRs). (Wizner et al., 2016)

N95 FFRs continue to be the most prevalent RPD used by health care workers (HCWs); however, increasing use of PAPRs in health care indicates the need for targeted education based on regional trends tailored to the types of RPDs used in health care facilities. (Wizner et al., 2016)

Recently, much interest has been directed towards the role of PAPRs in healthcare settings during infectious disease outbreaks, based upon multiple advantageous features like greater ' 'wearer's comfort, no fit testing requirements, and improved physiological parameters (Wizner et al., 2016). The use of HEPA filters in PAPRs implies that they have a greater level of respiratory protection than in N95 masks due to the ability of the HEPA filters to filter at least 99.97% of particles 0.3µm in diameter and their oil proof nature. (Roberts, 2014)

More than 11 million HCWs are expected to benefit from the use of RPDs during an infectious respiratory pandemic (Cooley et al., 2010). Since the outbreaks of SARS in 2003, H1N1 in 2009, and Ebola in 2015, more attention has been focused on using PAPRs for HCWs (Board on Health Sciences Policy & Institute of Medicine, 2015).

1.1.1 Pilot Study Background

Initial work in this area was conducted by the University of Cincinnati and Tyler Church at West Virginia University. These studies did find some evidence of bacterial shedding by persons wearing PAPRs and surgical masks. The methodological approach taken in the Cincinnati study was to have HCWs perform simulated work activities over the period of an hour in a simulated OR setting. Bacterial shedding was assessed by collecting viable colony forming units (CFU) using a settling plate method. While bacterial collection by settling plate is a recognized sampling method, it relies on the bacterial particles settling out of the air onto an agar plate. One of the identified problems with this method is the settling rate of small particle sizes.

In the Cincinnati study, assuming the distance from the ' 'subject's head to the top of the hospital bed was 3 ft, the settling plate sampling method would grossly under-sample particle sizes of 3um or less. Even particle sizes between 3um and 10um would be under-sampled. The same analysis holds true for the Church study at WVU. Particle mechanics calculations of settling times for unit density spheres indicated that the time to settle 5ft ranges from ≈41 hrs. for a 0.5μm particle to ≈8 minutes for a 10μm particle.

A second shortcoming of both the Cincinnati and Church studies is failure to consider the time required for the bacterial concentration in the test room to reach equilibrium or that homogenous mixing has occurred. Given this shortcoming in the methodology, it is not surprising that the CFUs were almost solely found on settling plates located very close to where the test subjects were doing their simulated work activities. This observation was recorded in both the Cincinnati and Church studies.

Before beginning the main OR study, a pilot study was conducted to evaluate the collection efficiency of different passive and active bacterial sampling methods, bacterial concentration equilibrium, and homogeneity in the test room. This pilot study evaluated different active sampling methods to replace settling plate sampling and more thoroughly consider issues of bacterial concentration equilibrium and homogeneity in the test room. The pilot study was conducted with an elastomeric half-mask respirator (EHMR) and two test participants.

1.1.2 Pilot Study Samplers and Sampling Procedure

We evaluated four sampling methods: the settling plate method, the Andersen 6-stage biological sampler, the Anderson single stage biological sampler and the SKC """"Bio-sampler" liquid impinger.

1.1.2.1 Andersen 6 Stage and Single Stage Bioaerosol Sampler

The Andersen bioaerosol sampler uses a 6- stage impactor to collect six aerosol fractions on the surfaces of agar medium contained in Petri dishes. The Andersen single-stage bioaerosol sampler uses a single stage to collect aerosol fraction on the surface of the agar medium. Petri dishes are placed in the instrument, and the sample of air is drawn in which the corresponding particulates are collected on the agar medium of each stage. The Petri dishes are then removed to be incubated and counted. The general sampling procedure was as follows:

- The sampling pump was calibrated to 28.3 L/min.
- The impactor was cleaned inside and outside with antibacterial wipes between each test cycle.
- Agar plates were identified with a date, sample number, and location.
- The agar plate cover was removed, and the plate, agar side up, was be placed on each impactor stage.
- Samples were to be collected initially for 1-5 minutes. This time could be adjusted depending on the number of CFU found on the agar plates.
- The agar plate was to be removed from the impactor stage, and the plate cover replaced and placed in a Ziplock bag.
- Plates were incubated at 37° C for 48 hrs. after which the CFUs were counted for each plate

1.1.2.2 SKC """Bio-sampler" liquid impinger

The SKC """Bio-sampler" liquid impinger (Eight Four, PA, USA) is an all-glass, swirling aerosol collector consisting of an air inlet, three tangentially arranged nozzles, and a collection vessel.

- The sampling pump flow rate was calibrated to 12.5 L/min.

- Before each use the """Bio-sampler""", including the inlet, nozzle section, collection vessel, and ground joint cap were sterilized, in an autoclave within a range of 160° to 180° C for 180 to 240 minutes. The collection vessel were coated with petroleum jelly/hexane solution, and ViaTrap mineral oil or glycerol was used as collection liquid.

1.1.2.3 Settling Plate Method

- The settling plate sampling method involved the use of Remel 5% Blood Agar (TSA with Sheep Blood) for sampling the air in the room for bacterial contamination while the subjects donned the EHMR. The blood agar plates were placed at specific locations on the body of a patient-simulating manikin positioned on a Surgical Table. The plates were uncovered at the beginning of the test, covered, and removed at the end. For instance, in the trials involving subjects, the plates were uncovered precisely when the subjects entered the chamber, then covered and removed when the subjects finished the test and exited. The sampled plates were then incubated at 37° C for 48 hrs. after which the CFUs were counted for each plate.

1.1.3 Sampling Location

For the pilot testing, contamination was measured at three sampling locations of increasing distance (1, 3, and 5 feet) from the head of the hospital bed. All three samplers (Andersen sampler, the settling plate method and "Bio-sampler" sampler) were placed at each location.

Subjects were located at the opposite sides of the bed for each test sequence. Holding subject location relatively constant and varying the position of samplers away from the head of the bed allowed us to see if CFUs are sampled at more distant locations from the head of the bed.

1.1.4 Sampling Plates

A Thermo Scientific Blood Agar (TSA with sheep Blood) medium was used for sample collection to facilitate bacterial growth. Agar plates were then incubated at 37 °C for 48 hours before colony-forming units (CFU) were counted.

1.1.5 Testing Procedures for pilot testing

Two test subjects wearing an EHMR were used for the pilot study. Each test included two subjects talking and performing specific work tasks around the hospital bed. Five-minute cycles of talking, flipping their position on the side of the bed, and resting were repeated seven times, making the overall test duration 45 minutes. Settling plate passive sampling occurred throughout the period. The agar plate lid was removed at the start of the test cycle and replaced at the end of the test cycle. The Andersen and "Bio sampler" was collected during the last five minutes of the test cycle to prevent oversampling.

1.1.6 Sample size for the Pilot study

An elastomeric half mask was evaluated by two test subjects. Contamination was measured at three locations of increasing distance from each test subject test, and three sampling devices were used at each location. Six agar plates were used for the Andersen six stages sampler, and one plate for the single-stage sampler, one for the settling plate method, and four for the SKC liquid impinger "Bio-sampler".

The overall results suggested that the active sampling involving the use of Andersen N6 single-stage cascade impactor generates the most CFU when compared to the settling plate or “Bio sampler sampling approaches.

1.2. Problem Statement

Air exhaled by a person is generally expected to contain some aerosolized microorganisms.

When using a surgical mask or N95 FFR, which are semi-tight fitting or tight-fitting devices, the 'wearers' exhaled air leaves the mask by one or all of the following means: through the exhalation valve; through the face seal; and back through the filter. If no exhalation valve is present, the exhaled air passes through either the 'devices' filter or face seal. That portion passing through the filter is filtered, thereby reducing the amount of aerosolized microorganisms released to the ambient air. With current PAPR designs, exhaled air from the wearer is not filtered at all before releasing to the environment. The exhalation volume is, however, diluted by the air volume generated by the PAPR. This suggests the use of PAPRs may have the potential for greater bio-contamination of sterile fields, such as an OR, compared to using surgical masks or N95 FFRs not equipped with an exhalation valve. There is no information on potential bacterial contamination of sterile fields from the air exhaled by healthcare workers wearing PAPR. This study will provide data to improve recommendations/standards for PAPRs, including the use of PAPRs in sterile field environments.

1.3. Research Objective

This study was conducted to evaluate the effect of bacterial shedding from the respiratory

tract of healthcare workers wearing PAPRs and half-mask respirators on sterile conditions in operating rooms (ORs).

Generalized Linear Model with categorical variables and it's assumption

1.4. Hypotheses

1.4.1 Specific Aims

- Determine the baseline contamination from the air exhaled from wearers of surgical masks
- Measure the contamination levels from the air exhaled from wearers of PAPRs and half-mask respirators
- Determine the difference in contamination between FFRs with and without a valve
- Determine the difference in contamination between loose-fitting PAPRs (APF=25) and PAPRs with hood and shroud (APF=1000)

1.4.2 Specific Hypotheses

Hypothesis 1: The air exhaled from wearers of N95 FFRs with and without an exhalation valve, elastomeric half masks EHMR, and PAPRs generates the same overall bacterial contamination of the sterile field in an OR as the baseline contamination when wearing a surgical mask.

Hypothesis 2: The air exhaled from wearers of FFRs with an exhalation valve generates the same contamination as that when wearing FFRs without an exhalation valve.

Hypothesis 3: The air exhaled from wearers of a loose-fitting PAPR (APF=25) will not increase the level of bio-contamination compared to that when wearing PAPRs with hood and shroud (APF=1000).

Chapter 2: Literature Review

Maintaining a sterile surgical field in an operating room (OR) helps prevent the surgical environment from becoming contaminated and thus can help reduce the incidence of surgical site infections. Historically, OR staff has used loose-fitting surgical masks cleared by FDA and respiratory protective devices (RPDs) like NIOSH-approved surgical N95 respirators to prevent microorganisms from the ' 'wearer's talking, exhaled breath, coughs, and sneezes from possibly contaminating the surgical field. However, during public health emergencies, supplies of surgical N95 respirators can become limited, and reusable options such as elastomeric half-mask respirators and loose-fitting powered air-purifying respirators (PAPRs) should be considered.

2.1. Surgical Masks and N95 FFRs in Healthcare

Surgical masks and N95 FFRs are widely used to reduce exposure to airborne hazards in healthcare settings, even though various research has demonstrated that surgical masks offer minimal protection to the wearer, and N95 FFRs are not comfortable to use due to the high air resistance of the filter (Davidson et al., 2013; Rengasamy et al., 2014). However, some N95 respirators are intended for use in a healthcare setting. Specifically, single-use, disposable respiratory protective devices are used and worn by healthcare personnel during procedures to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids, and particulate material. These N95 respirators are class II devices regulated by the FDA, under 21 CFR 878.4040, and CDC NIOSH (Health, 2020). Surgical masks are not classified as a respirator but as a medical device, thus needing to be approved by the Food and Drug Administration (FDA) (FDA, 2018). These masks cover the nose and mouth of the user and act as a barrier to guard against droplets contacting the patient.

An N95 FFR can be worn in place of a surgical mask; however, it must be FDA-cleared and NIOSH approved (FDA, 2018). Unlike the surgical mask, which can be worn by anyone, the N95 is required to be fit tested annually to provide proper protection, which can be costly and time-consuming for a health care facility (Board on Health Sciences Policy & Institute of Medicine, 2015). In addition to time and cost, health care workers who are properly fit-tested and trained on using an N95, may still be reluctant to wear them. Common complaints about wearing an N95 include moisture build-up, being harder to breathe after prolonged use, especially for people with an underlying respiratory condition. Other disadvantages associated with N95 FFR include the high cost of stocking different types and sizes, and the potential for contamination due to exposed face and neck (Roberts, 2014).

2.2. PAPRs Applications

PAPRs were originally developed in the '1960's to protect various industrial workers from respiratory and dermal hazards (IOM, 2015). PAPRs are increasingly used in healthcare settings during infectious disease outbreaks. Currently, there are 18 million US healthcare workers (HCWs) who rely on personal protective equipment (e.g., respirators, gloves, gowns, face shields, etc.) when exposed to a range of known and unknown occupational infectious agents (*CDC - Health Care Workers - NIOSH Workplace Safety and Health Topic*, 2020).

PAPRs use a battery-powered blower to force ambient room air through a filter, cartridge, or canister before supplying air to the wearer. The filter removes particles, vapors, gases, or a combination of these contaminants before they reach the ' 'wearer's breathing zone. Positive airway pressure respirators are available in tight-fitting half- or full-face pieces or a loose-fitting facepiece with a helmet or hood.

PAPRs provide a higher level of protection (assigned protection factor of APF = 25 or 1000) than the N95 FFR (APF = 10) because they supply maximally filtered air, eliminate face seal leakage, reduce breathing difficulty encountered in negative pressure air-purifying respirators, and provide contact protection for the head. They are also comfortable to use (especially for loose-fitting PAPRs) because the blower produces a cooling effect by forcing air into the mask. Loose-fitting PAPRs, unlike an N95 do not need to be fit tested to provide adequate protection, hence one of their advantages. In addition, the constant airflow provides a cooling effect on the user, the clear face shield will allow patients to see the worker's face, and they are reusable (Liverman *et al.*, 2015). Despite the added benefits, PAPRs are less common mainly due to their average cost of $768.20 vs. $1.50 for an N95 FFR (Liverman *et al.*, 2015). Added complaints include interferent with communication and mobility, required maintenance (i.e., charging batteries and cleaning), and inability to use a stethoscope. CDC primarily recommends the use of PAPRs for hospital first responders and in the event of a large-scale disaster or for an unknown biological/ chemical threat (CDC, 2014). Regarding an OR, CDC does not currently recommend the use of loose-fitting PAPRs, due to fear of contamination of the sterile field (CDC, 2014).

PAPRs are designed to protect the wearer but may not adequately filter the ' 'wearer's exhaled air. Currently, it is unknown if exhaled air may contribute to air contamination in the OR. To prevent exhaled air from contaminating the OR, some HCWs have chosen to wear a surgical mask under the PAPR; however, this is not a recommended practice by CDC. Current guidance from the National Personal Protective Technology Laboratory (NPPTL) and the Association of periOperative Registered Nurses (AORN) does not recommend the use of a PAPR in an OR due to a lack of scientific evidence to support safe usage and the possible contamination of the ' 'wearer's exhaled, unfiltered air onto the sterile field. (AORN Journal, 2015)

Currently, no data exist on how well reusable PAPRs maintain a sterile surgical field. This lack of data is a major concern for hospitals and will limit the adoption of reusable respirators in clinical practice. As PAPRs have not been approved for use in OR settings, perioperative team members often have to exercise caution when considering the use of PAPRs in the OR, weighing the risks of a surgical site infection from contamination of the sterile field or surgical wound versus the benefits to the health care ' 'worker's respiratory protection. The use of PAPRs in the surgical setting is an unresolved issue that requires further research.

There were two pilot experimental studies to compare the particle concentration in an OR with and without PAPRs being used due to the expense, time, and specialized facilities required. (Kim & Hale, 2017) conducted a pilot study to examine the use of a PAPR in the OR and found no discernable differences in the particulate counts at the surgical table when the PAPR-hood system was turned on or off (ranges: 1,700-1,850 particles/cm3). They concluded that the hooded PAPR did not increase particulate transfer to the surgical field. Grinshpun (2016) conducted another pilot study to simulate PAPR wearers in a simulated OR to assess the bacterial contamination of sterile field surfaces. He found that when comparing the respiratory and control groups per each agar plate location separately, there was no statistically significant difference in the mean contamination values associated with a specific agar plate location for either of the PAPR or N95 respirators tested. On average, the bacterial contamination of sterile fields by a pair of subjects operating in an OR-simulating facility while wearing either PAPRs or N95 respirators is significantly higher than that obtained in both negative control tests.

A recent study used computational fluid dynamics (CFD) modeling to simulate and visualize the distribution of particles exhaled by the PAPR wearer (Xu et al., 2019). In CFD simulations, the outward release of the exhaled particles, i.e., the ratio of exhaled particle concentration outside the

PAPR to that of inside the PAPR, was determined. The ratio of the exhaled particle concentration outside to inside the PAPR was found to be influenced by exhaled particle sizes, breathing workloads, and supplied-air flow rates. Outward concentration leakage from PAPR wearers was approximately 9% with a particle size of 0.1 and 1 μm at a light work rate and 205 L/min supplied-air flow rates. Supplied air flow rates and work rates were found to have a significant impact on outward leakage, i.e., the outward concentration leakage increased as particle size decreased, breathing workload increased, and supplied-air flow rate decreased.

The National Institute for Occupational Safety and Health (NIOSH) tests and certifies respirators, including PAPRs (*42 CFR Part 84 Respiratory Protective Devices | NPPTL | NIOSH | CDC*, 2020). There are two types of PAPR: 1) tight-fitting (full facepiece or half-mask facepiece) that is designed to seal to the face or neck, and 2) Loose-fitting (hood, helmet, or loose-fitting facepiece) that is designed to contact but not seal completely to the face or neck. The traditional NIOSH certification for PAPR filters is a silica dust loading test, which simulates a work condition found in industrial settings, primarily in mining. However, the workplace environments experienced by HCWs differ significantly from the industrial conditions, especially when it pertains to physical exertion when performing routine work activities. NIOSH is currently updating its certification standard to allow a new class of PAPRs for healthcare workers. More PAPRs may become available for healthcare workers, and the potential contamination question needs to be answered as soon as possible.

2.3. Microbial Air Contamination in the ORs

Basic science principles related to microbial air contamination are that microbes are dispersed into the air by personnel in the operating room and usually are carried on skin particles (Davies

& Noble, 1962). Contamination of surgical fields is a widely recognized cause of post-operative infections, and the dispersion of pathogens through the air is known as a cause of healthcare-associated infections ((Da Zhou et al., 2015), (Vincent & Edwards, 2016).

Current estimates indicate that infection occurs in 0.5% to 11% of surgeries, affecting the lives of thousands of patients each year (A report from the NNIS System, 2004).

It has been demonstrated that a correlation exists between airborne bacterial contamination and postoperative joint sepsis in joint arthroplasty surgery (Gosden et al., 1998). Microbial contamination of operating theaters is one of the most life-threatening sources of nosocomial infection for patients, most especially during transplant surgery, heart surgery, etc.(Madsen et al., 1985). There are multiple reservoirs reported to be responsible for contamination in the healthcare environment; they include unfiltered air, ventilation systems, antiseptic solutions, drainage of the wounds, transportation of patients and collection bags, surgical team, extent of indoor traffic, theatre gown, foot wares, gloves and hands, use of inadequately sterilized equipment, contaminated environment, and grossly contaminated surfaces (Fleischer et al., 2006). A study by Edmiston et al. evaluated microbial contamination in an operating room by means of air sampling. The study found coagulase-negative staphylococci in 51% of air samples and staphylococcus aureus in 36% of air samples within a half meter of the wound (Edmiston et al., 2005). Another study by Zhiqing et al. sought to determine how much contamination was present on a surgical mask after being worn. The study compares a surgical mask worn during procedures of varying lengths to that of a mask just sitting in an empty operating room. The bacteria levels were significantly higher for the worn mask compared to the unused mask, while the bacteria levels increased with time, starting at the two-hour time frame (Zhiqing et al., 2018).

The study recommends the changing of surgical masks at this point to help reduce the chance of infection.

While there are studies that indicate PAPRs effectiveness in protecting the user from airborne particulates and splashes, they do not address the extent that PAPRs may inhibit user-generated contamination from the air exhaled from affecting a sterile field or Operating Room (OR) surfaces.

Chapter 3: Methods

3.1. Study Summary

This study was conducted at the West Virginia Simulation Training & Education for Patient Safety (STEPS) center, at the West Virginia University (WVU), Ruby Memorial Hospital, Morgantown, WV. The STEPS center can be configured to simulate a typical OR room, as shown in figure 1. Two identical rooms were used. Each room had a volume dimension of 13.'5' x 13.'5' x '8' and had an air exchange rate (AER) of 25/hr. Eighteen patient care workers familiar with ICU/OR units were recruited from WVU Ruby Memorial Hospital. The choice of subject selection was based on the previous or current experience of working in ICU/OR units. The eighteen patient care workers were paired into nine teams. Each team was made to don six different RPDs while performing typical OR activities such as CPR and reading a rainbow passage to simulate talking.

Fig 1. A standard simulated Operating Room at the WVU STEPS center.

3.2. Room Information

Two identical rooms were utilized for the main testing at STEPS. Parameters such as the room size, the volume of air in cubic feet per minute (CFM), and air exchange rate (AER) were considered important for the OR simulation. While different existing ORs utilize different AERs depending on the age of the healthcare facility. Each room had a volume dimension of 13.'5' x 13.'5' x '8' and had an air exchange rate (AER) of 25/hr. Below is the information about the rooms and air exchange rate available.

Rm. #	Area Cu. Ft.	CFM	Existing ACH	Max. Cfm Avail.	Avail. ACH
3514	**1456**	**125**	**5.15**	**680**	**28**
3516	**1456**	**125**	**5.15**	**880**	**38**

3.3. Materials

3.3.1 Respiratory Protection devices

Negative pressure respirators:

- 3M model 9205+ N95 flat-fold filtering facepiece respirator (FFR),
- 3M model 8511 N95 cup-shaped FFR with exhalation valve,
- MSA Advantage 200 elastomeric respirator with exhalation valve, and
- Disposable surgical mask (Sultan Healthcare)

PAPRs:

- 3M Versaflo™ Healthcare PAPR Kit TR-300N+ HKL,
- Bullard EVA Powered Air Purifying Respirator (PAPR) System

Other materials

- Remel 5% Blood Agar (TSA with Sheep Blood) Plate

- 70% Isopropyl Alcohol from Decon Laboratories, Inc
- Microflex Nitrile gloves
- Ziploc bags
- Porta Count Pro+ from TSI
- Fisher Scientific Isotherm Incubator

3.3.2 Sampling Equipment

- Andersen 6 Stage Viable Impactor Sampling System by Tisch Environmental

Flow Rate:	28.3 lpm
Particle Size:	0.85 to 10µm and above

- Biostage Single-stage impactor by SKCinc (Required flow rate of 28.3l/min)
- QuickTake 30 (with programmable timer) Sample Pump with rotameter, Li-Ion battery pack, 110-240 V AC charger/adapter, cassette/tubing adapter, and tubing
  Flow range: constant flow 10 to 30 L/min

Fig 2. Pictures of the biostage single-stage impactor with the quicktake 30 pump and the andersen 6-stage viable impactor

3.3.3 Calibration and cleaning of devices

Both sampling devices pump were calibrated to 28.3l/min pre and post-testing. Cleaning and sterilization of apparel, the testing room, and equipment were done with a 70% solution of isopropyl alcohol.

3.4. Subjects Recruitment, Consenting and Medical Clearance

Eighteen healthcare workers from the WVU Ruby Memorial Hospital, Morgantown, WV were recruited for the main OR study. The choice of subjects was based on previous or active experience of working in healthcare or OR facilities. IRB approval with the consent number **(2009129419)** from the WVU Ruby Memorial Hospital was obtained before conducting the study. Subjects signed a consent form after a detailed explanation about the study was given and also filled out an OSHA questionnaire to determine their eligibility to wear all the respirators used for the study and were medically cleared (by Dr. Allen, co-investigator) before being allowed to participate in the study.

3.5. Fit Testing

The 18 subjects were fit tested for the two N-95 FFR and MSA Elastomeric half masks prior to the main testing. Fit testing was conducted using a Porta Count Pro+. Each N-95 FFR was prepared with an inlet so that the Porta Count could measure the concentration of particles in the respirator while the MSA uses a fit testing adapter to connect it to the Porta Count.

A NaCl particle generator was used to produce aerosol for respirator fit testing. Once everything was set up adequately, the instructions on the Porta Count were followed. Each fit test involved the following tasks.

- Normal breathing

- Deep breathing
- Head side to side
- Head up and down
- Talking
- Bending over
- Normal breathing

An overall fit factor of 100 or more had to be achieved to pass. All subjects needed to be trained to don the respirator and had to pass the fit test before they could participate in the main testing. The fit testing data can be referred to in the table section with the team composition.

3.6. Experimental Procedures

The operating room activities involve teams of people (surgeon, charge nurse, anesthesiologist, etc.). The minimum number of people on an OR team is two. To statistically handle data analysis on teams of 2 that stayed together for testing all the respirators, a randomized block design blocking on the subject and randomizing the RPDs was used. To reduce the chance of bacteria becoming airborne from non-respiratory sources, each team member wore a full-body Tyvek suit with hood and nitrile gloves over their street clothes and shoes. Pictures of each RPD while being worn are provided in Figures 11-16. The order of testing of the six RPDs was randomized for each team. In previous studies, a settled plate method was used to sample for CFU (Church, 2019), (Grinshpun et al., 2016). These studies reported very low CFU counts. Most likely, the CFU counts observed were the result of larger particles settling on the agar plates. Particle mechanics calculations of settling times for unit density spheres indicates that the time to settle 5 ft ranges from ≈41 hrs. for a 0.5μm particle to ≈8 minutes for a 10μm particle. As a result, active biological sampling was chosen as the sampling method for this study.

Active sampling of airborne bacteria was done using the Biostage Single-stage Impactor by SKC Inc. Eighty-four, PA and the N-6 Andersen Viable Cascade Impactor (Tisch Environmental Inc., Cleves, OH.). Both types of impactors were sampled at an airflow rate of 28.3 LPM. The pumps connected to the impactors were calibrated with a flowmeter pre and post-sampling to a flow rate of 28.3LPM. Also, the minimum flowrate of each PAPR was verified according to each ' 'manufacturer's instructions.

Figure 8 shows a schematic diagram of ' 'participant's placement during testing. Each team member, wearing the same model of respirator, stood on each side of a manikin positioned on an operating bed. One team member (L1) performs full chest compression CPR for 4 minutes on the manikin while the other team member (L2) reads the """"rainbow passage"""" or engages in conversation. After 4 minutes, both participants rest for 1 minute, then flip position on their side of the bed so they can switch activities.

Five of the SKC Biostage Single-stage impactors and one N-6 Andersen Viable Cascade Impactor were positioned on each side of the bed at three locations from the head of the bed, 1, 3, and 5 ft. The six-stage Andersen impactor (S1) was always located at the 1ft location. One of the single-stage impactors (S2) was also located at the 1 ft location. Single-stage impactors, (S3) and (S4) were positioned at 3ft from the head of the bed. Single-stage impactor, (S5) and (S6) was also positioned at 5ft from the head of the bed as shown in Figure 9. All sampling devices ran for 15 minutes at 28.3 LPM.

Background concentration levels of airborne bacteria serving as negative controls were measured in each OR before each test sequence. The background data for the nine teams can be found in the Appendix section. Due to COVID-19 guidelines involving the use of human participants in

research, a positive control in which background concentration levels of airborne bacteria was measured when subjects wore no respirators could not be conducted.

Given, we had nine teams, six RPDs, and three sample locations from the head of the bed (samplers at the same position were averaged), a total of 162 airborne samples were collected.

The blood agar Petri plates were incubated at 37°C for 48 hours. After 48 hours, the number of CFU was counted on each plate and converted to a concentration of CFU/m^3 following the procedure below.

Flow rate = **a** L/min. (28.3L/min)

Sampler running time = **b** minutes (15 minutes)

Volume of air sampled = **a** x **b** L = **ab**/1000 m^3 = **d** m^3

Bacterial or mold count = **c** CFU

Total CFU/m^3 air sampled = **c**/**d** CFU/m^3 air

The independent variables are respirator types and sample locations(distance) on the operating table. The dependent variable was the concentration of colony-forming units, CFU/m^3. The six RPDs tested (SM, 3M 9205+, 3M 8511, MSA, B-PAPR, V-PAPR) were tested in a randomized order.

Table 1. Respiratory Protection Devices evaluated

Negative Pressure RPD	**SM**	1. Medical grade Cardinal Health Surgical mask
	3M 9205+	2. 3M model 9205+ N95 flat fold FFR without exhalation valve
	3M 8511	3. 3M model 8511 N95 cup-shaped FFR with exhalation valve
	MSA	4. MSA Advantage 200 elastomeric respirator half mask with exhalation valve
PAPRs	**B-PAPR**	5. Bullard EVA Powered Air Purifying Respirator (PAPR) System
	V-PAPR	6. 3M Versaflo™ Healthcare PAPR Kit TR-300N+ HKL

3.7. Data Analysis

Adapting a global significance level of 5% and power of at least 80%, the required sample size was estimated to be two individuals per team (total of 9 teams) using six types of RPDs with sample collection at 3 locations (162 in total). A randomized block design was used in which each group participant wore one of six randomly assigned respirators to avoid habituation bias and no order effect to develop a statistical model that did not violate the assumption of independence between observations. The team composition was treated as part of the research design and as a background variable, while the RPDs and distances are the independent variables generating a response CFU counts (CFU/m^3). Statistical analyses were performed using IBM SPSS with Generalized Linear Model). Mean Colony-forming unit in CFU/m^3 for Respirator Types (SM, 3M 9205+, 3M 8511, MSA, B-PAPR, V-PAPR) and Distance (1ft,3ft and 5ft) were estimated.

3.8. Generalized Linear Model with Categorical Variables and it's assumptions

A Generalized Linear model analysis in IBM SPSS was performed on the dependent variable Mean Colony-forming unit in CFU/m^3 to test the effects of respirator types and sampling distances (categorical variables) at the significance level of $P \leq 0.05$.

Model :

$Y = \alpha + \beta_1 X + \beta_2 Y + \mathcal{E}$

Y – Effect of response, CFU/m^3

α – Mean of CFU/m^3

$\beta_1 X$ – Effect of treatment, Respirator types

$\beta_2 Y$ – Effect of treatment, Distance

$\mathcal{E}$ – Residual effect

The observations are assumed to be independent and the resulting distribution of the collective individual CFU/m^3 deviated from normality (Shapiro-Wilk <0.05) and took the form of a non-negative, positively skewed, integer distribution.

Using a regression analytical framework to estimate the mean difference in CFUm^3 between the Respiratory protection devices, the fit of a Poisson distribution was examined in relation to the Normal distribution. Consistent with the visual appearance of the data and the results of the Shapiro-Wilk test, the Poisson distribution was found to provide a better fit through ' 'Akaike's Information Criterion, Bayesian Information Criterion, and log-likelihood values.

Multivariate Poisson regression was used to examine differences in mean colony-forming unit among the respirator types in relation to demographic characteristics, including the categorical

variables distance (1ft, 3ft, 5ft), categorical Respirator Type (SM, 3M 9205+, 3M 8511, MSA, B-PAPR, V-PAPR) were estimated.

The mean colony-forming unit concentration, CFU/m^3 was calculated for each of the respirators,surgical mask and aligned with each of the distances in the dataset using a categorical variable. These categorical variables were entered into the regression models with the 1ft and the SM as the reference input. This allowed for the comparison of the CFU/m^3 at each of the other categorical levels; distances (3 ft and 5 ft) and respirator types (3M 9205+, 3M 8511, MSA, B-PAPR, V-PAPR) with the reference input of 1ft and SM respectively. A post hoc Bonferroni pairwise comparison was also entered in the context of Poisson regression to do side by side comparison to see if there is a significant difference between the CFU/m^3 at the distance of 3ft and 5 ft and between all the other Respirator Types, to determine their statistical significance. Wald $\chi 2$ p-values <0.05 were considered statistically significant.

Chapter 4: Results and Discussion

Eighteen participants were recruited into nine teams of two. The test of model effects (Omnibus test) in Table 2 showed a significant effect with distance and respiratory protection devices. This means that the concentration of CFU/m^3 significantly varies as a function of distance and as a function of respirator types. Total mean CFU/m^3 at distances of 1ft, 3ft, and 5ft were 10.4, 8.9, and 8.8, respectively. The total mean CFU/m^3 for respirator type; SM, 3M 9205+, 3M 8511, MSA, B-PAPR, V-PAPR were 7.9, 8.9, 11.7, 11.4, 7.8, and 8.9, respectively.

The percent difference, exp(B), at the distance of 3ft is 0.86 and 0.85 at the distance of 5ft. This means that 86% and 85% of CFU/m^3 are expected at the distance of 3ft and 5ft respectively when compared to the distance of 1ft or a 14% and 15% average decrease at 3ft and 5ft respectively compared to 1ft. Also, exp(B), for respirator type are as follows: 3M 9205+ (1.13), 3M 8511(1.48), MSA (1.44), B-PAPR (0.99), V-PAPR (1.13). This means that compared to the SM, an average increase of 13% in the CFU/m^3 concentration is expected when using the 3M 9205+, an average increase of 48% in the CFU/m^3 concentration when using the 3M 8511, an average increase of 44% in the CFU/m^3 concentration when using the MSA elastomeric respirator, an average decrease of 1% in the CFU/m^3 concentration when using the B-PAPR and an average increase of 13% in the CFU/m^3 concentration when using a V-PAPR. As reflected in Table 3, all comparisons were significant for the effect of distance and for respirator types 3M 8511 FFR and MSA elastomeric respirator, both of which have exhalation valves. No significant difference was observed between the CFU/m^3 concentration resulting from the use of the SM and the 3M 9205+ FFR without exhalation valve, the B-PAPR, and the V-PAPR respirators. Table 4 shows a post hoc Bonferroni adjusted pairwise comparisons between the respirator types that was not

answered with the regression table using a reference input. There is a significant difference in CFU/m^3 between the 3M 9205+ FFR without exhalation valve and the 3M 8511 FFR with exhalation valve, but none of the other respirator types. The CFU/m^3 produced while wearing the 3M 8511 FFR with exhalation valve was not significantly different from the MSA elastomeric respirator with exhalation valve, but it was significantly higher than with the 3M 9205+ FFR without exhalation valve, the B-PAPR, and the V-PAPR. The concentration of airborne bacteria resulting from wearing the MSA elastomeric respirator with exhalation valve was significantly higher than the concentration of airborne bacteria resulting from wearing the B-PAPR; however, it was not significantly different from all the other respirator types. The CFU/m^3 concentration resulting from using the B-PAPR, was significantly lower than the CFU/m^3 concentration resulting from using the exhalation valved 3M 8511 FFR or the MSA elastomeric respirators; however, there was no significant difference in the CFU/m^3 concentration resulting from using the 3M 9205+ FFR without exhalation valve or the V-PAPR respirators. The CFU/m^3 concentration resulting from using the V-PAPR, was significantly lower than the CFU/m^3 concentration resulting from using the 3M 8511 FFR with exhalation valve; however, the CFU/m^3 concentration resulting from using the V-PAPR, was not significantly different than the CFU/m^3 concentration resulting from using all the other respirator types.

Table 2. Tests of Model Effects

Source	Type III		
	Wald Chi-Square	df	P-Value
(Intercept)	7410.09	1	0.000
Distance	8.8	2	0.012
Respirator Type	41.0	5	0.000
Dependent Variable: CFU/m^3 Model: (Intercept), Distance, Respirator Type			

Table 3. Mean CFU/m^3 at different distances as compared to 1ft and for different respirator types compared to the surgical mask

Parameters	Mean CFU/m^3	Std. Error	95% Wald Confidence Interval Exp(B)			
			Lower	Upper	P-Value	Exp(B)
Distance						
1ft	10.4					1
3ft	8.9	0.06	0.76	0.97	0.02	0.86
5ft	8.8	0.06	0.75	0.96	0.01	0.85
RPDs						
SM	7.9					1
3M 9205+	8.9	0.09	0.94	1.36	0.19	1.13
3M 8511	11.7	0.09	1.24	1.76	0	1.48
MSA	11.4	0.09	1.21	1.72	0	1.44
B-PAPR	7.8	0.1	0.82	1.19	0.88	0.99
V-PAPR	8.9	0.09	0.94	1.36	0.19	1.13

Table 4. Post hoc Bonferroni adjusted pairwise comparison of mean CFU/m^3 concentration between respirator types

Pairwise Comparisons						
Respirator Type		Mean Difference (I-J)	Std. Error	Bonferroni Sig.	95% Wald C. I	
					Lower	Upper
3M 9205+	V-PAPR	0.0	0.81	1.00	-2.38	2.38
	MSA	-2.5	0.87	0.06	-5.02	0.07
	B-PAPR	1.1	0.79	1.00	-1.16	3.45
	3M 8511	-2.7[a]	0.87	0.03	-5.29	-0.17
3M 8511	V-PAPR	2.7[a]	0.87	0.03	0.17	5.29
	MSA	0.3	0.92	1.00	-2.45	2.97
	B-PAPR	3.9[a]	0.85	0.00	1.39	6.37
	3M 9205+	2.7[a]	0.87	0.03	0.17	5.29
MSA	V-PAPR	2.5	0.87	0.06	-0.07	5.02
	B-PAPR	3.6[a]	0.84	0.00	1.15	6.09
	3M 9205+	2.5	0.87	0.06	-0.07	5.02
	3M 8511	-0.3	0.92	1.00	-2.97	2.45
B-PAPR	V-PAPR	-1.1	0.79	1.00	-3.45	1.16
	MSA	-3.6[a]	0.84	0.00	-6.09	-1.15
	3M 9205+	-1.1	0.79	1.00	-3.45	1.16
	3M 8511	-3.9[a]	0.85	0.00	-6.37	-1.39
V-PAPR	MSA	-2.5	0.87	0.06	-5.02	0.07
	B-PAPR	1.1	0.79	1.00	-1.16	3.45
	3M 9205+	0.0	0.81	1.00	-2.38	2.38
	3M 8511	-2.7[a]	0.87	0.03	-5.29	-0.17
Pairwise comparisons of estimated marginal means based on the original scale of dependent variable Rounded CFU						

[a] Means with the same superscript are not significantly different at the .05 level.

4.1. Particle size Analysis

The bioaerosol samples collected with the six-stage Viable Cascade Impactor were used to determine the aerodynamic diameter of the bioaerosol exhaled from each respirator type. With the nine teams, we had 9, six-stage Viable Cascade Impactor samples collected on each respirator type. These agar plates were handled and incubated as the single-stage agar plates. The geometric mean (GM) and geometric standard deviation (GSD) calculated for each respirator type are given in Table 5, and the cumulative distribution from the exhaled breath resulting from wearing each respirator type are plotted in Figure 2.

Table 5. Aerodynamic Diameter GM and GSD for exhaled breath aerosol while wearing different respirator Types.

Respirator Type	Geometric mean (GM) aerodynamic diameter	Geometric Standard Deviation (GSD)
Surgical Mask	6.0	2.83
3M 9205+	8.0	3.50
3M 8511	6.4	2.96
MSA elastomeric half-mask	7.2	3.30
B-PAPR	9.8	3.67
V-PAPR	4.3	2.79

Discussion

This study measured the CFU/m^3 concentration of airborne colony forming bacteria resulting from the use of different types of respirators, as compared to a typical surgical mask, when used in a simulated operating room environment with users doing CPR and talking activities. The results of the experiments revealed that on the average, the airborne bacterial shedding in the sterile field of an operating room by a pair of subjects wearing PAPRs, with different assigned protection factors of 25 and 1000, does not significantly increase the bacterial concentration of

the sterile field when compared to the use of a surgical mask, which is the standard face-covering commonly employed in surgical room settings. The data revealed that the mean CFU/m^3 concentration resulting from using a SM is not statistically significantly different from the mean CFU/m^3 concentration resulting from using an N95 FFR without exhalation valve, the loose-fitting facepiece B-PAPR (APF = 25), or the full facepiece V-PAPR (APF= 1000). However, the N95 FFR with exhalation valve and the elastomeric half mask with exhalation valve generated statistically significantly higher CFU/m^3 concentrations than the SM, N95 FFR without exhalation valve, B-PAPR (APF of 25), or the V-PAPR (APF of 1000).

The volume of air exhaled by wearers of a PAPRs is simply diluted by the airflow minute volume of the PAPR, which must be a minimum of 170LPM for certification by NIOSH. The diluted exhaled volume is then released into the surrounding environment. Based on this operational feature, it would be expected that the PAPRs would generate more exhalation-associated bacterial contamination than wearers of the N95 FFR. However, the results of this study found that the airborne concentration of CFU/m^3 resulting from using either of the tested PAPR models did not significantly differ from the airborne concentration of CFU/m^3 resulting from using the N95 FFR respirator without an exhalation valve or the typically used SM. This result might be explained if the CPR and talking activities used in the simulated OR caused increased face seal leakage with the tight-fitting N95 FFR without exhalation valve or the loose-fitting SM, particularly during the exhalation cycle.

The data also revealed that the N95 FFR with exhalation valve generates significantly more bacterial contamination of the sterile field than the N95 FFR without an exhalation valve. No significant difference was found between the PAPR with an APF of 25 versus the PAPR with an APF of 1000.

A positive control, measuring the concentration of CFU/m^3 from test participants without wearing any respirator, could not be done due to COVID guidelines from the of WVU IRB restricting the use of research participants without wearing face covering. We believe an inclusion in future study would be beneficial because it helps refine the study methodology and allows for an independent database on the OR sterile field bio-contamination by unprotected healthcare workers. Other RPDs models can also be tested to see if there is any correlation with the RPDs used in this study.

The cumulative distribution plots indicated that 10% of the size of the exhaled breath bioaerosol was below approximately 1.6 µm with the SM, the 3M9205+, the 3M 8511, and the MSA Advantage 200 elastomeric respirators, while with the B-PAPR it was approximately 1.9 µm and for the V-PAPR it was 1.2 µm. The particle size data suggest that while wearing one of the respirator types used in this study, very little exhaled breath bioaerosol from these devices is smaller than about 1.5 µm (Figure 10). This could be a lower limit to the exhaled breath particle size. It should also be pointed out that it could also indicate that even with using active sampling and two test participants over a 15-minute test time, that particles below 1.5 µm were not in sufficient number or 'didn't have time to settle sufficiently to be sampled with the active samplers.

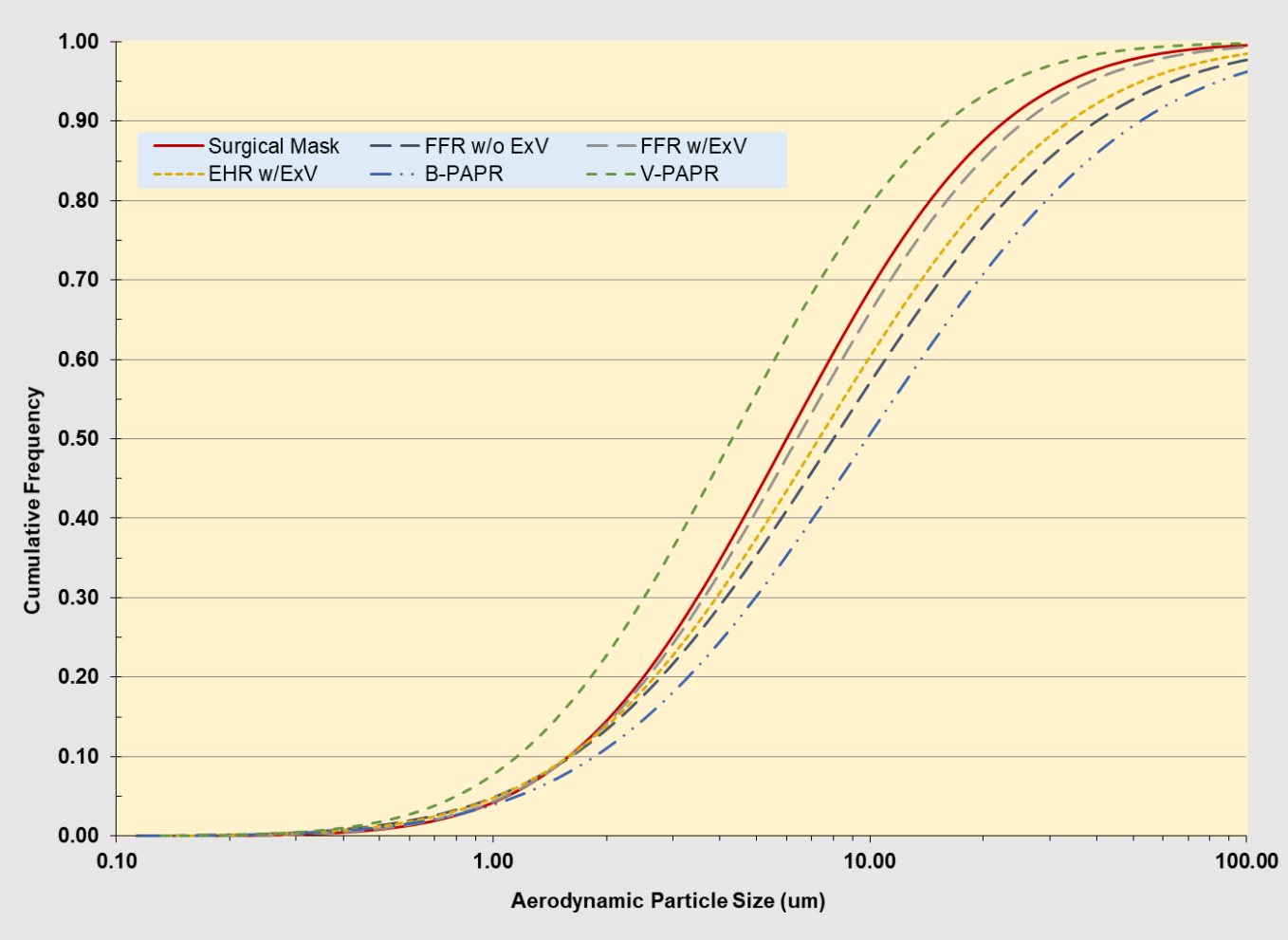

Fig 3. Exhaled Particle Distribution Produced While Doing CPR and Talking While Wearing Different Types of Respirators.

Chapter 5: Conclusion

The bacterial contamination of the sterile field by a pair of subjects wearing N95 FFR without exhalation valves, loose-fitting facepiece PAPRs or a full facepiece PAPRs was not significantly different from wearers of the SM. The N95 FFR with exhalation valve and EHMR with exhalation valve were found to generate significantly higher bacterial contamination of the sterile field than the SM, the N95 FFR without exhalation valve, or the two PAPRs. The airborne bacterial concentration resulting from using the N95 FFR with exhalation valve or the EHMR with exhalation valve were not significantly different. No significant difference was found in contamination between the PAPR with a loose-fitting oralnasal covering (APF=25) and the PAPR with hood and shroud (APF=1000).

This study found that using a SM, N95FFR without EV, and PAPRs equipped with loose-fitting oralnasal covering or hood and shroud resulted in equivalent levels of bacterial contamination of a sterile field. The benefits of a PAPR during an emergency or crisis can be invaluable, especially one that requires no fit testing to be completed. This research suggests that a PAPR could be used in a sterile field area such as an OR and not lead to bacterial contamination greater than what would occur with a SM . This is an important finding especially during a pandemic when PPE such as N95 FFRs may be in short supply., Another viable option, requiring more testing would be to evaluate new designs of EHMRs not equipped with an EV. The findings of the research may be used for future research purposes and have the potential to foster more controlled experimental research that is vital to understanding and improving the use of different types of respirators used by HCWs in healthcare settings.

Limitations, Overall Conclusions, and Future Directions

Limitations

There are still some limitations in this study.

1. Due to COVID-19 guidelines involving the use of human participants in research, a positive control, in which background concentration levels of airborne bacteria was measured when subjects wore no respirators, could not be taken.
2. Aerodynamic particle size evaluation of the bacteria shed from the test participants indicate that only a small percentage of particles were as small as virus size particles. Sampling for actual virus particles was not done because of the extensive means required to grow them so they could be counted. Therefore applying conclusions and findings made with airborne size bacteria to actual virus particles needs to carefully considered.

Due to the limited number and variety of tasks assessed in this study, it is important to not over-interpret the study findings to the broader list of HCW activities in sterile field areas such as ORs and ICUs.

Overall Conclusions

In summary, the data reported in this dissertation addresses the issue of bio-contamination of the sterile field in the operating room resulting from HCWs, using different types of RPD as compared to the common, medical grade SM. The information from the study could also served as guidance for respirator manufacturers, regulatory agencies, and respiratory protection researchers when designing, certifying, and testing respirators to be used in the healthcare environment. RPD have often been studied as an exposure control for workers in many industrial applications. In this use application however, the RPD must be evaluated as a source control limiting bacterial-contamination from the exhaled air of the RPD wearer to a

sterile field environment, such as an OR, or a patient. It is a unique role for the RPD to be evaluated as both a source control and as an exposure control. In these types of roles, the RPD selection criteria must consider the RPD's ability to protect the HWC using it for their personal protection as well as to protect the patient from the exhaled air of the HWC wearing the respirator.

Future Directions

The following five main directions are to be considered for the future research efforts:

1. If allowable by IRB human participant review board, testing should include a positive control to determine bacterial shedding rates when subjects are not wearing a RPD.
2. Additional testing should be done to include new designs of EHMR not equipped with an exhalation valve, or EHMRs equipped with device to filter exhaled breath.
3. A teams of more than 2 subjects should be used to see if there is increase in contamination with more people in the OR sterile field.
4. Additional evaluation to determine if different task activities covering light, medium and heavy minute volumes affects bacterial shredding rates.
5. Additional evaluation of appropriate sampling times should be done to confirm the suitability of the 15 minute sample time used in this study.

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FIGURES

Fig. 4 – Medical Grade Surgical Mask

Fig. 5 – 3M N95 8511 cup-shaped respirator (external and internal)

Fig. 6 – 3M N95 9205+ flat-fold respirator (External and internal)

Fig. 7 – MSA Advantage 200LS elastomeric half-mask respirator (External and Internal)

Fig. 8 – Bullard EVA Powered Air-Purifying Respirator with Loose Fitting Hood

Fig. 9 – 3M Versaflo TR-300 TR-300N +ECK PAPR Assembly kit with headpiece

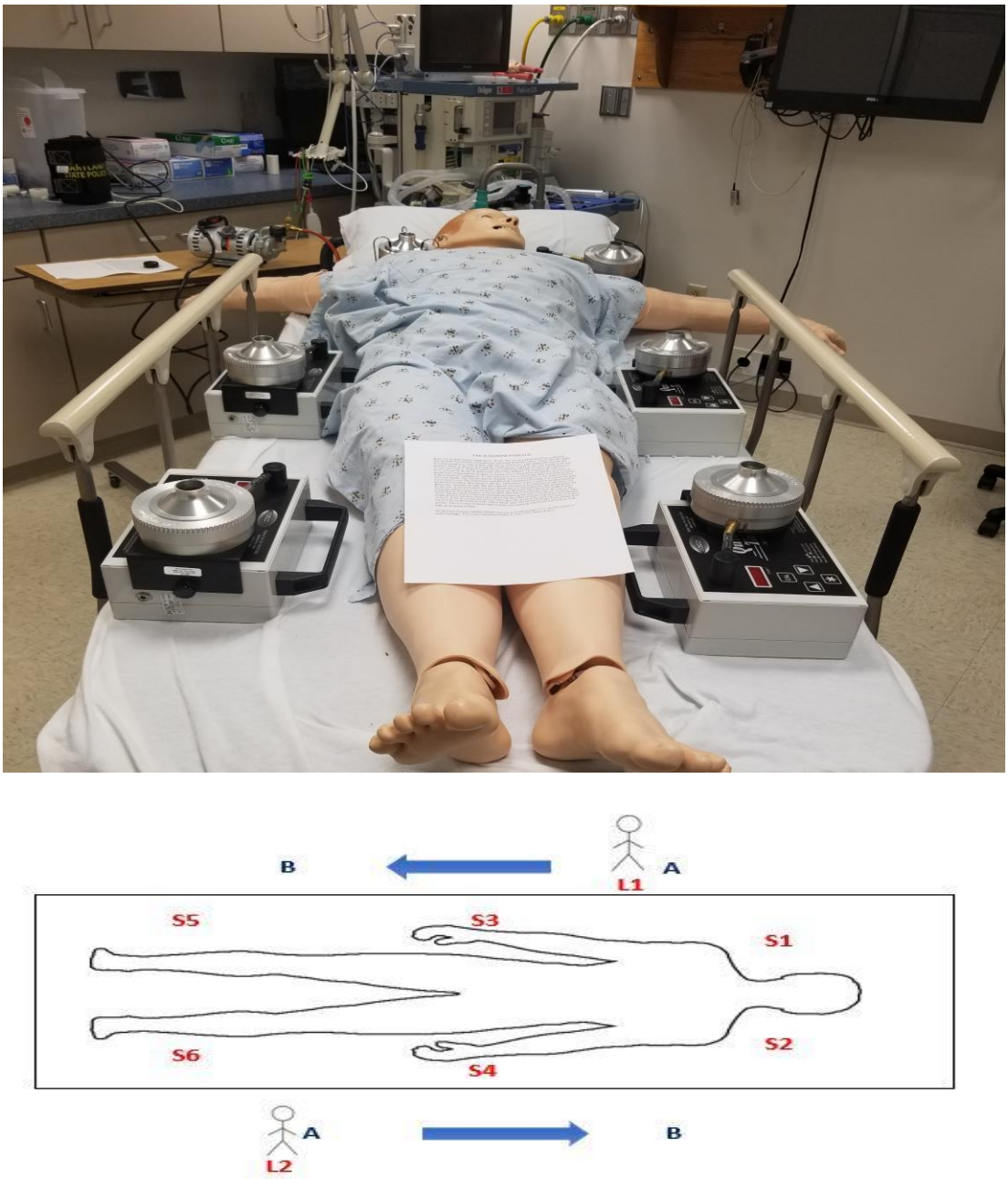

Fig. 10 - Sampling Devices and subject placement around the patient simulated manikin

Fig. 11 – Participants wearing surgical mask(SM) and performing simulated activities

Fig. 12 – Participants wearing 3M N95 9205+ and performing simulated activities

Fig. 13 – Participants wearing 3M N95 8511 and performing simulated activities

Fig. 14 – Participants wearing MSA half mask (EHMR) and performing simulated activities

Fig. 15 – Participants wearing Bullard EVA PAPR and performing simulated activities

Fig.16 - Participants wearing 3M Versaflo PAPR and performing simulated activities

TABLES

Table 6. Participants Gender, Age, Height, Average Age, Average Weight and Average Height

Team	Gender	Age	Weight (lbs)	Height(cm)	Avg Age	Avg. Weight	Average height
1	M	35	340	170			
1	M	24	142	178	29.5	241	174
2	F	30	130	163			
2	F	24	140	168	27	135	165.5
3	M	35	185	191			
3	M	41	250	191	38	217.5	191
4	M	48	225	183			
4	F	40	200	165	44	212.5	174
5	F	29	148	160			
5	F	29	104	155	29	126	157.5
6	F	23	125	163			
6	F	23	125	155	23	125	159
7	F	26	160	165			
7	F	42	148	163	34	154	164
8	M	29	200	180			
8	F	23	160	185	26	180	182.5
9	M	49	280	191			
9	M	22	280	198	35.5	280	194.5

Table 7. Participants fit testing overall fit factor results

Overall Fit Factor			
Team No	**3M N95 8511(100)**	**3M N95 9205+(100)**	**MSA (100)**
T1	194	200+	Passed(M)
T1	200+	200+	Passed(M)
T2	200+	200+	Passed(M)
T2	200+	200+	Passed(S)
T3	200+	200+	Passed(M)
T3	200+	200+	Passed(M)
T4	200+	200+	Passed(M)
T4	200+	200+	Passed(S)
T5	128	200+	Passed(S)
T5	163	142	Passed(M)
T6	192	169	Passed(S)
T6	181	200	Passed(M)
T7	200+	200+	Passed(M)
T7	200+	200+	Passed(M)
T8	195	136	Passed(M)
T8	200+	143	Passed(M)
T9	200+	141	Passed(M)
T9	200+	200+	Passed(M)

Table 8. Background Airborne CFU/m^3 for each of the Nine Teams of study participants

Team	Background CFU/m^3 levels
1	1.8
2	1.2
3	0.6
4	3.3
5	6.2
6	3.3
7	1.8
8	6.5
9	3.0