Analysis of Respiratory Program Practices

and Simulated Workplace Protection Factor Studies

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THESIS

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LIST OF ABBREVIATIONS

ANOVA	Analysis of Variance
APF	Assigned Protection Factor
ATD	Aerosol Transmissible Disease
BVA	Bivariate Analysis
CBRN	Chemical, Biological, Radioactive, and Nuclear
CDC	Centers for Disease Control and Prevention
CNC	Condensation Nuclei Counter
CPR	Cardiopulmonary Resuscitation
ESC	Electrostatic Classifier
FF	Fit Factor
FFR	Filtering Facepiece Respirator
GM	Geometric Mean
GSD	Geometric Standard
IV	Intravenous
LCL	Lower Confidence Limit
MB	Making Bed
NIOSH	National Institute for Occupational Safety and Health
OSHA	Occupational Safety and Health Administration
PAPR	Powered Air Purifying Respirator
PCA	Principal Component Analysis
PHLCP	Physician or Other Licensed Health Care Professional
PPE	Personal Protective Equipment
QNFT	Quantitative Fit Test
REACH I	Respirator Evaluation in Acute Care California Hospitals
REACH II	Respirator Evaluation in Acute Care Hospitals
RMCC	Royal Military College of Canada
RPP	Respiratory Protection Program
SWPF	Simulated Workplace Protection Factor
UCL	Upper Confidence Limit

VEM	Video Exposure Monitoring
WPF	Workplace Protection Factor

SUMMARY

A well-designed and implemented respiratory protection program can help reduce unavoidable exposures to harmful biological and chemical agents in workplaces. A successfully deployed respiratory protection program will have many moving elements that require constant vigilance to ensure the program is optimally functioning. Consequently, a well-informed program administrator is an essential element of a successful respiratory protection program.

The program administrator is responsible for ensuring all requirements of the respiratory protection program are met. Two key elements in a respiratory protection program are a comprehensive written program and annual fit testing. The written program describes all ways a given company will comply with the OSHA standard. Fit testing ensures that employees are afforded a specific level of protection by their respirator.

In the comparison of written programs and self-reported respiratory protection practices (chapter II) it was found that many acute care hospitals were lacking two crucial elements in their respiratory protection program: a program administrator and a comprehensive risk assessment. Most hospitals had not designated a single person as the program administrator; thus, we found either overlaps or gaps in program element responsibilities. Because hospitals represent a complex environment with a range of potential biological and chemical exposures, a properly trained program administrator is crucial to ensure all employees receive the correct level of respiratory protection and know when, where and how it should be worn.

In healthcare, a risk assessment is often difficult because very little is known regarding the transmissibility of infectious organisms. Healthcare facilities typically apply public health

guidelines from state or local departments of health and the Centers for Disease Control and Prevention (CDC) to determine when respiratory protection is necessary and for whom. For infectious disease exposures, CDC primarily relies on the 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings and the 2005 Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health-Care Setting (1, 2). The Federal Occupational Safety and Health Administration (OSHA) does not currently have a standard addressing worker exposures to biological infectious disease agents. Only in California, which has a state-run OSHA program, is there an Aerosol Transmissible Disease (ATD) standard explicitly requiring the use of respirators for airborne or droplet infectious organisms, as defined by the CDC (3).

We found that most acute care hospitals choose to use N95 filtering facepiece respirators (FFRs) for exposures to infectious diseases (in particular, tuberculosis) and appear to be conducting annual fit testing as required by the OSHA Respiratory Protection Standard (4). Thus, I decided to focus my research efforts on better understanding respirator fit of this type of respirator for healthcare workers. Most studies of fit have been conducted in industrial settings or with production work activities, which differ from healthcare settings in both work rate and nature of tasks. There are many obstacles to studying respirator fit in real-world healthcare settings; thus, I decided to focus my efforts on identifying representative surrogates for healthcare tasks and workplaces.

For many years it has been the practice to evaluate respirator fit for an individual wearer using a mandated set of eight exercises that are thought to represent typical head and body motions that could adversely impact the seal of a respirator facepiece against the face (4, 5). It is not known, however, whether this set of exercises is indicative of the “true” protection afforded

by a respirator during work. One strategy has been to conduct workplace protection factor studies which measure, over the course of a typical workday, the protection level of a respirator worn by employees while performing their daily activities. These studies have generally been conducted in large, dusty industries, comparing 8-hr gravimetric personal samples from inside the respirator facepiece and outside in the ambient environment (6–9).

These workplace protection factor studies require high particle concentrations and would not be feasible in healthcare settings, where particle concentrations are low and there are no personal sampling methods available for long-term sampling of infectious organisms. Another limitation is that these studies do not offer any insight into which job activities are responsible for loss in respirator fit.

Thus, my work has been motivated by the need for new methods that can measure lower particle concentrations, as well as identify specific motions or tasks that cause significant changes in fit. Based on work by Hauge et al. (2012) and others, I decided to explore whether a real-time method for measuring respirator fit coupled with more realistic work tasks and video imaging, could prove useful for eventual workplace protection studies in healthcare settings (10, 11). This new real-time methodology uses two respirator fit-test instruments (TSI Portacounts) simultaneously measuring second-by-second concentrations inside and outside of the respirator facepiece.

To conduct these studies, it was first important to demonstrate that the real-time two-instrument method would yield fit factors similar to those measured using just one instrument, as is typically done during annual quantitative respirator fit testing. I recruited 16 subjects to perform two fit tests, in random order, to compare the traditional single instrument method (as

described by OSHA) and the other using the new two-instrument real-time approach (chapter III) (4). My results showed that the two approaches differed only in the second half of the fit test, after the grimace exercise. Further data analyses showed that this was the case; thus, I concluded that the two methods yield similar results, allowing me to continue to use the real-time two-instrument method for further experiments with healthcare tasks.

It appears that the grimace exercise, as expected, causes the respirator to dislodge and then reseat. However, the manner in which the respirator reseats on the face is not consistent from one grimace to the next. For the purposes of this experiment, the grimace exercise introduced additional variability and should not have been included in the protocol.

I then conducted two experimental studies with subjects wearing N95 FFRs to examine the relationship between the fit received during a set of standardized exercises and respirator fit when performing simulated workplace activities (chapters IV and V). The first-responder study used many activities requiring full body motions, such as running on a treadmill, crawling on hands and knees, or climbing ladders, while the healthcare study used three simpler motions such as making a bed or conducting an ultrasound examination. Both studies found that respirator fit was specific to the person performing the activity and less specific to the activity itself. When data for all subjects were combined there was little change in the average fit of the respirator by activity.

A key difference between all of these studies was their use of different fit-test exercises for different time periods. My work comparing the two sampling methods employed the traditional US OSHA eight-exercise protocol (normal breathing, deep breathing, head side-to-side, head up-and-down, talking, grimace, bending over, and normal breathing), which has

subjects perform each exercise for 60 seconds (including purge time to switch between ambient and inside mask sampling) for a total of seven minutes overall. The grimace is only performed for 15 seconds and is not used in calculating an overall fit. My study of healthcare tasks used a fast fit test, which includes only five exercises (normal breathing, bending over, head side-to-side, head up-and-down, and talking) each performed for 30 seconds for a total of two and a half minutes; all of the data are used to calculate an overall fit factor (FF). The fast fit test was shown by Richardson et al. (2014) to be equivalent to the traditional OSHA fit test (without a grimace exercise). Finally, the study involving emergency responders included a fit test that followed a Canadian protocol, which includes seven exercises (does not include final normal breathing) each performed for 30 seconds for a total of two and a half minutes.

This body of research did not compare the longer OSHA protocol quantitative fit test (QNFT) to simulated workplace protection factors (SWPFs) in either of my workplace studies with first-responder and healthcare worker tasks, but it is expected that the longer fit test would be significantly correlated to the SWPF because the work of Richardson et al. (2014) demonstrated that the fast fit test produces the same FFs as the eight-exercise OSHA protocol (12).

The first-responder tasks were very different in number, physiologic demand, and length from those used in the healthcare scenario. What is most interesting, however, is that in both studies each person's initial fit test is predictive of their fit achieved during workplace activities. Both studies repeated the set of workplace activities at least two times, allowing us to examine overall trends in fit between activities. In both studies it was found that the first and second repetition had similar median values but the second or third repetition showed an increase in variance. During the first-responder experiment, when examining a single subject, the repetition

showed us specific activities where the respirator failed. This was not observed during the healthcare worker study. Although at least one of the selected healthcare tasks required fairly vigorous activity (performing cardiopulmonary resuscitation), this activity and the making-bed activity produced similar FFs while the ultrasound activity produced higher FFs.

The new two-instrument methodology opens the way to exploring aspects of respirator fit that have heretofore been difficult to study. For example, while a FF using a limited set of head and body motions appears to be representative of respirator performance during simulated work activities, little is known about the effects of redonning the same respirator or another respirator of the same make and model.

We also don't know whether infrequent donning impacts a person's ability to properly don a respirator without assistance. During this research respirator donning was carefully monitored. In the real world, however, employees typically receive no regular monitoring for proper donning. In settings where respirators are only rarely worn, employees may more easily forget their training and fail to perform important steps.

Finally, we could explore respirator fit when the wearer starts with a poor fit. These studies were all conducted with respirators that achieved the required FF of 100 or more. Little is known about fit over time when the respirator does not fit well initially. We also know little about the effect of different factors that may lead to poor fit, such as failure to form the nose clip, wearing a size that is too small or large, or improperly placing the headstraps. Starting with a poor fit might shed more light as to the type off head motions and activities that cause the respirator to fail.

For a variety of reasons it is difficult to perform this research in real time in a real-world setting with healthcare workers performing their job tasks. The instrumentation is bulky and not especially portable and could interfere with patient care tasks. Conducting research in the presence of patients introduces privacy and other concerns. However, this research could be expanded by using healthcare workers in either real or simulated patient care rooms with realistic perform job tasks. Hauge et al. (2012) demonstrated that this is possible with registered nurses conducting typical patient care activities (e.g., taking vital signs, changing a dressing, and adjusting an IV) on a programmable manikin in a medical education simulation facility (11).

There are some improvements to the current methodology that would make many of these explorations easier to accomplish. For example, adding video exposure analyses may help determine the exact motions that cause a respirator to fail. However, manually overlaying concentration data with video recordings of the healthcare activities was highly labor-intensive. The measures of particle concentrations are not consistent enough to visualize very short (one second) head motions that cause a change in respirator fit. Software that would allow real-time overlay of video and particle concentration information would save time and yield more useful information about the effect of head and body motions that impact fit. At least one research team has developed such software, although it is not available commercially (C. Hemmings, personal communication, September 25, 2014).

A long-term goal of this research would be the real-time evaluation of respirator fit in actual workplace settings. If this proves possible, perhaps it would no longer be necessary to perform a respirator fit test. The initial goal for developing the Portacount instrument used in this research was to provide a real-time warning to soldiers when fit dropped below a set point. As instruments continue to decrease in size and weight, we are approaching the time when they

could be incorporated into a respirator and coupled with wireless technology to signal failure or loss of fit as it occurs. This has been partially realized by the Canadian research team I partnered with (chapter IV), which uses wireless USB to send inside-mask data to a laptop located outside the experimental chamber.

There are a number of strengths and limitations that should be mentioned for this research. In terms of strengths, this work is the first to examine the relationship between a QNFT and an SWPF. Workplace studies have all used qualitative fit tests, which only determine whether the respirator passes or fails but provides no numerical measure of fit. Although Hauge et al. (2012) were able to measure an initial QNFT the commercial software did not allow recording of FFs greater than 200, preventing a direct comparison between the QNFT and SWPF (11). In both of the SWPF studies presented here that trend was analyzed and it was found that results from a fit test are highly correlated to how well the respirator fits during simulated work activities. This is gratifying, given the number of employers and employees that rely on annual fit testing as the only measure of respirator performance.

One limitation is that none of these experiments used a full 25-subject panel with a full set of representative face sizes, as recommended by the National Institute for Occupational Safety and Health (NIOSH). However, the subjects in all experiments had face sizes in a wide range of panel cells. Cells most frequently missing subjects were on the outskirts of the panel (i.e., people with very small or very large face sizes). Thus, the face sizes that we were able to recruit represent a large proportion of the public.

The most important limitation in my comparison of the one- and two-instrument methods was the inclusion of the grimace exercise (chapter III). As discussed above, I was able to

demonstrate that this exercise was the reason for lack of correlation between the two methods. When the exercises after the grimace were omitted, we were able to conclude that the two methods measured similar levels of fit for each subject.

While purchasing and maintaining a second Portacount instrument would be costly to a given workplace, I conclude that the two-instrument real-time methodology offers value to annual fit testing because it eliminates time required for switching and purging between sample locations. At this point in time, the real-time methodology is most useful for research purposes as it takes into consideration any fluctuations in ambient concentration that might occur while the subject is being fit tested. This research demonstrates that performing SWPF studies with the two-instrument method offers useful insights into respirator performance during typical work tasks while controlling other workplace variables.

I. INTRODUCTION

A. Preliminary Studies

1. Respirator need in healthcare settings in the United States

Infectious diseases are a significant occupational health risk for healthcare workers. While there is an abundance of information about the frequency and severity of hospital-acquired infections such as Methicillin resistant *Staphylococcus aureus*, Vancomycin-resistant *Enterococcus*, or *Clostridium difficile*, (13–15) very little information about occupational infections is available. In 1996, Sepkowitz completed a thorough review of occupationally acquired infections in healthcare workers and found that increased risk for occupationally acquired tuberculosis had been identified as early as the 1940s. He also noted that during a tuberculosis outbreak, 20% to 50% of susceptible workers may become infected and that vaccination in the United States is not common (16, 17). Sepkowitz indicated that there is also an increase in hospital employee-acquired varicella, measles, mumps, rubella, pertussis, and influenza. In most of these diseases vaccination has been shown to be an effective control method (16, 17). There were 13,278 reported cases of pertussis in 2008, and in Quebec, Canada, pertussis infection was found to be 1.7 times more likely in healthcare workers than in the general population (18).

Influenza is underreported in the United States because many people do not seek medical care and those that do are not often diagnosed via laboratory test (19). This makes it difficult to precisely document the full extent of the impact of influenza. It is estimated that between the years 1979 and 2001 more than 200,000 people per year on average in the United States were hospitalized for respiratory and heart conditions associated with complications from the flu (20). This demonstrates that seasonal influenza is a significant public health threat and would

therefore be a threat to healthcare workers. The costs of infectious diseases are both direct and indirect. Direct costs are those required for providing medical care and public health services. Indirect costs result from the social disruption caused by the disease—e.g., absenteeism from work or school. It was estimated that the total economic burden of seasonal influenza, for example, is close to $90 billion annually (21).

2. Respiratory protection programs

During the pandemic influenza outbreak of 2009 there was concern that hospitals may be unable to provide appropriate respiratory protection to healthcare workers exposed to patients infected or suspected of being infected with novel H1N1. In particular, there was uncertainty about the presence of adequate written respiratory protection programs (RPPs) in acute care hospitals, and whether hospital managers and employees were following regulatory and program requirements. These concerns prompted NIOSH in collaboration with the California Department of Public Health to assess written programs and policies at 16 acute care hospitals in California as part of the Respirator Evaluation in Acute Care Hospitals (REACH I) study. They found that all of the participating hospitals had implemented California's new (ATD) standard (4). Additionally the researchers found that most healthcare workers and managers knew the requirements of the OSHA respiratory protection standard (4, 22).

The California ATD standard specifies a specific list of diseases and procedures that might occur in a hospital and the level of respiratory protection required for anyone who might come in contact with a patient for those diseases. In this standard the most contagious diseases and higher-risk procedures mandate that healthcare workers use a powered air-purifying respirator while less-contagious diseases and lower-risk procedures require healthcare workers to use an N95 FFR. The lowest-risk category requires only a surgical mask (3). The CDC

guidelines list diseases and recommended respiratory protection but do not recommend respirators that offer a level of protection greater than an assigned protection factor of 10.

As a follow-up to the REACH I study, NIOSH funded a national project to examine RPPs, policies, and practices in acute care hospitals located in six states. Investigators from the University of Illinois at Chicago and the University of Minnesota collaborated on data collection in Illinois and Minnesota. Papers describing the demographics of participating hospitals in Illinois and Minnesota have previously been published (23, 24).

Neither state has an ATD standard; both were following the CDC guidelines for seasonal influenza during the study period (2010). In both states, it appeared that respiratory protection was mostly used for tuberculosis patients, and other levels of risk had not been considered in a comprehensive risk assessment. In general, it was observed that Illinois healthcare workers gave more protective responses than their counterparts in Minnesota. This may be partially due to the fact that Illinois had a greater percentage of larger urban hospitals than Minnesota. Conversely, Minnesota's written RPPs were more compliant with OSHA regulations than those in Illinois. These findings suggest that there are differences in how states implement RPPs and policies in healthcare settings.

The successful implementation of an RPP for infectious diseases is one that follows the OSHA Respiratory Protection Standard, (4) which describes procedures and policies for eleven required program elements:

Written Program

Program Administrator

Risk Assessment and Respirator Selection

Medical Evaluation

Communication

Fit Testing

Training

Respirator Maintenance and Use

Recordkeeping

Program Evaluation

Respiratory Availability

3. **Fit testing**

a. **History of Occupational Safety and Health Administration fit-test procedures**

The Occupational Safety and Health Administration selected seven of the eight required fit-test exercises based on Los Alamos studies of respirator performance conducted in the 1970s. These exercises included normal breathing, deep breathing, moving head side-to-side, moving head-up-and down, talking, grimacing, and normal breathing again. The grimace was included to evaluate the effect of an exercise that purposely breaks the seal, but is not used in calculating the final FF. Rather, the second normal breathing event is used to determine how well the respirator reseats after breaking the seal during the grimace (25).

b. **Quantitative fit test**

One commonly used fit test is the ambient aerosol condensation nuclei counter (CNC) quantitative protocol (4, 26). This method employs the Portacount instrument developed by TSI Incorporated, which operates by enhancing particle diameter through solvent condensation to a size that is easily detectable by a laser spectrometer and then employs light scattering to enumerate particle concentration. Number concentration is measured in alternating

fashion from outside and inside the respirator facepiece during each fit-test exercise; an FF is then computed by dividing these two concentrations for each of the eight fit-test exercises. The fit-test exercises include:

1. Normal Breathing
2. Deep Breathing
3. Turning Head side-to-side
4. Moving Head up-and-down
5. Talking
6. Grimace
7. Bending Over
8. Normal Breathing

Including the purge time before and after, each exercise is performed for 69 seconds. At the end of the fit test, an overall FF is computed by taking the harmonic mean of the FF achieved for seven of the eight exercises, excluding grimace, as described above.

c. Particle size selection of Portacount and Portacount Companion

Because particles measured inside the respirator could result from those penetrating either through the filter or around the facepiece, any method that relies on particle enumeration must be able to distinguish between these two sources. Respirator filters are tested during certification at very high flow rates (84 L/min) with particles near the most penetrating size for mechanical filters—approximately 0.3 μm (27). These conditions ensure that filters will

collect particles with very high efficiency—well above the filter designation—when used at typical breathing rates (10–30 L/min) and in typical aerosol exposures, with larger and more disperse particle sizes. Thus, the CNC method works well for the most efficient filters carrying the 99 or 100 designation. Less efficient respirator filters (i.e., those with a 95 designation) are generally constructed of electret materials, which usually exhibit their highest penetration at 0.06–0.1 µm. Although these filters are also tested for certification at a high flow rate (84 L/min), there is some chance that particles measured inside the facepiece could result from filter penetration in addition to face-seal leakage. Thus, for these less-efficient respirator filters an electrostatic classifier (ESC) is used to select only negatively charged 55 µm diameter particles prior to condensation and enumeration by the CNC. The instrument manufacturer has demonstrated that this ESC-CNC combination (called a Portacount with a N95 Companion) measures particles that are efficiently captured by the filter, thus any particles detected inside the respirator represent face-seal leakage only (28).

4. **Fast-fit-test history**

A study of N95 FFR fit conducted by Richardson et al. (2014) examined whether a fast fit-test protocol with fewer exercises could achieve similar overall FFs as the traditional OSHA fit test. The new fast fit-test methodology uses one instrument (a condensation nuclei counter) and a single purge and ambient sample at the beginning and end of all of the exercises instead of conducting an ambient sample after each of the exercises in the current OSHA standard (26). The new fast fit-test method then uses five exercises (normal breathing, bending over, talking, head side-to-side, and head up-and down) and takes a 30-second in-mask sample for each of those exercises. This entire protocol takes 2:29 minutes compared to 7:09 minutes for the current OSHA standard. A 25-person panel performed more than 100 fit-test pairs following

the American National Standards Institute Z88.10-2010 Annex A2, "Criteria for Evaluating New Fit Test Methods" to demonstrate that the new fast fit test was equivalent to the current OSHA standard.

Based on research demonstrating that a two-instrument real-time methodology was similar to that using one instrument when conducting an OSHA fit test with eight exercises (chapter III), I proceeded with additional research assuming that the real-time two-instrument fit-testing method would give valid results for different and smaller sets of exercises, if these had also been shown to be equivalent to a traditional OSHA fit test.

5. **Fit-test panels**

In the 1960s Los Alamos National Laboratory developed two fit-test panels, one for full facepiece and one for half facepiece respirators. Thirteen standard cells were chosen based on specific facial features using data from a 1967 anthropometric survey of young men working for the Air Force (29).

In 2007, the composition of these panels was reevaluated with a sample of nearly 4,000 workers selected from those currently wearing respirators in work settings, taking age, gender, and ethnicity into consideration, to obtain a more representative sample of the civilian workforce. A bivariate (BVA) panel with 10 cells was developed that separates subjects by face length and face width. This new panel (Figure 1) has been adopted by NIOSH as representative of the general working population in the United States (30).

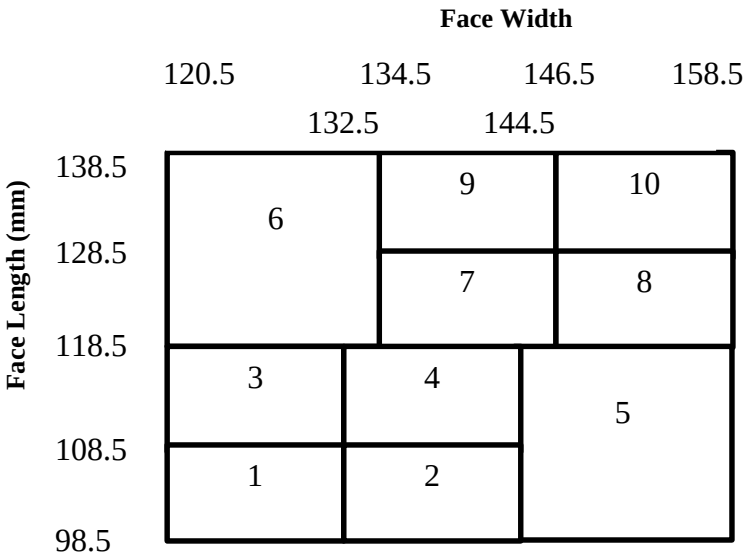

Figure 1. Bivariate fit test panel as determined by Ziqing et al.

6. Workplace protection factor

The workplace protection factor (WPF) is a field measure of respirator fit during work. To date, studies of WPF have compared gravimetric samples collected inside the respirator and on the lapel, over a three-year period, Meyers et al. (1995–1998) performed WPF studies in three different industries (foundry, paint spraying, and sinter plant), taking simultaneous 8-hour personal and inside-facepiece gravimetric samples. All subjects passed an initial *qualitative* fit test and were required to wear the respirator throughout the day, with the exception of during lunch (6–9).

This test protocol cannot be easily performed in healthcare, however, for several reasons. First, there are no gravimetric (filter-based) methods sensitive enough to measure the relatively

low concentrations of infectious respiratory aerosols, even if sampling were conducted over an 8-hour period. As well, observing healthcare tasks is complicated by the presence of patients and privacy concerns. And finally, healthcare workers rarely wear a respirator on a continuous basis, but may don and redon a respirator multiple times, which may negate the initial measurement of fit.

A few investigators have explored the use of two CNC instruments simultaneously sampling particle concentrations inside and outside a respirator, as a means of obtaining more frequent measures of fit (11, 32). Hauge et al. (2012) demonstrated the feasibility of this two-instrument approach in a simulated healthcare environment with eight subjects (registered nurses) (11). Each subject first passed a traditional OSHA quantitative condensation nuclei counter (CNC) fit test (eight exercises) using a single ESC-CNC instrument (Portacount model 8020, TSI Inc.). Without removing the respirator, each subject was connected to two side-by-side ESC-CNC instruments and performed three randomized 10-minute healthcare scenarios (Patient Assessment, Wound Care, and Intravenous (IV) Care) in a simulated patient care room. For each scenario an SWPF was calculated by finding the average of all one-second FFs (outside divided by inside concentration) measured during that scenario.

Hauge et al. (2012) found that the protection afforded by a respirator varied significantly between subjects and that IV treatment and wound care produced SWPFs that were significantly different from each other (11). The order of the three scenarios was randomized; Hauge et al. found that the second scenario SWPFs were significantly different SWPFs compared to those measured in the first and third scenarios. Their data were also suggestive of an association between each subject's initial quantitative FF using the traditional instrument with the eight

OSHA exercises and their fit using the new two-instrument method with simulated healthcare tasks (11).

Some problems encountered in this study were that FFs measured by the single Portacount instrument were truncated at 200, which limited their ability to test statistically whether a quantitative fit test was predictive of the simulated workplace FF. As well, their video files could not be easily synced with the fit-factor data because there was not a clear point in time where concentration changes could be linked with subject activities (11).

Gijp et al. (2004) used two Portacount instruments (one measuring inside-facepiece concentration and one measuring ambient concentration) and two soldiers each performing five tasks (digging, walking and shooting, patrol, decontamination, and exercise) to assess SWPFs in a military setting (32). The authors found high levels of between-subject variability. The authors had difficulty correlating SWPF with the activities that were performed. This might have been due to the small subject pool. This study did not take advantage of the real-time capabilities of the two-instrument methodology by analyzing the data second-by-second.

7. **Video exposure monitoring**

Video exposure monitoring (VEM) has been conducted in workplaces to determine which tasks are responsible for the largest fraction of an aerosol or vapor exposure. These assessments have typically been used in four capacities: task analysis to control exposures, as a training aid for risk communication, to encourage worker participation and motivation for improvements in workplace environments, and for occupational hygiene research (33–35).

Several research groups have developed different technologies for presenting and analyzing VEM data. In all cases, their software has the ability to overlay animated concentration data with video images to visualize which tasks associated with an increase in exposure levels.

All but one of the software packages requires a synchronization methodology to correctly line up video images with exposure concentrations.

Synchronization is often difficult because it requires precise alignment of exposure data and video images. Instrument measurements are not precise enough to measure exactly on the second; over time, small fluctuations can prevent correct video alignment. It has been found that including brief moments of high exposure measured periodically throughout an experiment can provide video alignment "check points," where the software can be used to stretch out or compress the video between these high-exposure data points.

To apply the VEM to respirator fit evaluations, we need software that allows real-time overlay of video and fit measurement data. This would save significant time in the synchronization process and would yield more useful information about the effect of short-duration head and body motions on fit. At least one research team has developed such software, although it is not available commercially (C. Hemmings, personal communication, September 25, 2014).

B. **Aims**

The overall goal of this research is to evaluate the use and performance of respiratory protection in the context of healthcare settings. Respiratory protection in any industry requires the development and implementation of an RPP, which includes a number of elements, including a comprehensive written program. A comparison between the comprehensiveness of a hospital-written RPP and healthcare worker knowledge of RPPs and policies is the subject of this dissertation's specific aim 1.

The protection afforded by a respirator depends on individual moment-by-moment fit experienced throughout a given work shift. However, current practice is to conduct an annual fit test and assume that the chosen respirator affords the protection necessary at all times during on-the-job usage. Specific aims 2 through 4 target the correlation between an initial quantitative fit test and how the respirator fits while an employee performs their job. This methodology also begins to address how respirator fit changes while an employee performs their job and how respirator fit changes over time.

1. **Aim 1**

In my first research project (chapter II), I used the data from a study of respirator programs in Minnesota and Illinois acute care hospitals to explore the following questions:

   a. How well do acute care hospitals' written RPPs meet the requirements of the OSHA respiratory standard?
   b. How well do healthcare workers and managers follow their hospital's respirator program guidelines?
   c. Is there a correlation between written RPPs and practices observed?

The following research projects were focused on testing the application of a two-instrument method to the measurement of respirator fit in simulated workplace settings.

2. **Aim 2**

In the first of three experimental studies, I explored whether a new real-time two-instrument methodology would yield similar FFs as the current single instrument. In particular, I hoped to answer the following questions:

a. Does the real-time methodology produce FFs that are the same as the traditional OSHA quantitative fit test using a single instrument?

b. What is the effect of wear time on respirator fit?

3. **Aim 3**

In partnership with colleagues in Canada, I explored the relationship between quantitative FFs and SWPFs using the two-instrument method, in the context of emergency-responder tasks. In addition to gaining more expertise with the real-time approach to measuring respirator performance, I also hoped to answer these questions:

a. How can real-time methodology be best used in an SWPF study?

b. How do QNFTs and SWPFs compare when subjects don respirators and protective ensembles together?

4. **Aim 4**

Finally, I developed a new set of healthcare activities representative of more vigorous head and body motions encountered in real-world settings. Using the two-instrument methodology, I explored these questions:

a. How do FFs derived from a fast fit test and SWPFs compare in a study of healthcare worker activities?

b. What are the differences in respirator fit between healthcare activities and across time?

c. Can video recordings combined with exercise FFs be used to predict SWPFs for healthcare activities and scenarios?

II. COMPARING WRITTEN PROGRAMS AND SELF-REPORTED RESPIRATORY PROTECTION PRACTICES IN ACUTE CARE HOSPITALS

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Abstract

Background: Airborne biological hazards in hospitals require the use of respiratory protection. A well-implemented RPP can protect healthcare workers from these exposures.

Objectives: This study examines the relationship between written respiratory programs and reported practices in healthcare settings.

Methods: Twenty-eight hospitals in Illinois and Minnesota were recruited to a study of RPPs and practices in acute care settings. Interviews were conducted with hospital managers, unit managers, and healthcare workers from departments where respirators are commonly required. Each hospital's written RPP was scored for the 11 elements required by OSHA, using a standardized tool, for a maximum possible score of 22 (2 pts. per element). Twenty interview questions associated with program practices were also scored by percent correct responses.

Results: Written program scores ranged from 2 to 17 with an average of 9.2. Hospital and unit managers scored on average 82% and 81%, respectively; when compared to the OSHA standard healthcare workers scored significantly lower, 71% ($p < .001$); Minnesota written program scores were not significantly higher than Illinois hospitals ($p = .16$), while all Illinois survey respondents scored higher than those in Minnesota ($p < .001$). There was no trend between written programs and interview responses.

Conclusions: Written RPPs in the study sites did not provide the level of detail required by OSHA. Interview responses representing hospital practices surrounding respiratory protection indicated that hospitals were aware of and following regulatory guidelines.

C. **Background**

Following a study of RPPs and practices in California acute care hospitals during the 2009 novel H1N1 influenza outbreak (REACH I) (22), NIOSH supported a similar nationwide assessment of hospitals' prevention practices for aerosol-transmissible diseases. The Respirator Evaluation in Acute Care Hospitals (REACH II) study was conducted in six states in 2010 and 2011. The overarching goals of REACH II were (1) to describe the extent to which hospitals in the United States had implemented RPPs for influenza and other aerosol-transmissible diseases, and (2) to determine healthcare workers' use of respiratory protection for infectious aerosol exposures in representative hospitals.

Results of interviews and program reviews in hospitals in two of these states (15 in Minnesota and 13 in Illinois) have been described by Brosseau et al. (2015) (24). Briefly, a total of 363 healthcare workers and 171 hospital and unit managers representing the highest-risk departments (emergency, intensive care, and medical/surgery) were interviewed about respiratory program policies and practices. Written programs from each hospital were evaluated for required elements (4) and respirator donning and doffing was observed with 77 healthcare workers.

The OSHA Respiratory Protection Standard regulates the provision and use of respirators in all US workplaces to protect employees from "harmful dusts, fogs, fumes, mists, gases,

smokes, sprays, or vapors" (36). An employer is required to address eleven key elements that include a written program and policy; designated program administrator; risk assessment and corresponding respirator selection; regular medical evaluation; annual fit testing; annual training; communication, maintenance and use procedures; recordkeeping; program evaluation; and ensuring respirator availability (4).

The most serious written program deficiency was the lack of a program administrator in almost all hospitals. Most programs also did not adequately describe medical evaluation, fit testing, and training; however, respondents indicated receiving these at appropriate intervals. Most healthcare workers did not have an adequate method for identifying their fit-tested respirator model and size. However, every observed healthcare worker was able to easily obtain a respirator when asked to demonstrate proper wear (correct model and size were not assessed). In most cases, healthcare workers were able to properly don and doff the respirator; the most frequent failures involved correct strap placement, user seal-check performance, and using straps for removal.

In healthcare settings, respiratory protection plays an important role in preventing the transmission of infectious diseases that are spread by droplet or airborne routes of exposure (37). Because exposure guidelines and sampling methods are lacking for most infectious diseases, hospitals must rely on published guidelines for selecting the correct respirator for a particular organism. Most relevant to acute care hospitals are guidelines from the CDC and recommendations from the Healthcare Infection Control Practices Advisory Committee (1). California Occupational Safety and Health Administration has incorporated all of these into a single set of respirator and exposure control recommendations for a wide range of infectious organisms in its ATD Standard (3).

To examine further the relationship between the written programs and self-reported practices in participating hospitals, we developed a method for scoring each written RPP for the eleven required program elements. As well, respirator practices scores were developed for each hospital using selected interview responses from managers and healthcare workers. Program and practices scores were compared among hospitals, between states, and by employee group. We hypothesized that well-written RPPs meeting most of the OSHA criteria would be associated with a higher fraction of positive interview responses about respirator policies and practices.

D. Methods

1. Data collection

Interview and observation tools from the REACH I study were used as a starting point for REACH II instrument design, following a collaborative process involving personnel from the six participating states and NIOSH (22). Changes to the REACH I interviews included matching interview questions across the three employment categories (department managers, unit managers, and healthcare workers), expanding the focus from influenza to all types of aerosol-transmissible diseases, and revising the respirator donning and doffing observation tool. Minor changes were made in organization, skip patterns, wording, and response categories. More detailed information about the interview and observation tools can be found in Brosseau et al. (2015) (24).

The sampling frame is described in detail in Brosseau et al. (24). Briefly, participating hospitals, selected using random and convenience sampling, included 15 in Minnesota and 13 in Illinois. These were generally representative of all acute care hospitals in each state with more large urban and fewer small rural hospitals than expected.

At each hospital we obtained a copy of the written RPP and conducted interviews with three hospital managers (directors of infection control, nursing, and employee health), managers of three units most likely to require respirators for aerosol-transmissible diseases (intensive care (adult or pediatric), emergency, and medical/surgical), and five healthcare workers most likely to require respirators from each of these three units (for a total of 15 healthcare workers). Our sample included 43 hospital managers, 47 unit mangers, and 183 healthcare workers from Minnesota hospitals, and 46 hospital managers, 35 unit managers, and 180 healthcare workers in Illinois. The most common were nurses (57%); nursing assistants (11%); and physicians, technicians, respiratory therapists, receptionists, and environmental services (~5% each). More details about the interview instruments can be found elsewhere (24).

2. **Demographic data coding**

To combine hospitals from both states into a single dataset, demographic data for Illinois hospitals were re-coded based on the median bed number in Minnesota (small <90.5 beds; large >=90.5 beds), which resulted in 1 small and 12 large hospitals. The Minnesota sample had seven small and eight large hospitals. Hospitals were also sorted on location (rural versus urban). Some demographic information for interview participants was also re-coded dichotomously: job type (nurse versus non-nurse) and union status (in a union versus not in a union).

3. **Scoring written programs**

An instrument was developed to consistently score written RPPs for each of the eleven OSHA respiratory protection program elements (the full instrument is available in appendix A):

1. Written Program
2. Program Administrator
3. Risk Assessment and Respirator Selection
4. Medical Evaluation
5. Communication (how hospitals convey information about selection and use of respirators)
6. Fit Testing
7. Training
8. Respirator Maintenance and Use
9. Recordkeeping
10. Program Evaluation
11. Respirator Availability

Each element received 2 points if completely met, 1 point if partially met, and 0 points if not met or missing, for a maximum total of 22 points. For example, for a written program to receive the full two points for the element “fit testing” it should include written procedures that ensure annual fit testing. Specifically, each of following items should be addressed:

1. The fit-test method should be described and appropriate for the selected respirator(s).
    a. Describe the use of qualitative fit-test methods (e.g., Bitrex or saccharin) for respirators with assigned protection factors of 10 or less
    b. Describe the use of quantitative fit-test methods (e.g., controlled negative pressure or ambient particle concentration) for all other types of respirators (at a minimum)

c. Mention the OSHA protocol (Appendix C of the OSHA regulation) and include a complete list of fit-test exercises

2. The program must indicate when a fit test is required, which must include (at a minimum):
   a. Prior to initial use
   b. At least annually thereafter
   c. If specific changes have occurred (e.g., weight gain, facial scarring, or cosmetic surgery)
   d. Whenever an employee reports that the respirator is unacceptable for whatever reason

A program would receive a score of 2 if all of these aspects were described in the written program, a 1 if one or more aspects were missing, and a 0 if no fit testing policies or practices were addressed.

We also developed a model program that addressed all of the criteria necessary for a perfect score, as well as advice to hospitals for implementing a successful RPP.

4. **Scoring respirator practices**

To obtain a score for self-reported respirator practices, we selected 20 questions from the hospital manager interview relevant to each respirator program element that could be scored dichotomously (true or false). Where possible, matching questions were selected from the unit manager (18 questions) and healthcare worker (14 questions) interviews. No questions were available on any of these interviews for four program elements: program administrator, communication, maintenance and use, and record-keeping. Questions were scored as yes (1) =

met OSHA standard or CDC guideline requirements or no (0) = did not meet OSHA or CDC requirements. A complete list of questions and correct answers is shown (TABLE I).

A practice score for each program element was determined by dividing the number of correct answers for that element's questions by the total number of respondents (TABLE I). The number of people answering a specific question may not match the number of people interviewed if a respondent failed to answer a particular question. A question was left unanswered if an employee did not feel capable to respond. A survey question might also be left unanswered if an employee did not have enough time to complete the interview.

TABLE I

INTERVIEW QUESTIONS USED IN SCORING PROCESS BY ELEMENT AND INTERVIEW TYPE*

Program Element, Questions, Responses (underline = correct)	Interview		
	HM	UM	HCW
Written Respiratory Protection Program			
Does your facility have a written Respiratory Protection Program? Yes, No, Don't know	x	x	x
Respirator Selection			
1. Which guidelines are used to determine which infectious disease exposures require respiratory protection? CDC recommendations, OSHA recommendations, State Department of health recommendations, Other (specify), Don't know	x	x	
2. Does your facility conduct a risk assessment to determine which employees should be included in the respiratory protection program? Yes, No, Don't know	x	x	
3. What is the minimum level of respiratory protection employees are required to use when in **close contact** with a patient who has a suspected or confirmed infectious disease requiring **airborne precautions**, [such as tuberculosis]? None, Surgical Mask, N95 filtering facepiece (disposable respirator, Elastomeric half-face N95 respirator, (PAPR), Other (specify), Don't know	x	x	x
4. What is the minimum level of respiratory protection employees are required to use when performing **aerosol-generating procedures** with a patient who has a suspected or confirmed infectious disease requiring **airborne precautions**, [such as tuberculosis]? None, Surgical Mask, N95 filtering facepiece (disposable respirator, Elastomeric half-face N95 respirator, PAPR, Other (specify), Don't know	x	x	x

INTERVIEW QUESTIONS USED IN SCORING PROCESS BY ELEMENT AND INTERVIEW TYPE

Program Element, Questions, Responses (underline = correct)	Interview		
	HM	UM	HCW
5. What is the minimum level of respiratory protection employees are required to use when performing **aerosol-generating procedures** with a patient who has a suspected or confirmed infectious disease requiring **droplet precautions**, [for example, pertussis]? None, Surgical Mask, N95 filtering facepiece (disposable respirator, Elastomeric half-face N95 respirator, PAPR, Other (specify), Don't know	x	x	x
Medical Evaluation			
1. Did you receive medical evaluation and clearance before wearing a respirator? Yes, No, Don't know	x	x	x
2. How frequently are you medically evaluated? Once at hire only, Once at hire, and then annually, Once at hire, then as required by a physician, No requirements, Other (specify), Don't know, Annually, Just in time, More than annually	x	x	x
Fit Testing			
1. What happens if an employee cannot be successfully fit-tested? They are put into a PAPR, They are reassigned to a lower-risk job classification, Other (specify), Don't know, I haven't been fit-tested, Given another mask	x		
2. Do employees receive fit testing before being allowed to wear a respirator? Yes, No, Don't know	x	x	
3. How often do employees receive fit testing? Once at hire only, Once at hire, and then annually, Once at hire, then as required by a physician, No requirements, Other (specify), Don't know, Annually, Just in time, Biannually, More than annually	x	x	x

INTERVIEW QUESTIONS USED IN SCORING PROCESS BY ELEMENT AND INTERVIEW TYPE

Program Element, Questions, Responses (underline = correct)	Interview		
	HM	UM	HCW
Training			
How often are employees required to attend respirator training? Once at hire only, Once at hire, and then annually, Once at hire, then as required by a physician, No requirements, Other (specify), Don't know, Annually, Just in time, More than annually	x	x	x
Program Evaluation			
1. Are healthcare workers formally asked to provide input on respiratory protection policy decisions? Yes, No, Don't know	x	x	x
2. Are unit managers formally asked to provide input on respiratory protection policy decisions? Yes, No, Don't know	x	x	
3. Does your facility have a formal mechanism or method to evaluate the effectiveness of the respiratory protection program? Yes, No, Don't know	x		
Availability			
1. Are respirators located close to the point of use (i.e., rooms with suspected or confirmed seasonal influenza or patients on airborne precautions)? Yes, No, Don't know	x	x	x
2. Does your facility have Powered Air Purifying Respirators available when employees need them? Yes, No, Don't know	x	x	x

*Answers scored as correct are underlined

5. Data analysis

Data were analyzed using SAS version 9.2 (SAS Institute Inc. Cary, North Carolina). Comparisons of means were performed using a student's t-test. Analysis of variance was used to compare scores between the three interview types. For each state a mixed-effects linear regression was used to explore the impact of fixed demographic variables (hospital size [large versus small], location [rural versus urban], job type [nurse versus non-nurse], and union status [in a union versus not in a union]) on healthcare worker interview response scores with random variables including state and hospital. Lastly, a comparison was performed to identify any correlation between a hospital's written RPP score and the average interview score for a hospital across all employee groups (managers and healthcare workers).

E. Results

1. Written respiratory protection program evaluation

No written RPP had all required program elements (TABLE II). Written program scores ranged from 2 to 17 out of a possible 22. The average score for Minnesota hospitals was 10.3 (CI: 8.1–12.3) and did not differ significantly from the average Illinois hospital program score of 7.9 (CI: 5.1–10.7) (p=.16) (TABLE III).

TABLE II

WRITTEN PROGRAM SCORES BY HOSPITAL AND PROGRAM ELEMENT*

	MINNESOTA															ILLINOIS												
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	1	2	3	4	5	6	7	8	9	10	11	12	13
WP	2	0	0	2	0	0	2	2	2	1	0	2	2	2	1	2	1	2	2	1	0	0	1	0	2	2	1	1
PA	2	0	0	0	0	0	1	2	0	0	0	0	1	0	1	0	1	1	2	0	0	0	0	0	1	0	0	0
R	2	1	1	1	2	1	0	1	2	2	1	1	2	2	2	1	1	2	2	1	1	0	0	1	1	0	0	2
C	2	0	0	1	1	0	1	0	1	1	0	2	1	0	0	0	0	1	1	0	0	0	1	1	1	0	0	0
ME	1	1	1	1	0	1	1	1	0	1	1	2	1	1	0	1	0	1	1	1	0	1	1	0	1	1	0	0
FT	1	1	1	1	2	0	1	1	1	1	0	2	2	1	0	1	1	1	1	1	1	1	1	1	2	1	0	1
M	2	2	2	2	1	1	2	2	1	2	1	2	2	1	1	2	1	2	1	1	0	0	0	0	1	1	0	1
T	1	1	1	1	1	0	1	1	1	1	0	1	1	0	0	2	1	0	2	1	0	0	0	0	1	1	1	0
PE	1	0	0	1	0	1	2	1	0	1	1	2	2	2	0	2	1	1	2	1	0	0	1	0	0	1	1	0
Re	1	0	0	0	0	1	0	0	1	2	1	2	0	1	0	1	0	1	2	0	1	0	1	1	2	1	0	0
A		1	1	1	2	0	1	1	0	1	0	1	1	1	1	2	2	0	0	1	0	0	0	0	1	0	0	0
Score	15	7	7	11	9	5	12	12	9	13	5	17	15	11	6	14	9	12	16	8	3	2	6	4	13	8	3	5

*WP–Written Program; PA–Program Administrator; R–Risk Assessment/Respirator Selection; C–Communication; ME–Medical Evaluation; FT–Fit Testing; M–Maintenance and Use; T–Training; PE–Program evaluation; Re–Record-keeping; A–Availability

TABLE III

SUMMARY OF WRITTEN PROGRAM SCORES BY ELEMENT AND TWO-SAMPLE T-TEST*

	WP	PA	R	C	ME	FT	M	T	PE	Re	A	Score
Minnesota (N=15)												
Mean	1.2	0.5	1.4	0.7	0.9	1.0	1.6	0.7	0.9	0.6	0.8	10.3
(SD)	(0.9)	(0.7)	(0.6)	(0.7)	(0.5)	(0.7)	(0.5)	(0.5)	(0.8)	(0.7)	(0.6)	(3.8)
Illinois (N=13)												
Mean	1.2	0.4	0.9	0.4	0.6	1.0	0.8	0.7	0.8	0.8	0.5	7.9
(SD)	(0.8)	(0.7)	(0.8)	(0.5)	(0.5)	(0.4)	(0.7)	(0.8)	(0.7)	(0.7)	(0.8)	(4.6)
Both States Combined (N=28)												
Mean	1.2	0.4	1.2	0.5	0.8	1.0	1.2	0.7	0.9	0.7	0.6	9.2
(SD)	(0.9)	(0.7)	(0.7)	(0.6)	(0.5)	(0.5)	(0.7)	(0.6)	(0.8)	(0.7)	(0.7)	(4.3)
p-value	0.89	0.76	0.09	0.24	0.21	1.00	0.00	0.86	0.57	0.55	0.21	0.16

* WP–Written Program; PA–Program Administrator; R–Risk Assessment/Respirator Selection; C–Communication; ME–Medical Evaluation; FT–Fit Testing; M–Maintenance and Use; T–Training; PE–Program evaluation; Re–Record-keeping; A–Availability

Most commonly, hospitals were missing two program elements: communication and program administrator. Seven (47%) Minnesota and eight (62%) Illinois hospitals did not describe how respirator information was conveyed to employees; only two Minnesota hospital programs received full credit for this element. Ten (67%) Minnesota and nine (69%) Illinois programs did not indicate a designated program administrator; only three hospitals (two in Minnesota and one in Illinois) received a full score.

2. **Interview response evaluation**

Overall, hospital managers were most similar to unit managers in their responses, and both answered correctly (compared to the OSHA standard) significantly more often than healthcare workers ($p<.001$). For eight program elements, managers more often identified the correct response than healthcare workers (TABLE IV). Most respondents (>82%) answered correctly the questions about medical evaluation, fit testing, and respirator availability, with no differences among employment groups.

TABLE IV

INTERVIEW SCORES BY EMPLOYMENT GROUP FOR ALL HOSPITALS (MN AND IL COMBINED)

	Hospital Managers (N=88)	Unit Managers (N=82)	Healthcare Workers (N=362)		p-value
Written Program	96%	96%	82%	HM=UM>HCW	<.001
Respirator Selection	83%	77%	75%	HM>HCW	0.006
Medical Evaluation	85%	88%	82%		0.487
Fit Testing	92%	91%	87%		0.410
Training	85%	88%	82%	UM>HCW	0.024
Program Evaluation	41%	39%	16%	HM=UM>HCW	<.001
Availability	95%	89%	86%		0.057
Overall Score	82%	81%	71%	HM=UM>HCW	<.001

Managers were more likely than healthcare workers to indicate their hospital had a written program and conducted program evaluations ($p<.001$). Hospital managers were more likely than healthcare workers to say their hospital had conducted a risk assessment ($p=.006$), while unit managers were not significantly different from either group. Unit managers were significantly more likely than healthcare workers to indicate training met OSHA guidelines ($p=.024$), while hospital managers were not significantly different from either group.

The average overall interview score in Minnesota was significantly lower than in Illinois ($p<.001$) (TABLE V). Further examination indicates that this is entirely due to differences in healthcare worker responses between the two states. Minnesota healthcare worker interview scores were significantly lower than those in Illinois ($p<.001$). When examining interview responses for each program element (data not shown), Illinois healthcare workers answered

correctly significantly more often than those in MN for all program elements except written program.

TABLE V

AVERAGE INTERVIEW RESPONSE SCORE BY EMPLOYMENT GROUP AND STATE

Site	N	Mean (%)	95% CI		p-value
MN All Respondents	267	70.5	68.1	73.0	
IL All Respondents	255	79.9	78.3	81.6	<.0001
MN Hospital Managers	42	82.8	78.7	86.9	
IL Hospital Managers	46	85.5	82.1	88.9	0.3
MN Unit Managers	47	79.2	75.0	83.3	
IL Unit Managers	35	82.1	78.4	85.8	0.3
MN Healthcare Workers	178	65.4	62.2	68.5	
IL Healthcare Workers	174	78.0	75.9	80.0	<.0001

The mixed-effects model showed that overall interview scores differed significantly by job title, with nurses scoring significantly higher than non-nurses ($p<.001$). Union status, hospital size (large versus small) and hospital location (rural versus urban) of hospitals were not important factors.

We found no correlation between overall written program scores and overall interview responses scores by hospital ($r= -0.086$) (Figure 2).

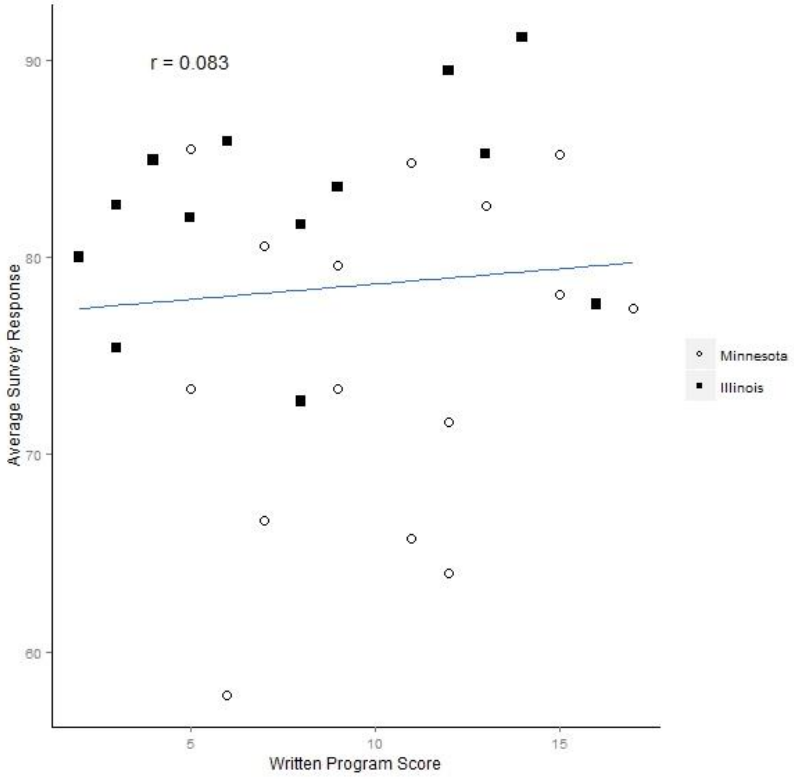

Figure 2. Interview response score versus written program score by hospital.

F. **Discussion**

In general, hospitals' written programs did not provide adequate details for most of the RPP elements while the overall interview scores demonstrated that hospitals were generally following regulatory guidelines. Hospitals with the better-written programs did not always have the better survey responses and vice versa. This is most likely due to the lack of a program administrator in most hospital programs. Programs without a designated administrator were most often missing a comprehensive risk assessment and on-going program evaluation.

Other investigators have found similar results in different workplace settings. In a study of RPPs in 20 small UK industrial sites, Bell et al. (2012) found that fewer than half of sites had

considered respiratory risks (38). Graveling et al. (2011) found that the most important factors in a successful RPP are organizational and management support (39). Key to these is a program administrator who serves as a single centralized person charged with managing the entirety of the RPP. Having a trained program administrator has been shown to ensure a comprehensive detailed written RPP (40). This is a common problem with many RPPs. In a 2001 survey of nearly 300,000 private-sector establishments, Doney et al. (2005) found that 14% of RPPs did not identify a single program administrator. In those organizations with a program administrator, 42% had not received appropriate training (40).

In the model RPP developed for acute care hospitals we included a description of a program administrator's responsibilities, which include ensuring that:

- a risk assessment is conducted; that the work areas, processes, or tasks requiring respiratory protection are identified; and that appropriate respiratory protection devices are selected for those work areas, processes, or tasks
- the program is fully implemented in all appropriate departments and units
- employees receive medical surveillance, fit testing, and training at the time of hire and at appropriate intervals thereafter
- adequate records are maintained
- medical evaluation is performed by a physician or other licensed healthcare professional
- information regarding medical clearance, fit testing, and training is communicated to all appropriate departments, managers, and employees
- only NIOSH-certified respirators are used in accordance with their certification
- respirators are properly stored and maintained

- the program is evaluated periodically and updated as needed

There continues to be uncertainty and disagreement about which infectious disease hazards require respiratory protection in healthcare settings. This may explain the lack of clarity in hospital programs about infectious organisms other than tuberculosis. Graveling et al. (2011) found that when respiratory hazards are not recognized or risks are not readily apparent, management support of respiratory protection is often lacking (39). With the exception of California, there are no OSHA regulatory requirements specific to respiratory infectious disease exposures. Hospitals have some choice about which CDC and other guidelines to follow, depending on local, state, and hospital accreditation requirements.

In many of the written programs we reviewed, hospitals had not undertaken a formal risk assessment. We expected to find a detailed list of infectious organisms, descriptions of jobs and tasks where exposures might occur, and identification of the specific respirator required for each exposure accompanied by a clear explanation for each selection. We also expected hospitals to select higher levels of respiratory protection for higher exposures (e.g., aerosol-generating procedures such as intubation or bronchoscopy).

While five of the 28 written programs did not describe any risk assessment/respirator selection strategy, of the 23 that did, about half (11 of 28) were primarily focused on tuberculosis. Written programs that received a full score of 2 for the risk assessment/respirator selection program element most often mentioned varicella, SARS, and pandemic influenza in addition to tuberculosis. No program addressed the full range of infectious diseases for which the California OSHA ATD standard currently requires the use of a respirator (3):

- Aerosolizable spore-containing powder, e.g., Anthrax
- Avian influenza
- Varicella disease (chickenpox, shingles)
- Measles (rubeola)
- Monkeypox
- Novel or unknown pathogens
- Severe acute respiratory syndrome (SARS)
- Smallpox (variola)
- Tuberculosis (TB)

One-third (10 of 28) of written programs did not discuss how the program would be periodically evaluated. Only 40% of hospital managers and 16% of healthcare workers said their hospital conducted periodic evaluation of the respiratory protection. Again, having a trained, designated program administrator would ensure that evaluation takes place on a regular basis and that the program is updated based on the results. A well-conducted program evaluation would include:

- Reviewing the risk assessment to ensure all potentially exposed employees are included in the program and use the proper level of respiratory protection
- Consulting with employees who use respirators and their supervisors
- Random and periodic observations of employee respiratory protection practices, availability, signage, and training content and delivery
- A review of records (training, medical evaluation, and fit testing) to ensure they are properly maintained and that information is being communicated appropriately

In contrast to the written program scores, interview scores indicated that respirator practices often met OSHA regulatory requirements for medical surveillance, fit testing, and training, although managers consistently scored higher than healthcare workers. Thus, it appears that hospital and unit managers are aware of and following the OSHA respiratory protection regulation, even if the hospital's program does not adequately reflect this. Again, the lack of a single centralized program administrator may explain this finding.

G. **Limitations**

Several limitations should be noted. The interview questions were not developed with the intention of scoring a hospital's program; thus, many questions did not have a single right or wrong answer. Recruitment was a significant hurdle in both states and random sampling proved difficult to sustain. In Illinois, a convenience sample resulted in a greater fraction of large urban hospitals than expected. Initial data analysis plans did not include a comparison of hospital programs with interview responses. This resulted in an uneven distribution of interview questions with some program elements having no relevant questions.

Our data collection procedures allowed respondents to review the questionnaire during the interview, which may have led to social desirability bias, i.e., selection of the "right" rather than the most representative response.

Lastly, program scoring was originally developed for the purposes of reporting results to each hospital. A better approach might have been to divide each program element into a series of yes/no questions (as is outlined in the evaluation tool) and score each element as a percentage of

“correct out of total” questions. We did not undertake this type of scoring, however, because it is unlikely that it would change the outcome for a comparison of program and interview scores.

III. COMPARISON OF TWO QUANTITATIVE FIT-TEST METHODS USING N95 FILTERING FACEPIECE RESPIRATORS

A. Background

The gold standard for assuring proper respirator performance is to conduct one or more WPF studies in a representative population of workers. A WPF study measures respirator fit in a given workplace for the duration of the workday while subjects perform their jobs. Such studies are expensive and difficult to perform in industrial settings; additional barriers make them almost impossible to conduct in healthcare settings (11).

An SWPF study can be conducted when a WPF assessment is infeasible. During an SWPF study experimental activities should be as similar as possible to tasks performed in the workplace. The benefits of an SWPF study are that specific activities can be chosen based on key variables, such as work rate or body movements. In a simulated setting activities can be repeated to see how fit changes over time and multiple pieces of personal protective equipment (PPE) can be tested together to determine which combination provides the optimal level of protection.

Developing a simulated test that realistically reflects respirator performance in an environment like healthcare should satisfy several criteria. First, the tasks or exercises should be both realistic and those most likely to cause failures in respirator fit. Second, sampling methods should be able to detect both short- and long-term changes in fit. Ideally, changes in fit should be linkable to the tasks or exercises. Finally, it should be possible to predict an individual's WPF using a small set of representative exercises or motions.

Respirator fit tests in the United States use a prescribed set of eight exercises: normal breathing, deep breathing, moving head side-to-side, moving head up-and-down, talking, grimacing, bending over, and normal breathing once more (4). These exercises were derived from tasks performed in military and industrial settings (25). There are no data, however, demonstrating that the FF measured in a laboratory setting using these eight exercises is relevant to or predictive of an individual's fit during actual wear in a workplace (WPF).

A few investigators have used a real-time methodology for measuring respirator fit that employs two-particle count instruments to simultaneously measures particle number concentrations inside and outside a respirator facepiece second-by-second (10, 11). Hauge et al. (2012) recently used this approach in an SWPF study to measure the fit of an N95 FFR worn by eight registered nurses performing typical healthcare tasks in a simulated patient care room. They demonstrated the feasibility of this two-instrument approach in a simulated healthcare environment. Their data were also suggestive of an association between each subject's initial quantitative FF using the traditional instrument with the eight OSHA exercises and their fit using the new two-instrument method with simulated healthcare tasks (11), but the association is confounded by the use of the two methods to evaluate fit during different tasks. Thus, the goal of this work was to determine conclusively if fit measured with the new real-time methodology is similar to that measured using the traditional method.

We describe here the results of experiments designed to demonstrate that the new real-time methodology produces similar FFs as a traditional quantitative fit test for each of the eight fit-test exercises as well as for the exercises combined. We explore in more detail, as well, the effect of wear time on respirator fit, the nature of fit for each of the exercises, and the effect of each exercise on overall fit.

B. Methods

Use of human subjects approval was obtained from the University of Illinois at Chicago Institutional Review Board prior to recruitment (approval number 2013-1160).

1. Subject recruitment

The goal was to recruit at least 15 subjects with a range of face sizes and at least three subjects in cells 3, 4, 7, and 8 in the NIOSH BVA panel (Figure 3). This number was selected as a feasible scope for this project. These cells were selected because they would be the most representative of the US population. Subjects were recruited using posted flyers and emails and screened by telephone or email survey using a preliminary questionnaire to assess health conditions and willingness to be clean shaven and refrain from smoking and drinking at least 60 minutes prior to a test. Subjects were scheduled for a one-hour time period. No compensation was offered.

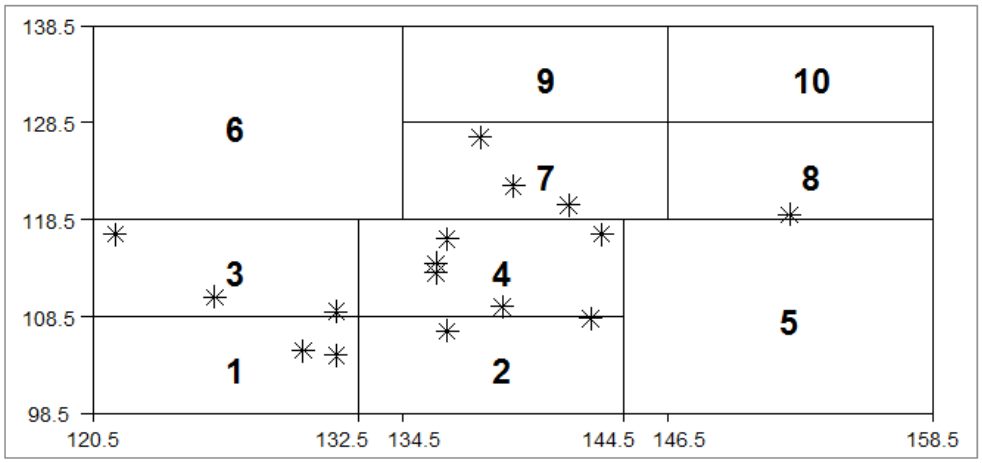

Figure 3. Bivariate cells by face length and width as determined by Zhuang et al. (30) and distribution of subjects' face length and width (indicated by stars).

Upon arrival, each subject completed a written survey with questions similar to those used in screening, ensuring they had no respiratory or other health concerns that would make wearing a respirator difficult, did not experience claustrophobia, did not have facial impediments that would interfere with fit, were clean shaven, and were between 18 and 65. Subjects were also asked to confirm they had refrained from eating and smoking. Subjects not meeting these criteria were not tested further. Written informed consent was obtained for each subject.

Each subject's face length (menton sellion) and width (bizygomatic breadth) were measured using a sliding caliper (Seritex Model 104) and spreading caliper (Seritex Model 106), respectively. These measurements were used to determine each subject's cell in the NIOSH BVA fit-test panel (41).

2. **Experimental setup**

All fit tests were conducted in a test chamber consisting of a 5 ft. (width) × 5 ft. (length) × 9 ft. (height) portable tent with clear plastic sides and zipper access at all corners.

Three salt aerosol generators (TSI Model 8026) and an ultrasonic humidifier (Vicks) were used to generate particles and a floor fan was employed to maintain a steady, uniform aerosol concentration inside the test chamber. Aerosol concentration ranged from 1000 to 2500 p/cm^3.

Three TSI Portacount Plus (Model 8020) with N95-Companion^{TM} (Model 8095) instruments were used throughout the study: Portacount A was used to measure fit following the OSHA ambient aerosol CNC quantitative fit-testing protocol and Portacounts B and C were used to measure real-time fit simultaneously inside and outside the respirator (26). All pair-wise combinations of Portacounts were tested using a range of particle concentrations to ensure a similar (± 15%) and linear response (Appendix B)

3. **Fit tests**

The respirator was previously probed just in front of the mouth using the TSI probing tool (Model 8025-N95). The respirator was attached to 8-foot non-conductive Tygon tubing and the subject was instructed to don the respirator. The researcher ensured the respirator was donned correctly. The respirator tubes were run through a binder clip attached to the subjects clothing ensuring enough slack was given for head movements. While wearing the respirator the subjects sat still for five minutes to allow for any comfort adjustments and to ensure proper fit during the experiment.

Once the size of the face was determined, an N95 FFR was selected (3M 1860 or 3M 1860s). Subjects began the experiment using the size thought to give the best fit. If, after the first fit-test exercise, the measured FF was less than 100, the experiment was stopped and the other size respirator was used. If the second size respirator did not result in a FF greater than 100, the experiment was stopped and the subject was excluded from the study.

During each fit test, subjects performed the eight traditional exercises in the order mandated by OSHA (normal breathing, deep breathing, turning head side-to-side, moving head up-and-down, talking, grimace, bending over, and normal breathing) (4).

a. **Traditional fit-test instrument**

A single CNC instrument was used to measure respirator fit as described in the OSHA ambient aerosol CNC method (26). The instrument employs a switch valve to take alternating samples of ambient and inside-facepiece particle concentrations, with 5-second purges after each ambient sample to ensure zero particles in the sampling tube prior to inside-facepiece sampling. Purge times were extended to 20 seconds in this study to account for the longer 8-foot tube lengths, which were employed in preparation for later studies involving more strenuous healthcare tasks. The instrument software (TSI Fitplus, version 3.4) was used to capture and record all measures of ambient and inside-facepiece concentrations and calculated FFs for each exercise; the displayed FFs were also recorded manually.

b. **Real-time fit-test method**

During the real-time fit-test protocol, two Portacount instruments (TSI model 8020) were used, one measuring particle concentrations every second inside the facepiece while the second simultaneously measured particle concentrations in the ambient air just outside the facepiece. Proprietary software (3M Company) recorded second-by-second particle counts from each instrument simultaneously.

During the traditional fit test, the tube measuring ambient concentrations and the tube measuring inside-facepiece concentrations were both connected to the same Portacount (Portacount A). To switch to the real-time measurements, the tube measuring ambient concentrations was moved from Portacount A to Portacount B and the tube measuring inside-

facepiece concentrations was moved from Portacount A to Portacount C. In this manner the tubing was never disconnected from the respirator and the face seal of the respirator was unaffected.

4. **Experimental protocol**

Each subject completed two fit tests, one traditional and one using the new protocol, in sequence without removing or adjusting the respirator. The order in which the fit tests were performed was randomized. Subjects performed the same sequence of exercises for the same time periods during each of the two fit tests. Each set of exercises takes 15 minutes to complete; an entire experiment was completed in about 35 minutes.

5. **Data analysis**

For the traditional fit test, the instrument software assumes the data will be normally distributed and calculates two averages for each exercise: (1) for all data recorded for 15 seconds of ambient concentration measurements taken before and after the exercise, and (2) for all data recorded for 50 seconds of inside-facepiece concentration measurements taken throughout the exercise. The software then reports and calculates an FF for each exercise by dividing the latter by the former. An overall FF is calculated by taking the harmonic mean of seven of the eight exercise FFs. The grimace exercise is omitted because it is designed to purposefully break the seal of the respirator and produce a lower FF. The software records and reports only the FFs for each exercise and for the seven exercises combined (42).

Prior to and after each experiment, side-by-side measures of ambient concentration were recorded to derive a correction factor to adjust for small differences between the two Portacounts (B and C) used in the real-time fit test. After each experiment, the real-time data from Portacount B were adjusted using the correction factor to match concentrations from Portacount C.

Real-time FFs were calculated using second-by-second measures of ambient and inside-facepiece concentrations recorded by the 3M software and transferred to Microsoft Excel spreadsheets for analysis. The 50 seconds of mask-sampling data were used to calculate an FF for each exercise by dividing the mean of the concentrations outside the facepiece (C_{out}) by the mean of the inside-facepiece concentrations (C_{in}) (Equation 1). Data below the limit of detection (0.6 p/cm^3) were replaced with a concentration of 1 p/cm^3, to be consistent with the TSI software for the single instrument method.

$$FF = \frac{\bar{C}_{out}}{\bar{C}_{in}} \qquad \textit{Equation 1}$$

The overall FF was calculated excluding the grimace exercise using equation 2.

$$Overall\ FF = \frac{n}{\frac{1}{FF_1}+\frac{1}{FF_2}+\cdots+\frac{1}{FF_n}} \qquad \textit{Equation 2}$$

where FF_i = FF for each exercise and i = {1, 2, … n} numbers of exercises.

Statistical analysis and graph generation were done using RStudio® (Boston, Massachusetts http://www.rstudio.com). Boxplots were used to explore data distributions by type of fit test, exercise, and sequence. Spearman rank correlation coefficients were generated to evaluate the relationship between the traditional and real-time fit-test exercises. A repeated measure analysis of variance (ANOVA) was used to control for variability within subjects to determine the effect of time on the normal breathing. A Bartlett test was applied to the normal breathing data to test for differences in the normal breathing repetition variances.

Multiple linear regression was performed to identify which fit-test exercises had the greatest influence on overall respirator fit for both the traditional as well as the real-time fit tests.

C. Results

1. Subjects

The study was conducted during February and March of 2014. Twenty-two subjects expressed interest, two subjects decided not to participate because there was no compensation offered. One subject was not located in Chicago and would not have been able to travel to participate. Nineteen subjects were successfully recruited to participate. All subjects kept their appointments but three were rejected from participation because a good respirator fit could not be established. Sixteen subjects (ten female and six male) successfully completed the experimental protocol. The subjects' face sizes placed them in five of the ten NIOSH BVA panel cells: 1 (two subjects), 3 (four subjects), 4 (six subjects), 7 (three subjects), and 8 (one subject) (Figure 3).

2. Comparing two protocols

The 16 subjects had a similar distribution of FFs under either protocol for each exercise and for all exercises combined, with the grimace showing the lowest FF and the largest difference between the two protocols (Figure 4). The two tests were highly correlated ($r>.7$) for the first five exercises and not at all correlated ($r<.1$) for the last three exercises (grimace, bending over, and the second normal breathing). The overall FF for the two tests was moderately correlated ($r=.5$) (TABLE VI).

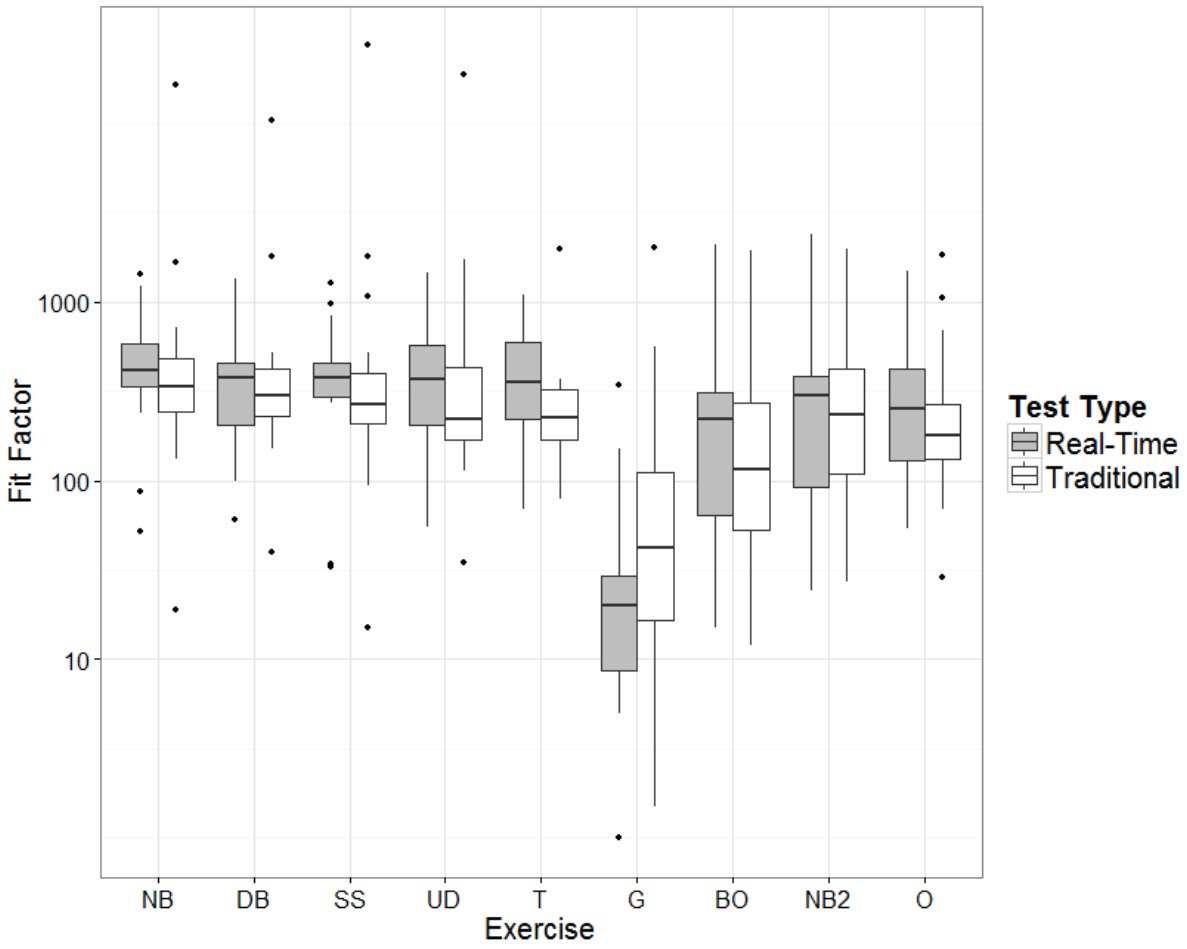

Figure 4. Real-time versus traditional FFs by exercise and for all exercises combined.
(n=16) (NB–Normal Breathing; DB–Deep Breathing; SS–Head Side-to-Side; UD–Head Up-and-Down; T–Talking; G–Grimace; BO–Bend Over; NB2–Normal Breathing 2; O–Overall)

TABLE VI

CORRELATION COEFFICIENTS COMPARING REAL-TIME FIT FACTORS TO TRADITIONAL FIT FACTORS

(n=16)

Exercise	**Spearman's r**	**p-value**
Normal Breathing	0.685	0.003
Deep Breathing	0.762	0.001
Side-to-Side	0.718	0.002
Up-and-Down	0.720	0.002
Talking	0.422	0.117
Grimace	0.031	0.904
Bend Over	0.071	0.795
Normal Breathing 2	0.062	0.826
Overall	0.469	0.067

A paired t-test indicated no significant differences between the FFs from the two protocols for each exercise and for all exercises combined (p-values ranged from 0.196 to 0.956) (TABLE VII).

TABLE VII

PAIRED T-TEST COMPARING FIT FACTORS MEASURED DURING EXERCISES USING THE REAL-TIME AND TRADITIONAL METHODS

Exercise	p-value
Normal Breathing	0.36
Deep Breathing	0.33
Head Side to Side	0.33
Head Up and Down	0.36
Talking	0.85
Grimace	0.19
Bend Over	0.86
Normal Breathing 2	0.93
Overall	0.90

3. **Effect of time on fit**

Boxplots comparing FFs by test sequence (first versus second) (Figure 5) indicate similarities in both median and range for the first five exercises, as was observed when comparing the two protocols without respect to sequence (Figure 4). The highly positive and statistically significant correlations between FFs measured by the two protocols for the first four exercises (ranging from 0.80 to 0.93 with p-values<.016) indicate that the fit-test sampling protocols are similar (TABLE VIII).

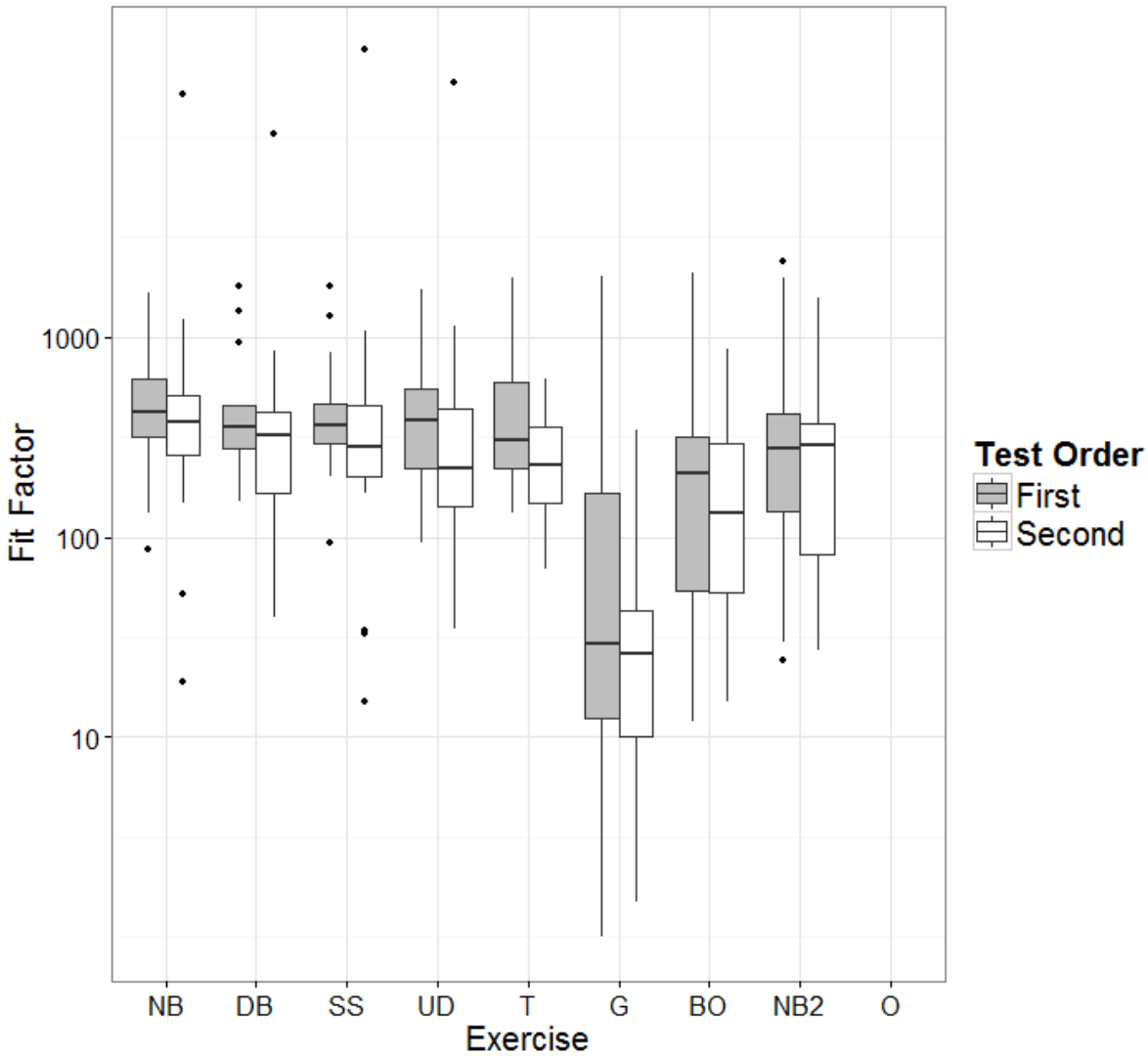

Figure 5. First fit test versus second fit test by exercise.
(NB–Normal Breathing; DB–Deep Breathing; SS–Head Side-to-Side; UD–Head Up-and-Down; T–Talking; G–Grimace; BO–Bend Over; NB2–Normal Breathing 2; O–Overall)

TABLE VIII
CORRELATION COEFFICIENTS BY TIME

(n=8)

	Traditional then Real-Time		**Real Time then Traditional**	
	Spearman's r	p-value	Spearman's r	p-value
Normal Breathing	0.93	<.001	0.80	0.016
Deep Breathing	0.84	0.009	0.81	0.014
Head Side-to-Side	0.91	0.001	0.88	0.004
Head Up-and-Down	0.92	0.001	0.87	0.005
Talking	0.74	0.034	0.64	0.120
Grimace	-0.04	0.926	0.29	0.485
Bend Over	-0.05	0.905	0.33	0.429
Normal Breathing 2	-0.37	0.364	0.24	0.571
Overall	0.22	0.598	0.95	<.001

A

A comparison of boxplots of the FFs for the four normal breathing exercises, for all data from the two fit-test protocols combined, shows that the first three repetitions are almost exactly alike with respect to the medians and variance (Figure 6). The fourth repetition, which follows the second grimace exercise, shows a large increase in variance. Repeated measures ANOVA indicated, however, that none of the mean FFs during normal breathing are significantly different

from any of the others (p-value=.275). A Bartlett test found that the variance in at least one repetition is significantly different from the others (p-value<.001).

4. **Effect of exercise on fit**

A step-wise multiple linear regression analysis was conducted to identify exercises with the greatest influence on overall fit (TABLE IX). For the traditional fit-test protocol the deep breathing, head side-to-side, and bending over exercises were all significant variables in the model. The second normal breathing exercise was included in the model because it approaches significance. In the real-time protocol the bending over and talking exercises had the greatest influence on overall fit.

TABLE IX
RESULTS OF STEP-WISE MULTIPLE LINEAR REGRESSION ANALYSIS PREDICTING OVERALL FIT FACTOR BY EXERCISES FOR (A) TRADITIONAL FIT TEST AND (B) REAL-TIME FIT-TEST METHODS

(a)Traditional Fit Test

Exercise	Coefficient	P-Value
Intercept	-16.85	0.422
Deep Breathing	0.49	0.002
Head Side-to-Side	-0.15	0.005
Bending Over	0.50	0.001
Normal Breathing 2	0.14	0.066

(b)Real-Time Fit Test

Intercept	29.91	0.44
Talking	0.55	<.001
Bending Over	0.33	<.001

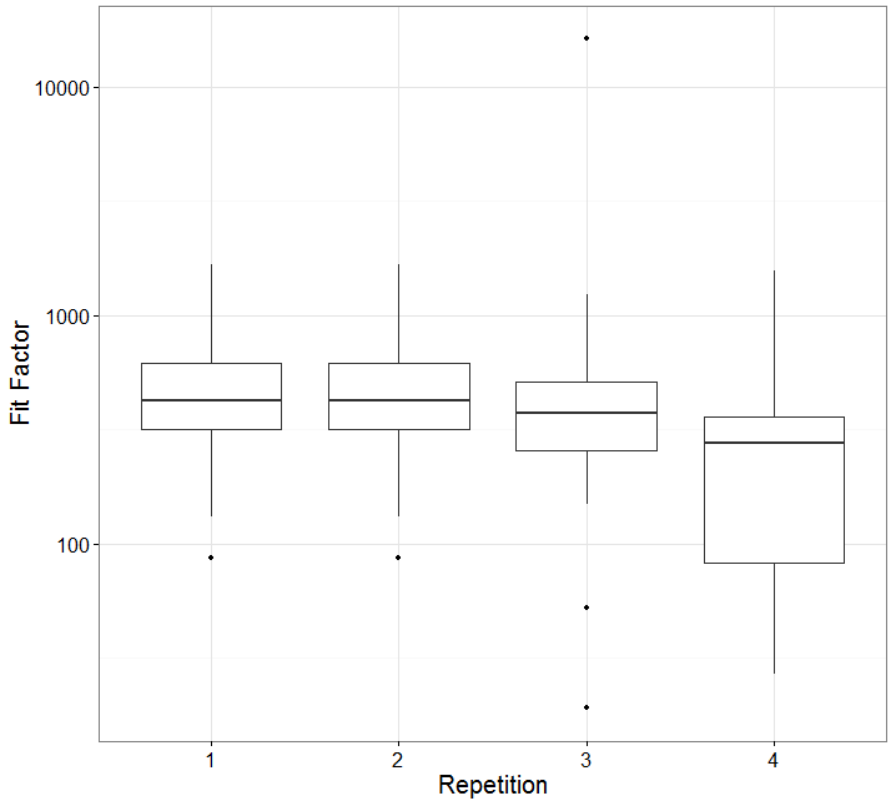

Figure 6. Normal breathing distribution by order performed.

D. **Discussion**

As expected, we demonstrated that the new real-time two-instrument method measures FFs in a similar manner as the traditional single-instrument quantitative fit test. This was clearly illustrated by the fact that the first four exercises had almost identical FFs when comparing the two protocols directly or when examining the data by testing order.

Our analyses suggest that respirator fit is altered during either the talking or grimace exercise, both of which involve facial movements that could dislodge the facepiece. However,

the manner in which these exercises influence fit is not consistent, which was only apparent when we compared the data by test order.

Our test-order analyses also suggest that after the first talking or grimace exercise, regardless of protocol, respirator fit returns to its initial level. After the second talking or grimace exercise, however, the respirator does not reseat in the same manner (TABLE VII). For some subjects the respirator fit improved during the second test while for others it deteriorated. That this happened for either protocol indicates that this phenomenon is associated either with wear-time in general or more specifically due to inconsistent resealing following the talking or grimace exercise, or perhaps a combination of these variables.

In linear regression models, bending over was the only exercise that predicted overall fit in either the traditional or new fit-test protocols. Deep breathing, head side-to-side, and talking are also highly predictive of overall fit for at least one of the protocols. These findings are similar to those of Crutchfield et al. (1999), who found in a study with 14 subjects that talking and bending over were most likely to cause leaks in an elastomeric or full-facepiece respirator (43). Richardson et al. (2014) found similar results in a study of 50 fit-test pairs examining how well a faster fit-test protocol predicts respirator fit. The exercises included in this faster fit test were bending over, talking, head side-to-side, and head up and down (12). Richardson et al. determined that performing each of these exercises for 30 seconds results in a FF similar to the traditional OSHA QNFT (12). Our study found the same exercises to be most predictive of overall fit.

To our knowledge this is the first study comparing repeated fit tests without redonning. In addition, few studies have examined the effect of wear-time or exercise on long-term respirator

fit. Hauge et al. (2012) evaluated respirator fit in the context of three simulated healthcare-related work scenarios with eight subjects using the real-time methodology (11), and found the SWPFs measured for the third scenario were significantly different from the first and second scenarios, suggesting that wear-time or multiple respirator dislodgements (or both) may be important to on-going respirator fit. These investigators were not able to explore the relationship between traditional and real-time FFs due to software limitations.

In retrospect, the grimace exercise should have been excluded from the experimental protocol. This exercise is not used in the calculation of an FF and has an unpredictable effect on fit that introduces a source of unnecessary variability to the comparison of the fit-testing protocols. Other limitations are the small number of subjects and the lack of subjects in all cells of the BVA panel. More subjects in more cells would expand the generalizability of these findings.

It was observed during this set of experiments that there is some moisture buildup on the sampling tube measuring inside-facepiece concentrations. The relationship between the two Portacounts used for the real-time methodology changed over time; after the experiment the inside-facepiece Portacount measurements were lower than at the start. It is assumed that moisture in the tube results in particle collection and loss to instrument measurement. The time at which such particle loss occurs is not easy to determine, thus the line of best fit between the initial and the final sets of data was used to derive a correction factor between the two instruments. A real-time sampling method offers important advantages over the traditional single-instrument approach. There is great interest in understanding how respirators perform over time in real-world workplace settings. In many instances, however, workplace conditions or sampling requirements preclude the measurement of WPFs. It has been proposed that laboratory-

based scenarios comprising multiple donnings or realistic work tasks might be used to measure a simulated WPF, although no investigator has yet shown a predictive relationship between WPFs and SWPFs for a respirator model or class. The real-time methodology also allows exploration of respirator performance in environments where traditional WPF methods cannot be used, such as healthcare settings where the ambient particle concentration is too low to measure gravimetrically.

This new real-time methodology will be used in future healthcare SWPF studies in which simulated healthcare tasks will be performed in a laboratory setting to measure and predict respirator fit. In future work, by overlaying concentration data on top of video, I hope to use real-time data to determine specific tasks or head motions that cause a healthcare respirator to fail.

IV. EVALUATING SIMULATED WORKPLACE PROTECTION FACTORS FOR A FIRST-RESPONDER LOW-LEVEL PROTECTIVE ENSEMBLE

This paper has been submitted to the *Journal of International Society for Respiratory Protection.* It has been accepted with revisions. The following paper incorporates revisions made in response to reviewers' comments.

A. **Abstract**

First responders are required to wear multiple layers of PPE while performing a range of physiologically demanding tasks for long periods of time. They are often required to wear high levels of respiratory protection, which can adversely impact their ability to work safely.

The goal of this study was to evaluate the respiratory protective performance of a lower-level protective ensemble in the course of performing typical first-responder activities. This ensemble included an N95 FFR in combination with a disposable hooded suit and latex gloves.

Eleven subjects (10 male; 1 female) were recruited for a range of facial sizes. Each subject donned an N95 FFR, disposable suit (without hood), and latex gloves. An initial FF was measured following the Canadian fit-test protocol. The subject then donned the hood, entered a test chamber, and performed a 31-minute exercise protocol. Real-time measurements of particulate concentration of duration one-second, inside and outside facepiece, were simultaneously performed using two Portacount instruments. Subjects exited the chamber, removed the hood, and completed a final quantitative fit test.

While limited by the small number of subjects and few small faces, we were able to show that N95 FFRs can provide a high degree of protection (SWPFs ranging from 100 to 1000). We found no consistent relationship between initial and final FFs or between FFs and SWPFs.

The two-instrument method combined with a challenging exercise protocol can elucidate several important respirator performance factors, including most challenging work tasks, effects of sweating and higher metabolic output, and interactions from other PPE.

B. **Background**

As a premise of employment, first responders often put themselves in potentially dangerous situations to protect the lives of others. When responding to a chemical, biological, radiological, and nuclear (CBRN) event, it is important that first responders can count on their respirator to provide an adequate level of protection. A quantitative test that employs a short, limited set of exercises may not provide sufficient information about respirator fit for such hazardous work.

Each class of respirator has an assigned protection factor (APF), which is the protection a trained population can expect to receive from a properly fitting and functioning respirator. Assigned protection factors are used by regulators and standards development organizations, such as OSHA and CAN/CSA Z94.4 (4,44). The APF is multiplied by a safety factor, to determine the necessary FF each employee is required to receive prior to being issued their respirator; this takes into account expected degradation between the FF and the performance expected in the workplace (which should not be worse than the APF). As a result, APFs are conservative values and may underestimate achievable performance.

An APF should be derived from measures of actual respirator performance conducted on a variety of workers performing a range of work tasks in a variety of workplaces. Measuring respirator performance in the workplace—a WPF—requires full-shift samples of inside and outside concentrations of a contaminant during work activities. High-quality WPF data could provide adequate knowledge of how an individual's respirator performs in a given industry and perhaps eliminate the need for a safety factor.

Previous workplace protection studies in industrial settings have compared 8-hour gravimetric samples collected inside the respirator and on the lapel. Subjects usually receive a qualitative fit test prior to WPF sampling and their activities are noted throughout the day. This test protocol cannot be easily performed with first responders for several reasons. First, there are no gravimetric methods sensitive enough to measure the relatively low concentrations of infectious respiratory aerosols, even if sampling were conducted over an 8-hour period. In addition, observing first responders is complicated by the presence of hazards and the unpredictable nature of their work.

Hence, it is only possible to measure the performance of a respirator in first-responder settings using a simulated environment in which subjects (ideally first responders) perform typical field tasks. A proposed methodology has been described for conducting a simulated fit or protection factor assessment using two Portacounts continuously monitoring inside-facepiece and ambient concentrations (10, 11). By controlling the work rate it may be possible to use simulated settings to provide very accurate information regarding the fit a respirator might provide to first responders. This knowledge could lead to more informed respirator selection.

The US Respiratory Protection standard (1910.134) does not specifically address how to select a respirator when exposed to biological hazards, for which there are commonly no exposure limits nor easy methods for measuring airborne concentrations. The recently updated Canadian Selection, Use, and Care of Respirators standard (CAN/CSA Z94.4-11) describes a control banding approach to respirator selection for bioaerosols in general and healthcare workplaces. Neither of these standards, however, is appropriate for selecting respiratory protection for first responders.

In Canada, the Protection of First Responders from CBRN Events (CAN/CGSB/CSA-Z1610-11) requires testing respiratory protective devices as part of a full ensemble (protective clothing and other equipment) using SWPF tests. The standard notes that while highly protective, CBRN full-facepiece air-purifying or air-supplying respirators are most appropriate for unknown or high-hazard situations; lower levels of protection—including FFRs—may be possible for some situations and organisms.

The goals of this research paper are to describe a novel methodology for conducting SWPF assessments of a low-level protective ensemble using real-time data collection and to compare quantitative FFs and SWPFs for a small group of first responders wearing N95 FFRs with a disposable hooded suit and latex gloves.

C. **Methods**

1. **Equipment**

A test chamber was set up to have sufficient space for one volunteer to perform the activity routine, with one staff operator present to assist and carry the sampling instrument.

The test chamber consisted of a 3.1 m (width) x 5.8 m (length) x 2.2 m (height) portable garage tent retrofitted with plastic windows with an antechamber on one end. The antechamber allowed easy entry and exit from the chamber with minimal disturbance to a uniform aerosol concentration. Experiments were conducted on four separate days; across all days, as measured by the N95 Companion, the concentration inside the tent ranged from 1,500 particles p/cm^3 to 5,000 p/cm^3. The tent was lined along the inside walls with plastic drop sheets and a large tarp draped along the floor, and contained various equipment needed to perform the activity routine, including a treadmill, step ladder, weighted dummy, and loaded weight on a cart.

Within the tent, eight salt aerosol generators (TSI Model 8026) and floor or standing fans in each corner were used to maintain a steady uniform aerosol concentration throughout the space. Concentrations in the tent ranged from 40,000 to 80,000 p/cm3, permitting a reliable measurement of protection factor greater than 6,500. Validation of the uniformity of the challenge aerosol was assessed by measuring the concentration at various locations and heights throughout the chamber; concentrations in the chamber varied by no more than 15%.

Two TSI Portacount Plus (Model 8020) with N95-Companion™ (TSI Model 8095) instruments were used to measure concentrations inside and external to the respirator facepiece. The two instruments were calibrated together over a range of ambient concentrations to ensure their measurements would be within 15% of each other. A correction factor derived from the ratio of side-by-side ambient concentration measurements was used to correlate the two instruments' results after data collection was finished.

Tests were usually performed at ambient temperature. A portable air conditioner (Simplicity SPAC9507, 9,500 BTU/h) was used to maintain humidity levels at less than 60%

(45). Environmental conditions were monitored with a temperature/humidity probe inside the chamber.

Software developed by the Royal Military College of Canada (RMCC) was used to record second-by-second particle counts from each instrument connected to a computer laptop. The software collects information about activity timing and operator comments, and displays approximate instantaneous and cumulative protection factors in real-time. Side-by-side data collection from two instruments is conducted by simultaneously starting the software on each computer, with activity timing controlled with a timer inside the tent.

A sampling tube was attached to a sampling probe affixed to the side of the respirator facepiece. The instrument used to sample inside-facepiece concentrations was connected to a Bluetooth device and an external battery supply and placed in a case with the sampling tubes extending through a hole in the side of the case. This case was transported by a staff operator inside the chamber throughout the activity routine. Data from this instrument were recorded via the Bluetooth connection by a laptop placed on a table outside the chamber.

Also located outside the chamber were the second instrument and a second laptop computer, which were used to measure and record chamber concentrations via a sampling tube extending into the chamber through a hole in the tent wall.

2. **Activity routine development**

Through consultation with various first-responder groups, an activity routine was developed to incorporate workplace activities commonly used by police emergency response, police public order, firefighters, paramedics, and CBRN response teams responding to a CBRN event (TABLE X). Although some of the activities are more relevant to certain groups than others, the variety of activities in the routine ensured that the protective system could be

evaluated for a wide range of first-responder use. For example, the activity “perform traffic gestures” would be more relevant to police public order units, while “squat, turn over manikin, and examine” would be more relevant to paramedics. Activities that produce a wide range of basic body and head movements and may potentially place added stress on the seal of the respirator were also included in the protocol (e.g., “bend over” and “lunge, leg, and look”).

TABLE X

EXERCISE ROUTINE PERFORMED DURING SWPF

Activity #	Activity
1	Stand still, normal breathing
2	Bend over for 15 sec., rest for 15 sec., and repeat.
3	Smile, frown, yawn, and rotate jaw; repeat 5 times, every 10 sec.
4	Lunge right leg forward and turn head left and right, tilt head forward and backwards, stand, repeat with alternate leg. Repeat alternating legs 4 more times (once every 12 sec.)
5	Step onto step stool or platform, raise left arm to touch ceiling, small jump off platform, touch floor with left arm, repeat and raise alternate arm (5 times, once every 10 sec.)
6	Jog on treadmill (or equivalent) at 7 km/h. (4.3 miles per hour) and zero inclination
7	Jog on treadmill (or equivalent) at 4 km/h. (2.5 miles per hour) and zero inclination
8	Stand still, normal breathing
9	Lie in prone position, look at target objects (10 sec.), rest (5 sec.), repeat 3 times, stand
10	Carry equipment (5 sec.), load and pull the cart (15 sec.), unload equipment (10 sec.), repeat once
11	Perform traffic control gestures
12	Crawl on hands and knees (5 sec.), look up, left and right (5 sec.), repeat 5 times
13	Climb up and down 2 rungs of the ladder repeatedly (once every 6 sec.)
14	Squat, turn over manikin, and examine, repeat once
15	Drag manikin by a rope tied under the arms (15 sec), rest (5 sec), repeat 2 times
Repeat exercises 1–15	
Final	Stand still, normal breathing

The 31-minute activity routine consisted of two repetitions of 15 one-minute activities followed by a final one-minute normal breathing activity (TABLE X). Each activity was repeated to reveal whether particular activities had a consistent impact on respirator performance

as well as to evaluate the effects of increasing work rate and sweating over the course of the routine.

The activities ranged from light-to-heavy work rates and generated an average moderate metabolic work rate for the complete routine (46). Running on the treadmill was incorporated to bring test participants to a high work rate. Rest periods and light-work rate activities were interspersed between the high-work rate activities to maintain the test subject's stamina and allow time to recuperate. Rest periods (i.e., normal breathing) also provided a "baseline" measure with no movement to assess the long-term effects of dislodging the respirator facepiece. The total duration and nature of the activities were generally sufficient for test participants to achieve sweating and maintain a moderate work rate.

3. Experimental protocol

a. Initial quantitative fit test

Eleven subjects were recruited (10 males and 1 female) to participate in the study. Initial subjects were first responders but the subject pool was subsequently supplemented with nonresponders to obtain a broader anthropometric distribution. The final group included 6 responders and 5 nonresponders. Both the Principal Component Analysis (PCA) and the BVA (30), are currently being used by NIOSH and the International Organization for Standarization to ensure that a respirator fits 95% of the general population. Anthropometric measurements were performed on each subject to determine their fit-test cell in both the BVA and PCA facial panels (30). The BVA and the PCA panels are represented by 10 and 8 test cells, respectively, where the larger-numbered cells represent large size faces. Final distribution included bivariate cells 3, 5, 7, 8, 9, and PCA cells 1, 5, 6, 7, 8, showing more of a bias towards

larger-size faces (which is more characteristic of first responders, as there tends to be disproportionately fewer females compared to the general workforce).

Each subject donned a single-use coverall (Kleenguard A60) and latex gloves in addition to their respirator. A probed N95 FFR was chosen (either the regular size 3M 8210 or the small-size version 3M 8110s) to fit the subject, and worn for five minutes to allow the mask to adjust to the face. A QNFT was then performed using two Portacount Plus and N95 Companion instruments, as described above. The Canadian standard Z94.4-11 exercise protocol was followed, which consists of seven 30-second activities (normal breathing, deep breathing, turn head side-to-side, nod head up-and-down, slowly recite alphabet, bend over once every two seconds, normal breathing) (44) suit hood was not donned during the QNFT.

If the subject did not achieve an FF of at least 100 during the QNFT, they were retested with a respirator of a different size. In some cases, the test participant was retested in the same respirator size used initially, if an inappropriate donning of the mask or other error was suspected.

b. **Simulated workplace protection factor test**

Prior to beginning any tests, each subject was walked through all 15 activities to be sure they understood what they were expected to do. Following the QNFT, the subjects completed donning the full ensemble by placing the hood of the coverall over their head. The SWPF routine took place immediately following the initial QNFT without removing the respirator or any of the tubing. Clocks were synched between the two operators and the 31-minute SWPF routine begun (TABLE X) using the double Portacount methodology described above.

c. **Final quantitative fit test**

Nine of the 11 subjects performed an additional quantitative fit test immediately following the SWPF. Subjects were instructed to remove the hood of their suit prior to starting the second QNFT. This was performed in exactly the same manner as the preliminary fit test following the Canadian standard Z94.4-11 and using the double Portacount methodology (44).

4. **Data analysis**

The quantitative FF for each activity is calculated by dividing the average of the ambient (challenge) concentrations by the average concentration inside the respirator facepiece, over the duration of each 30-second activity.

Since the concentration inside and outside the respirator are measured simultaneously, the SWPF is determined by comparing the average particle concentration inside the respirator to the average ambient particle concentration for each exercise. The same calculation is applied for all of the exercises combined to calculate the overall SWPF.

Descriptive statistics of the averages of the activities were used to examine the data including box and whisker plots which show 1st and 3rd quartiles and median indicated by a line in the middle.

Bar graphs were used to determine, by activity, how many of the subjects achieved an SWPF greater than specific cut-points; this helps to accentuate exercises where subjects achieved the lowest fit. Figure 8 includes both repetitions so the maximum number for each exercise is 22 (11 subjects x 2 repetitions).

D. **Results**

Two subjects (3 and 7) achieved an initial quantitative FF of at least 100 with the small-size respirator while the remaining subjects wore the regular size. Two subjects (1 and 4) completed only an initial fit test; the remaining nine subjects completed quantitative fit tests before and after the SWPF test. Initial FFs ranged from 69 to 1867 (median=303); final FFs ranged from 19 to 5,369 (median=324) (Figure 7).

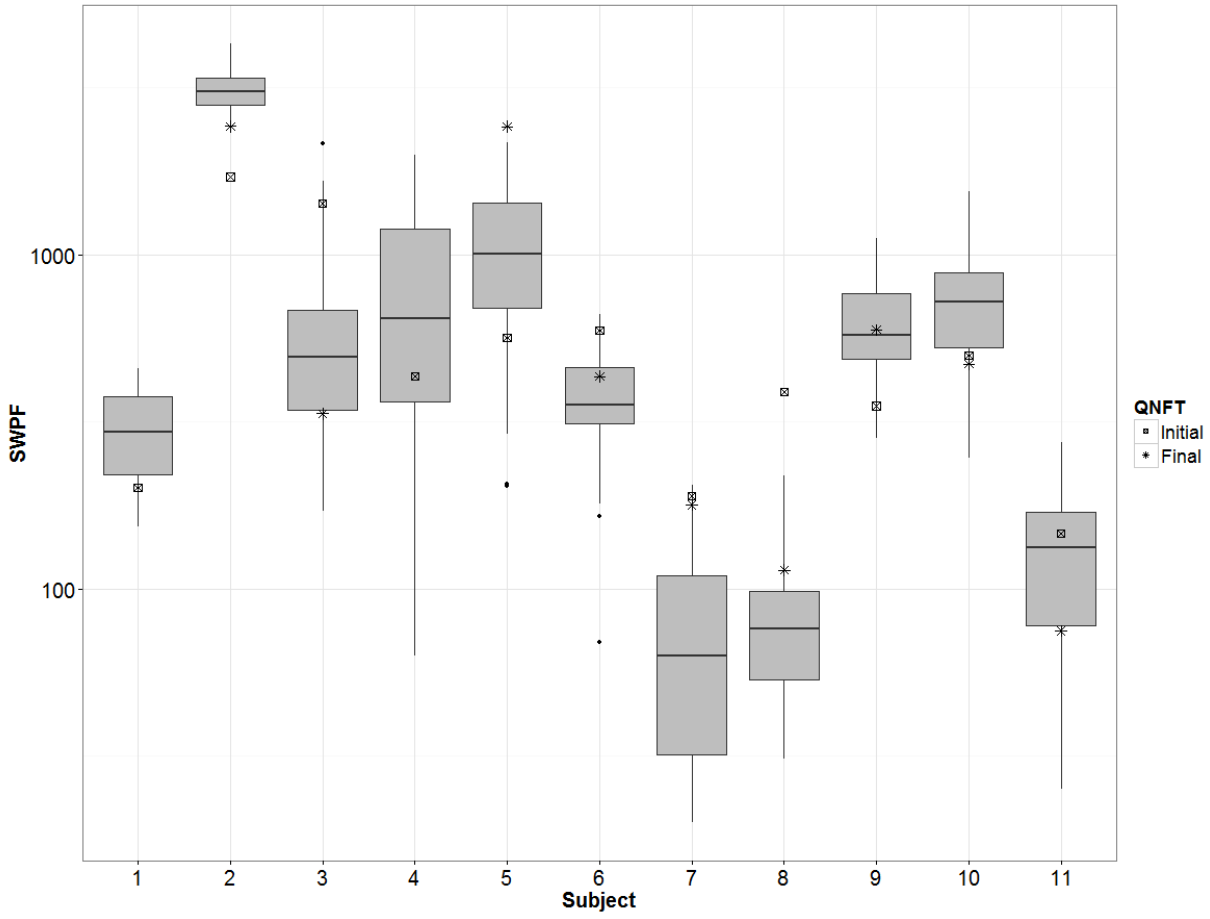

Figure 7. Initial and final FFs and simulated workplace protection factors by subject.

All subjects successfully completed the 31-minute SWPF routine while wearing the N95 respirator, suit and hood, and gloves. The average overall SWPF was greater than 100 for all but two subjects (7 and 8) (Figure 7). For the nine subjects completing both QNFT tests there was no clear trend in the initial and final FF. For three subjects (3, 8, and 11) the FF decreased after the SWPF test; the FF improved after the SWPF test for two subjects (5 and 9), and the FF was similar before and after the SWPF test for four subjects (2, 6, 7, and 10). For one of the subjects with lower post-SWPF FFs (11) the second FF was less than the regulatory requirement of 100 (Figure 7).

For most subjects (8 of 11) the mean overall SWPF ranged from 100 to 1,000 and their initial and final quantitative FFs were also clustered in this range (Figure 7). One subject (2) had an overall SWPF much greater than 1,000 (mean=3,122); this person also achieved initial and final FF>1,000 (1,135 and 1,457, respectively). Two subjects (7 and 8) had overall SWPF well below 100 (42 and 57, respectively); their initial and final quantitative FFs were among the lowest measured. While the average overall SWPF for subject 11 exceeded 100, the lower range fell below 100 and the initial and final FF were also among the lowest measured (134 and 69, respectively).

For most subjects, the initial FF was not representative of respirator performance experienced throughout the SWPF routine (Figure 7).

It may be possible to use these data to elucidate the effect of the full ensemble on respirator fit. For example, among the four subjects who had similar initial and final FFs there were two (subjects 6 and 10) with closely matching SWPFs. It would appear that wearing a suit and hood did not change respirator fit for these two subjects.

For subjects 2 and 7, however, the results were different. For subject 2 adding the hood of the single-use coverall appeared to increase the protection the respirator provides. During the 31-minute exercise routine the SWPF was much higher than either the initial or final FFs measured without the hood. For subject 7 the opposite was true—the initial and final FFs are much higher than the SWPF, suggesting that the hood may have adversely impacted respirator fit when active. This subject noted that the hood was tugging on the straps causing the mask to dislodge during the SWPF exercises.

The subjects in Figure 7 were placed in the order that they performed the test. The effect of face size was examined by placing subjects along the x-axis by BVA panel cell number (data not shown). There did not appear to be any trend in respirator fit based on face size.

For all subjects, the exercises that involved expressions (smile, frown, yawn, and rotate jaw) and crawling (crawl on hands and knees, look up, left, and right) had the lowest exercise SWPFs (Figure 8).

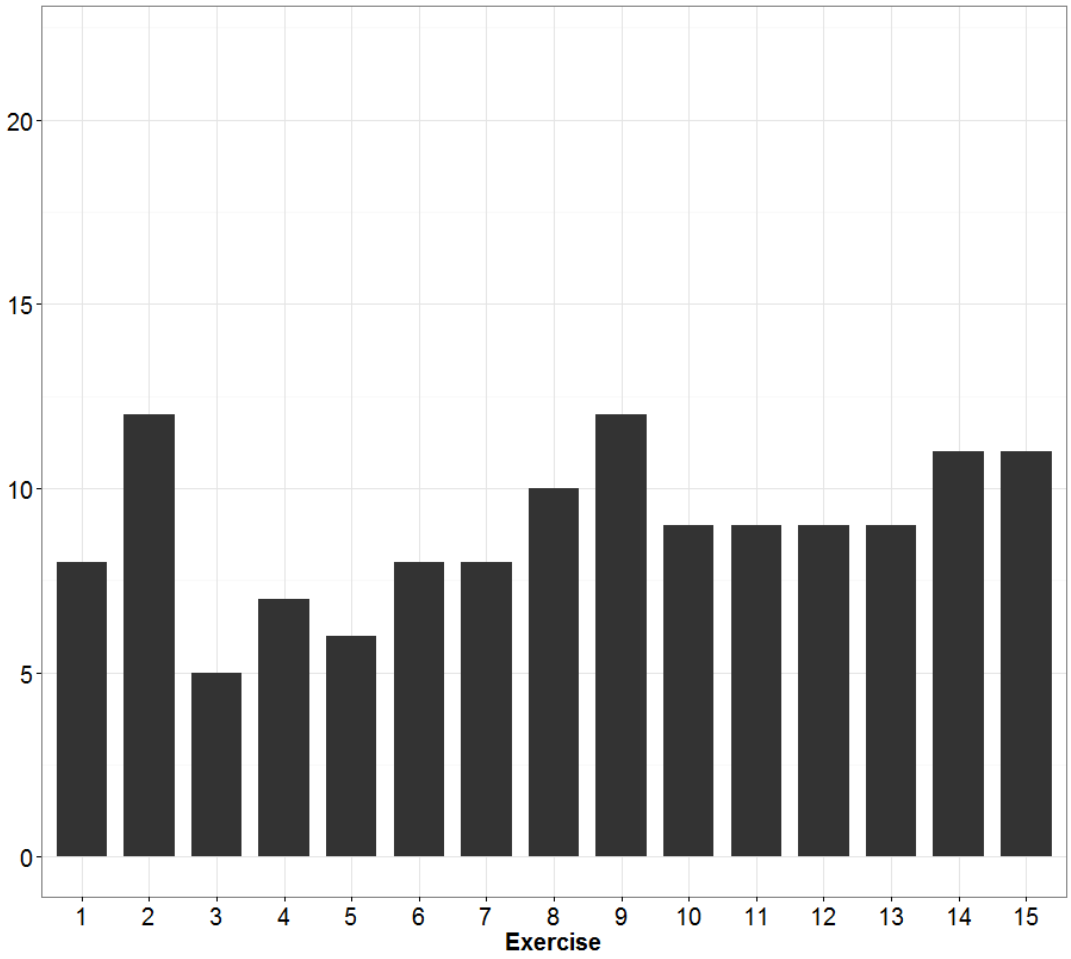

Figure 8. Frequency of SWPF>500 by exercise for entire activity routine.
(refer to Table I for details on exercises) (maximum=22; 11 subjects x 2 repetitions, final normal breathing is not shown)

Comparing the exercise SWPFs between the two repetitions may indicate how the fit changes over time. For exercises early in the routine (1 through 10), subjects often had a higher SWPF during the second repetition, but for exercises later in the routine, the second repetition SWPF was often lower. These trends are particularly clear when examining the number of subjects achieving SWPF>500 for each exercise and repetition (Figure 8).

One subject's second-by-second SWPF has been plotted over the 31-minute exercise period (Figure 9). The fit of the respirator is clearly compromised during jogging and walking on the treadmill but improves during normal breathing immediately afterward; differences in the quality of the seal during the activity can account for the changes.

Box plots of exercise SWPFs by repetition (Figure 10) show that, in addition to decreases in SWPF for second repetition in later exercises, the second repetition was also more variable for many of the exercises (Figure 10).

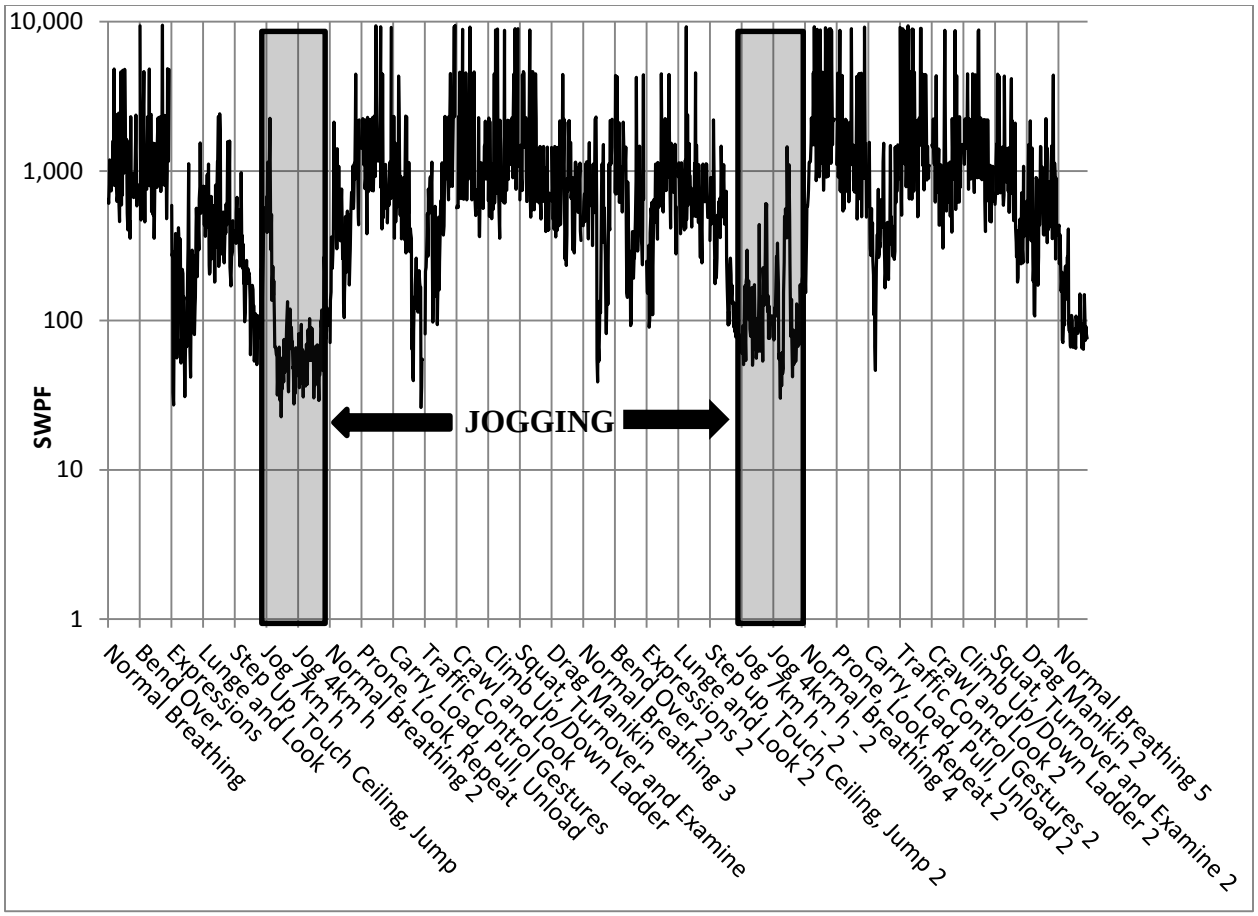

Figure 9. Example of instantaneous SWPF for 30-minute activity routine.

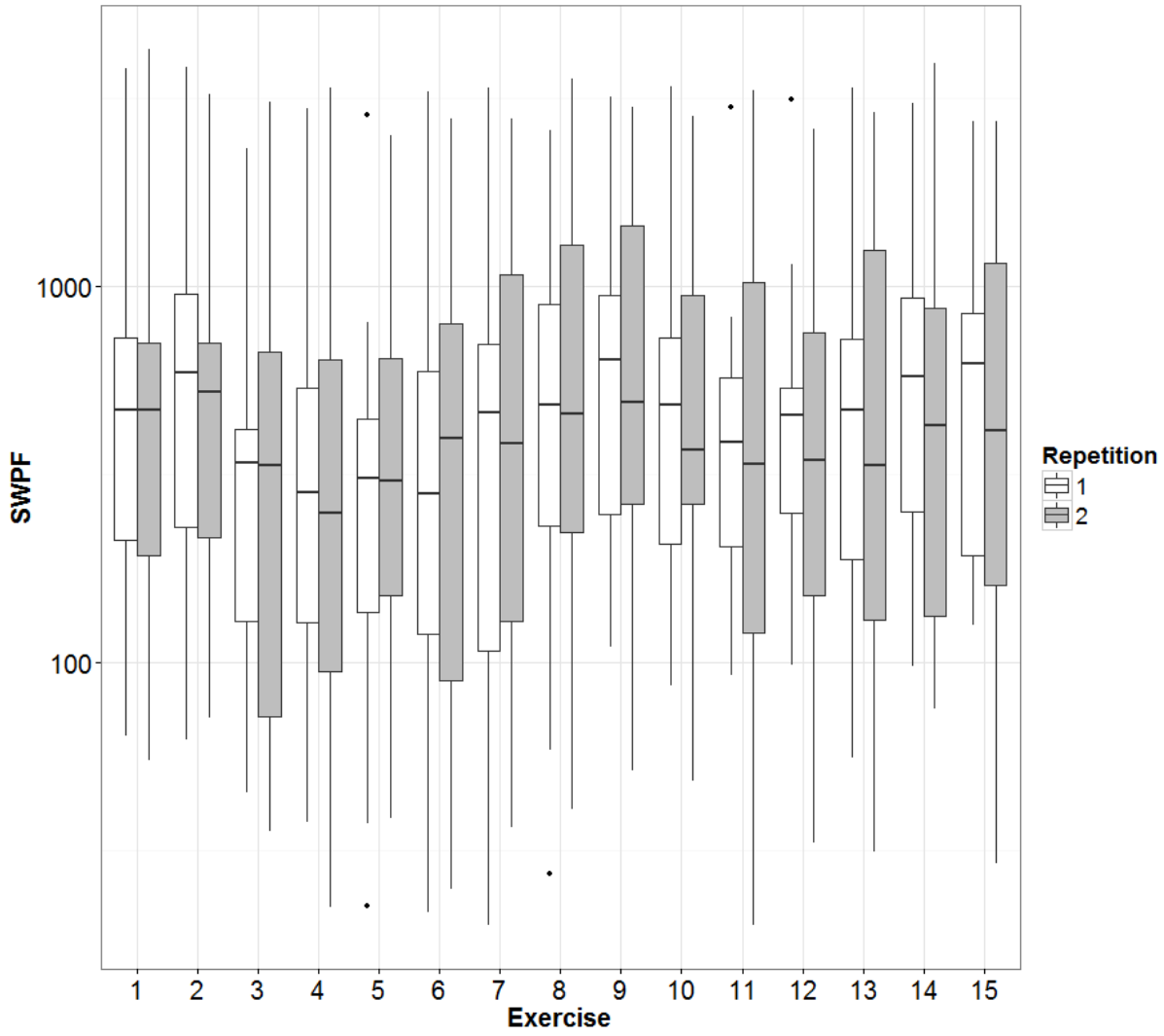

Figure 10. Each exercise SWPF by repetition for all subjects combined.
(n=11) (refer to Table I for details on exercises)

E. **Discussion**

The fit of the N95 FFR during the SWPF exercises depended on how the mask fit initially, how it changed with activity and how the respirator fit changed over time. These changes were person-specific and were seen to be highly variable. This presentation further illuminates which motions cause the SWPF to drop as leakage increases due to respirator movement, higher air flow, sweating, or a combination of these.

First responders are often required to wear multiple levels of PPE. Currently, the US standard (36) requires only that the respirator to be used during work be fit-tested to ensure it provides adequate protection. The Canadian standard dictates that when other PPE is required during respirator use, it "shall be worn during respirator fit testing to ensure that the respirator seal is not compromised" (44). While the Canadian standard describes the effect of multiple PPE layers, neither standard addresses how well the respirator will function in a realistic workplace scenario.

A simulated environment, in which real first responders perform typical first-responder tasks, yields a close estimation of how respirators respond to specific tasks for a given population. This has many benefits over performing a single initial QNFT.

While the Canadian standard requires donning other PPE, the entire QNFT protocol can be completed in under four minutes. This gives just a brief snapshot of interactions between the respirator and other PPE. This study suggests that an SWPF protocol that captures second-by-second measures of respirator fit while performing many realistic tasks for a realistic time period can yield useful information about respirator fit over time. This can make it easier to see long-term ensemble effects where certain features—such as a hood—may cause the respirator fit to

change incrementally over time. Longer routines can also show what happens to fit once the respirator user begins to sweat, and may identify when random dislodging events occur. Including repetition of activities can also make clear what motions or tasks cause a respirator to consistently fail.

In the future, we recommend that similar SWPF studies should evaluate initial fit with and without the full ensemble. This might capture initial ensemble effects that could be remedied with different sizes or designs. In addition, it would elucidate whether drops in respirator performance are due to the ensemble or other effects, such as sweating and breathing rate.

There are a few limitations that should be noted. This study had only 11 subjects, whose facial measurements did not include all cells in the NIOSH BVA or PCA panels. It was particularly difficult to find enough emergency responders with smaller faces, because the population is predominantly male. A broader range of face sizes would have allowed us to identify more specific trends and reach more firm conclusions; various standards suggest upwards of 25 subjects to get a more complete distribution (45, 47, 48).

Face-seal leakage can often occur quickly and for short amounts of time, making it sometime difficult to notice when respirator performance was adversely impacted by an exercise during an SWPF test. The RMCC software has been recently updated and now allows ongoing observation using a real-time plot of the SWPF, which may further elucidate exact points at which respirator fit decreases along with the specific activities responsible.

Each subject was interviewed by an investigator after completing the final QNFT. Subjects were asked whether they noticed anything about their respirator, ensemble, or test conditions that might have affected respirator fit. There was no interview protocol, or

requirement that subjects respond to these questions. In future research, we recommend including a written survey or interview after each SWPF trial, provided for familiarization before the trial, which might include questions such as the following:

- When did the subject start sweating?
- During which (if any) exercise did they notice the respirator fit change?
- Did they feel the coverall suit pulling on the respirator in any way?
- Did the fit at the end feel similar to the fit at the beginning of the trial?
- Did they have to adjust the respirator at any time during the trial?

First responders are often required to work long shifts while wearing respirators. Depending on the required level of protection, they might be expected to wear a full facepiece respirator. There are disadvantages to this type of respirator, including greater physiological and psychological stress, limited field of view (e.g., paramedics needing to perform medical procedures on injured victims), and more difficulty with communication (e.g., police responsible for public order and crowd control), which may limit their ability to work safely or for long periods of time. This study demonstrates that it may be possible for an emergency responder to consistently achieve high levels of protection wearing an N95 FFR. As well, we have demonstrated that the SWPF protocol offers important insights into respirator fit over time using realistic simulated activities. It may be possible, in time, to employ such protocols in lieu of combining an assigned protection factor with a QNFT for selecting an appropriate respirator and other PPE.

F. **Acknowledgments**

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V. RESPIRATOR FIT DURING REALISTIC SIMULATED HEALTHCARE ACTIVITIES

A. Background

In the United States, OSHA requires that every worker who uses a respirator at work receive an annual respirator fit test, which involves eight exercises (normal breathing, deep breathing, head up-and-down, head side-to-side, talking, grimace, bending over, and normal breathing) (4). One popular QNFT method employs a CNC with a single TSI Portacount instrument (Model 8020, Shoreview, Minnesota) with a switch valve to alternate particle-concentration measurements inside and outside the respirator facepiece (26). An FF is calculated for each exercise and for all exercises combined (excluding the grimace). If employees receive the expected FF (at least 100 for a half-facepiece negative-pressure air-purifying respirator), they are permitted to wear only that respirator model and size in the workplace.

There is limited evidence that these eight fit-test exercises provide a valid measure of respirator fit during work activities. Where respirator performance has been measured in the workplace, initial fit has been determined qualitatively, which precludes direct comparisons of FFs with WPFs. Studies of respirator performance using simulated work activities have demonstrated that the CNC instrument yields valid and reliable measures of fit (49–51), but there have been no investigations to date validating that laboratory-based SWPFs are representative of respirator performance in the workplace.

Studies of respirator fit in real workplaces are difficult to perform, because they rely on full-day gravimetric samples requiring high ambient-particle concentrations. In workplaces with

low particle concentrations or where respirators are not worn every day, such as healthcare or emergency response, workplace performance tests are not feasible. For laboratory-based studies of simulated work activities relevant to such workplaces, we need more discriminating measurement methods and realistic work tasks. As demonstrated by Hauge et al. (2012) and my work described in earlier chapters, two CNC instruments simultaneously measuring inside- and outside-facepiece particle concentrations can yield more detailed information about respirator fit over time and between exercises or work activities. To expand on this work, I designed an SWPF study employing the two-instrument real-time method to (1) examine whether a fast fit-test method using a smaller number of exercises would be predictive of respirator fit during repeated scenarios of three simulated healthcare tasks, (2) explore differences in respirator fit between simulated healthcare activities and across time, and (3) explore whether video recordings combined with exercise FFs can be used to predict SWPFs for healthcare activities and scenarios.

B. Methods

1. Method development

a. Initial and final fit tests

Initial fit ($QNFT_{initial}$) and final fit ($QNFT_{final}$) of the respirator were assessed with two CNC instruments (real-time fit-test method) and a fast fit-test protocol, which included five exercises performed for 30 seconds each (normal breathing, bending over, talking, head side-to-side, and head up-and-down) (12). Richardson et al. (2014) demonstrated that this protocol yields similar FFs to the traditional eight-exercise 8.5-minute OSHA fit test (deep breathing, grimace, and a second normal breathing exercise in addition to the five fast fit-test exercises) (26). Based on my results comparing the one- and two-instrument (real-time) methods

for the traditional OSHA exercises, I assumed that the latter was a valid approach to quantitative fit testing with a shorter set of exercises.

b. **Healthcare activities**

In consultation with physicians, registered nurses, industrial hygienists, and experts from the University of Illinois at Chicago's Clinical Performance Simulation Center, we identified tasks performed by healthcare workers likely to be included in an RPP and requiring more strenuous head and body motions thought to impact on respirator fit. Three activities were selected: performing cardiopulmonary resuscitation (CPR), conducting an ultrasound examination (ultrasound), and making a hospital bed (MB).

The CPR activity was performed using a specially designed manikin (Preson Professional, Mayfield, Ohio) with a green light indicating the expected 100 compressions per minute. If subjects experienced pain or could not maintain this speed, they were encouraged to perform the CPR compressions at whatever pace was considered comfortable. During this exercise, the subject bent over and turned their head to the side two times to listen for breathing and then leaned over the manikin while performing compressions for the remainder of the time. This activity lasted 90 seconds.

During the ultrasound activity, subjects were asked to simulate an examination of a human torso by running a small filter (representing an ultrasound probe) across the manikin surface. Subjects were instructed to move their gaze between looking down at the manikin and a simulated ultrasound screen located to the side of the manikin. Subjects were allowed to select their own pace for these activities for a total of 120 seconds.

The MB activity required the subject to continuously turn over the manikin while changing the sheet for a 120-second period. A warning was issued with 20 seconds remaining to

allow subjects to finish with the manikin lying flat on the table. This activity required subjects to move their head up and down and side-to-side. In general, subjects were able to make the bed two times during each repetition of this activity.

To ensure the three activities were performed in a similar manner, prior to beginning the simulated study each subject was shown how to do each activity and then demonstrated each activity to the researcher. Initially, each activity was expected to take 120 seconds; the CPR activity was shortened to 90 seconds due to its greater metabolic work-rate requirements.

The three activities were performed as a single scenario in a set order (CPR, ultrasound, and MB); each scenario was repeated three times based on results of a similar study with emergency responders (chapter IV). The final experimental protocol consisted of a 28-minute routine (TABLE XI) that included an initial and final QNFT and the three healthcare scenarios each repeated three times in the same order.

Each subject was video recorded throughout the scenario. Each subject periodically opened a three-way valve during each scenario to collect five-second measurements of the ambient concentration from the inside-facepiece probe, which were later used to align fit-test results with the video recordings.

TABLE XI

EXPERIMENTAL PROTOCOL

Length (sec)	Exercise/Activity	Part of Protocol
30	open/close valve	
30	Exercise 1—Normal Breathing	Initial QNFT
30	Exercise 2— Bending Over	
30	Exercise 3— Talking	
30	Exercise 4—Head Side-to-Side	
30	Exercise 5— Head Up-and-Down	
30	Open/Close Valve	
30	Exercise 1—Normal Breathing	SWPF Repetition 1
90	Activity 1 – CPR	
30	Open/Close Valve	
120	Activity 2 - Ultrasound	
30	Open/Close Valve	
120	Activity 3 - Making Bed	
30	Open/Close Valve	
30	Exercise 1 - Normal Breathing	SWPF Repetition 2
90	Activity 1 – CPR	
30	Open/Close Valve	
120	Activity 2 – Ultrasound	
30	Open/Close Valve	
120	Activity 3 - Making Bed	
30	Open/Close Valve	
30	Exercise 1 - Normal Breathing	SWPF Repetition 3
90	Activity 1 – CPR	
30	Open/Close Valve	
120	Activity 2 – Ultrasound	
30	Open/Close Valve	
120	Activity 3 - Making Bed	
30	Open/Close Valve	
30	Exercise 1 - Normal Breathing	Final QNFT
30	Exercise 2 - Bending Over	
30	Exercise 3 - Talking	
30	Exercise 4 - Head Side-to-Side	
30	Exercise 5 - Head Up-and-Down	

c. **Video fit monitoring**

An R (Version 3.0.3) software program was used to create a moving bar graph video with three inputs (time in seconds, FF [outside- divided by inside-facepiece concentration], and inside-facepiece concentration). For each second of data the program creates two bar graphs: one showing the overall FF and the other indicating the inside-mask particle concentration. Each two-bar graph plot is saved as an image; all images are then compiled into an animated video of continuously changing bar graphs. Camtasia Studio 8 (Techsmith, Okemos, Michigan) software was used to remove the white from the bar graph frame and then overlay two video files (bar graphs and subject activities). The concentration spikes from the open/close valve exercise were used to align the video images; as necessary, the speed of one video was adjusted to ensure alignment of activities and data.

2. **Experimental setup**

All fit tests were conducted in a test chamber consisting of two 5 ft. (width) x 5 ft. (length) x 9 ft. (height) portable tents with clear plastic sides and zipper access at all corners placed side-by-side (volume = 450 $feet^3$). Three salt aerosol generators (TSI Model 8026), two ultrasonic humidifiers (Vicks and Holmes), and a floor fan were used to maintain a steady uniform aerosol concentration inside the test chamber.

Two TSI Portacount Plus (Model 8020) with N95-Companion^{TM} (TSI Model 8095) instruments were used throughout the study: one (Portacount A) for measuring real-time concentrations inside the respirator and the other (Portacount B) for measuring simultaneous real-time concentrations outside the respirator.

Prior to all experiments, the two Portacount instruments were compared to ensure a similar (± 15%) and linear response across a range of particle concentrations (Appendix B).

Before and after each experiment five 30-second side-by-side measures of the ambient concentration were recorded from the two instruments simultaneously. These ten datasets were used to generate a correction factor for each subject's results by finding the line of best fit. The real-time data from Portacount A were then adjusted using the correction factor to match those from Portacount B.

3. **Subject recruitment**

The goal was to recruit at least 15 subjects with a range of face sizes in the NIOSH BVA panel. This number was selected as feasible within the time available for this project. Subjects were recruited using posted flyers and emails as well as from participants in previous research phases agreeing to further contact. Initial screening was conducted by telephone or email to assess health conditions and willingness to be clean shaven and refrain from smoking and drinking at least 60 minutes prior to a test. Subjects were scheduled for a one-hour time period. No compensation was offered. Human subjects approval was obtained from the University of Illinois at Chicago Institutional Review Board prior to recruitment (approval number 2013-1160).

Upon arrival each subject completed a written survey with questions similar to those used in screening, ensuring they had no respiratory or other health concerns that would make wearing a respirator difficult, did not experience claustrophobia, did not have facial impediments that would interfere with fit, were clean shaven, and were between 18 and 65. Subjects were also asked to confirm they had refrained from eating and smoking. Subjects not meeting these criteria were not tested further. Written informed consent was obtained for each subject.

Each subject's face length (menton sellion) and width (bizygomatic breadth) were measured using a sliding caliper (Seritex Model 104) and spreading caliper (Seritex Model 106),

respectively. These measurements were used to determine each subject's cell in the NIOSH BVA fit-test panel (41). If a subject had participated in a previous research phase, face measurements from the first phase were used.

4. **Experiments**

Each subject received a probed N95 FFR in a size estimated to give the best fit (3M 1860 or 3M 1860s). The respirator was attached to tubing used throughout the experiment and the subject was then instructed to don the respirator, with input from the researcher as necessary. A binder clip attached to the subject's clothing was used to ensure adequate slack in the tubing for head movements without dislodging the respirator.

Both instruments were set to the count function. An initial FF of 100 was estimated using the outside concentration divided by the inside concentration. For example, if Portacount A showed an ambient concentration of 2,000 p/cm^3 an inside-facepiece concentration of 20 p/cm^3 was expected. If the initial respirator size could not achieve an initial FF of 100, the second size was donned. Subjects who could not obtain an FF greater than 100 with either respirator size were excluded.

5. **Data analysis**

Microsoft Excel was used for data cleaning and preliminary analyses. Data points below the limit of detection were replaced with a concentration of 1 p/cm^3 for consistency with TSI software protocols (42). A correction factor was applied to Portacount A (ambient) data, as described above. Real-time FFs were then calculated by dividing each one-second ambient particle concentration by its corresponding inside-facepiece concentration. All data points were log-transformed to ensure a normal distribution for statistical analyses.

Plots of all data points and 10-second running averages were used to compare the FF profiles for each subject's $QNFT_{initial}$ and $QNFT_{final}$ as well as the profiles of fit received for each repetition of the three healthcare scenarios ($SWPF_1$, $SWPF_2$, $SWPF_3$).

Boxplots were used to examine FF distributions by subject and fit test; bar graphs were used to examine the number of subjects receiving FFs greater than 200 for each fit-test exercise and healthcare activity. This was the lowest FF at which we could easily observe differentiation in respirator fit between exercises and activities.

Geometric mean FFs were calculated for overall $QNFT_{initial}$ and $QNFT_{final}$ (all exercises combined) and each fit-test exercise. A geometric mean simulated workplace FF ($SWPF_{1-3}$) was calculated for each repetition of the three healthcare scenarios and for each of the activities across the three scenarios.

Spearman's correlation coefficients were used to compare initial and final overall FFs with the SWPFs for each healthcare scenario repetition (1, 2, and 3) and each healthcare activity (CPR, MB, Ultrasound). A Bartlett test was used to examine differences in variance between the three healthcare scenario repetitions. A repeated measures ANOVA was performed to identify differences between healthcare activity SWPFs, and multiple linear regression was performed to explore the association between fit-test exercises and healthcare activities.

For five subjects, the number of times they moved their head up-and-down, moved their head side-to-side, or bent over was totaled for all three simulation scenarios. It was assumed that it takes approximately one second to move your head side-to-side or up-and-down and that it takes two seconds to bend over. Using these assumptions the total amount of time spent doing these three activities was added up. The percent time spent performing each motion was then calculated, using the total time of 990 seconds to perform three scenarios (3 x [90 sec. + 120 sec.

+ 120 sec.]). For example, if a subject moved their head side to side 25 times during the nine activities it was assumed that they performed this motion for 25 seconds. The percent of time spent conducting this motion was then calculated to be $\frac{25}{990}$ or 0.024. The percent of time spent moving their head in a specific way was then multiplied by the average FF that subject received for that motion during their initial and final quantitative fit tests, to obtain an FF for that exercise during a healthcare scenario. If the FF was 120 for the head side-to-side exercise during $QNFT_{initial}$ and the FF was 160 for the head side-to-side exercise during $QNFT_{final}$ the subject's head side-to-side SWPF would be: $\frac{25}{990} * \frac{120+160}{2}$ = 3.55.

This calculation was performed for the three repetitions of each healthcare activity. It was assumed that normal breathing occurred throughout the entire experiment and talking did not occur for any seconds during the experiment.

A predicted SWPF was calculated using the sum of the weighted averages of all of the activities. Paired t-tests were used to compare predicted and measured SWPFs.

C. **Results**

1. **Subjects**

The study was conducted during October and November of 2014. Twenty-one subjects expressed interest; four subjects were unable to participate (three could not match schedules and one did not think they would be able to perform all of the required healthcare tasks). Two subjects were not able to get a good fit with either respirator size. Fifteen subjects (7 male and 8 female) completed the experimental protocol. Subjects were located in seven of the ten NIOSH BVA panel cells (Figure 11). Log-transformed FFs were normally distributed for all

of the subjects (Appendix C). Four subjects had an initial QNFT less than the 100 (Figure 12). By subject, the geometric mean (GM), geometric standard deviation (GSD), upper confidence limit (UCL), and lower confidence limit (LCL) are presented in Appendix D.

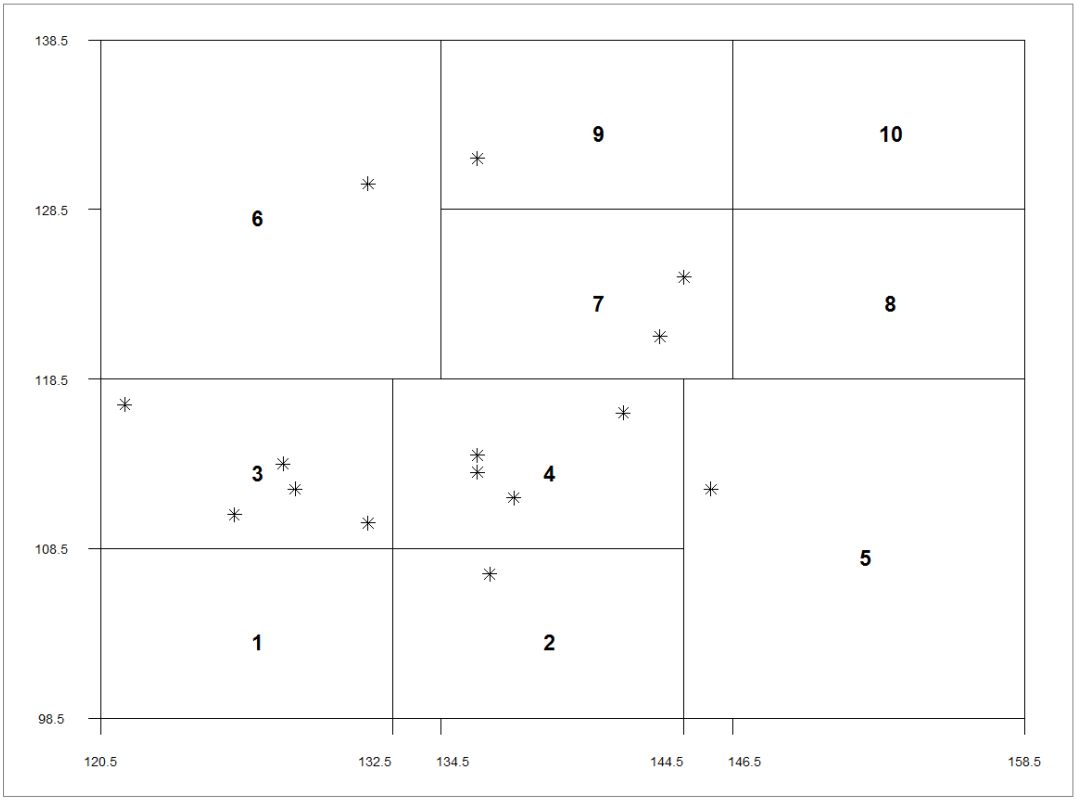

Figure 11. Bivariate cells by face length and width as determined by Zhuang et al. (30) and distribution of subjects' face length and width (indicated by stars).

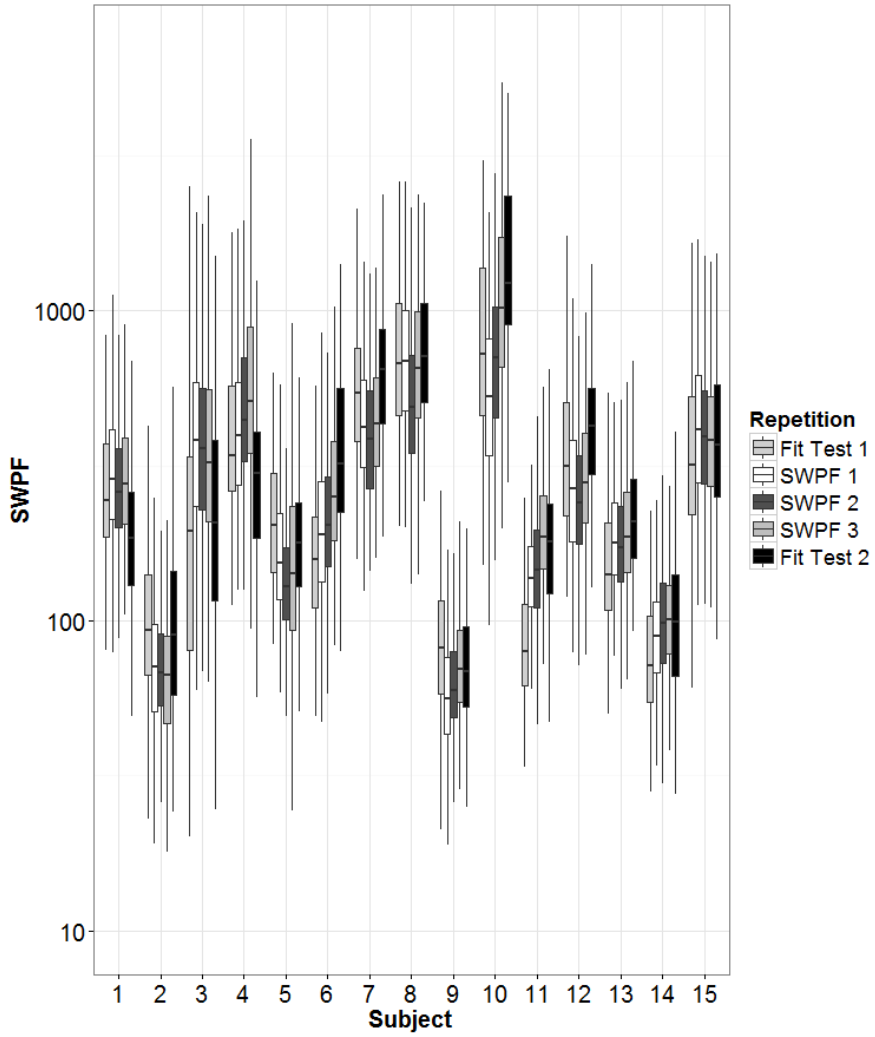

Figure 12. Fit factors by subject and repetition of QNFT or SWPF for all exercises combined.
(n=250 for each of the fit tests (30 seconds x 5 exercises) and n=390 for each SWPF (30 sec.–normal breathing; 90 sec.–CPR; 120 sec.–Ultrasound; 120 sec.–MB)

2. **Comparing fit factors and simulated workplace protection factors**

There appears to be more variability in respirator fit between subjects than within each subject, suggesting that the fit of an N95 FFR is person-dependent (Figure 11). Low within-subject variability also suggests that each person's FF is likely to be correlated with their SWPF. Data analyses corroborate this—FFs measured during the two QNFTs were highly correlated with each other and with the SWPFs measured during the three scenarios (repetitions 1, 2, and 3) and the three healthcare activities (combined across scenarios) (TABLE XII).

TABLE XII
SPEARMAN'S CORRELATION COEFFICIENT (r)
n=15

	$\mathbf{QNFT_{initial}}$	$\mathbf{QNFT_{final}}$
QNFT2	0.88**	-----
CPR1	0.89**	0.86**
CPR2	0.82**	0.80**
CPR3	0.84**	0.83**
Ultrasound1	0.89**	0.86**
Ultrasound2	0.94**	0.92**
Ultrasound3	0.92**	0.93**
Make Bed1	0.89**	0.75*
Make Bed2	0.85**	0.79**
Make Bed3	0.88**	0.81**
SWFF Overall	0.92**	0.88**
SWPF1	0.93**	0.90**
SWPF2	0.90**	0.86**
SWPF3	0.9**	0.86**

*0.001 < p-value <.01; **0.001 > p-value

a. **Between scenario repetitions**

The number of subjects with a geometric mean FF greater than 200 is higher during the third scenario repetition when compared to the first scenario repetition (Figure 13). A Bartlett test indicated that the variability of at least one of the repetitions of the scenarios was significantly different from the others ($p<.001$). It is unclear which repetition has a different variance based on Figure 13. A repeated measures ANOVA indicated that there was no difference between geometric means by scenario repetition ($p=.437$).

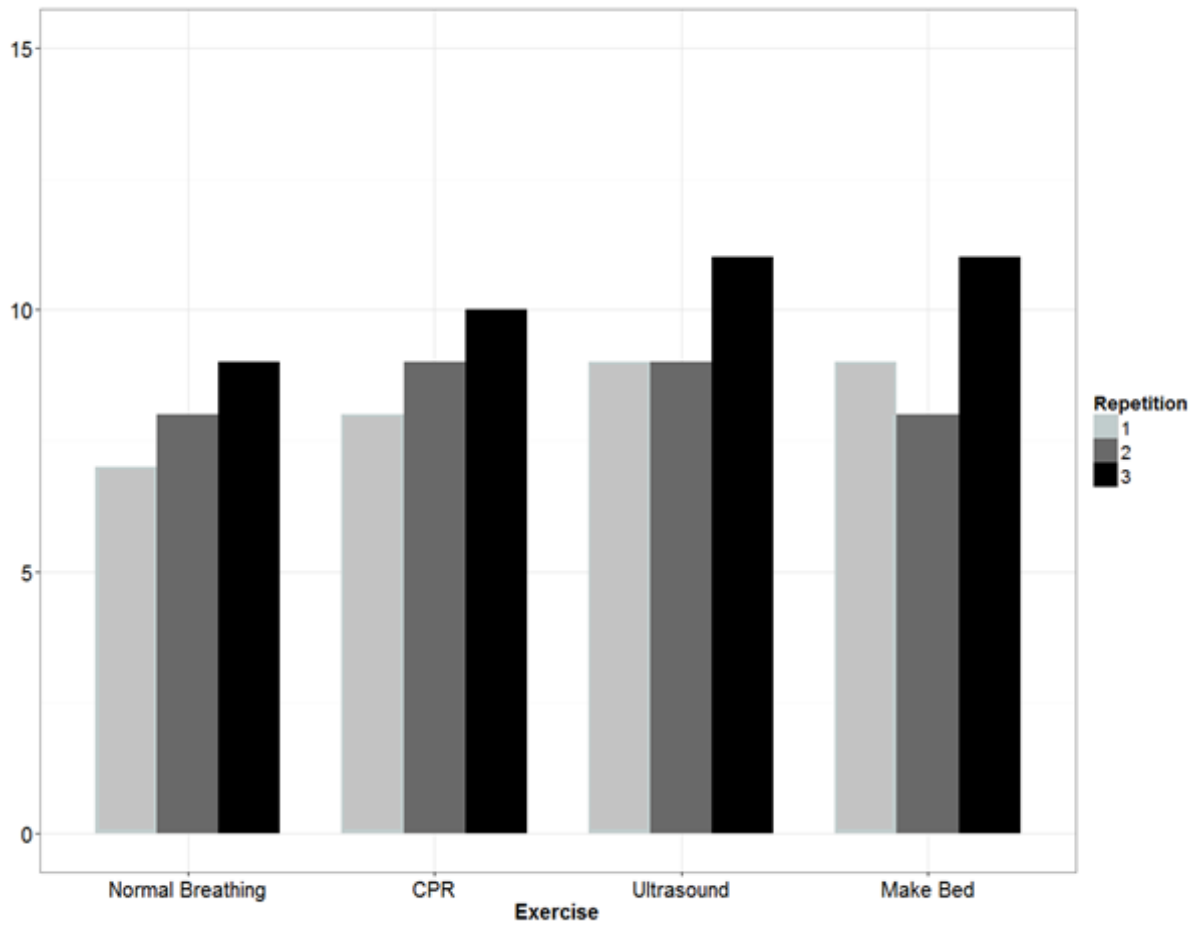

Figure 13. Bar graph number of subjects achieving SWPF>200 by activity and repetition.

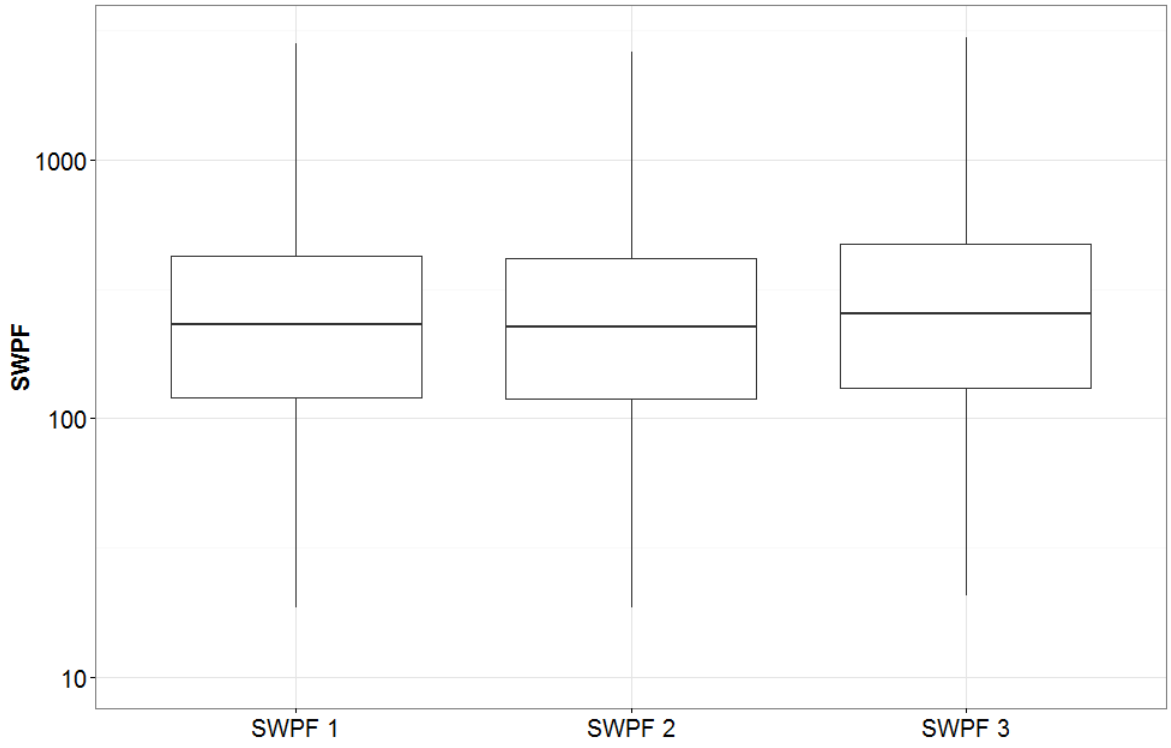

Figure 14. Boxplot of SWPFs by repetition.

b. **Between healthcare activities**

A repeated measures ANOVA also showed there were differences between the three healthcare activities (p=.01); FFs were highest during the ultrasound activity and lower but similar for the CPR and MB activities (Figure 15).

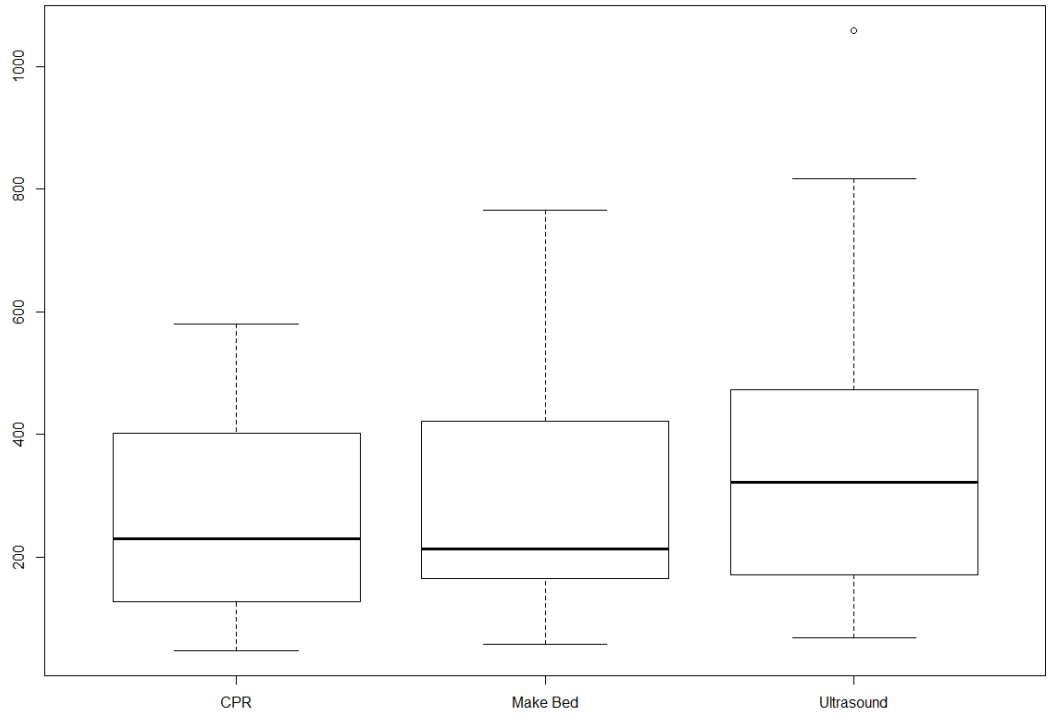

Figure 15. Boxplot of all fit factors for each activity.
CPR n=4,050 (3 reps * 15 subjects * 90 sec.); MB and Ultrasound n=5,400 (3 reps * 15 subjects * 120 sec.)

3. **Comparing fit-test exercises and healthcare activities**

Multiple linear regression was used to examine the relationship between each healthcare activity (CPR, ultrasound, and MB) and the five QNFT exercises (normal breathing, talking, turning head side-to-side, moving head up-and-down). None of the exercises was independently predictive of fit during CPR. Only the normal breathing exercise was significantly associated with fit during ultrasound (p-value=.03). Normal breathing, moving head up-and-down, and talking were each statistically significantly associated with fit during MB (p-values=.005, 0.01, 0.08, respectively).

Paired t-tests comparing predicted and measured SWPFs for five subjects indicate that these are significantly different from each other (p=.5) (TABLE XIII and TABLE XIV).

TABLE XIII

PREDICTED VERSUS MEASURED SWPF

	Subject A	**Subject B**	**Subject C**	**Subject D**	**Subject E**
Up and Down	2.1	7.2	11.8	14.3	6.0
Side-to-Side	7.4	9.5	18.4	25.5	14.8
Bending Over	15.8	13.9	13.2	20.9	10.3
Normal Breathing	156.5	316.5	380.5	540.5	177.5
Talking	0.0	0.0	0.0	0.0	0.0

TABLE XIV

PREDICTIVE SWPF AND MEASURED SWPF FOR SUBJECTS 5–9 AND RESULT OF T-TEST

	Subject A	**Subject B**	**Subject C**	**Subject D**	**Subject E**	**p-value**
Total FF Weighted	181.8	347.1	423.8	601.1	208.6	0.50
Actual SWPF	359.0	293.0	268.0	487.0	142.0	

D. **Discussion**

The fast fit-test methodology produced respirator FFs that were indicative of how well the respirator fit during realistic simulated healthcare activities.

Fit factors from both fast fit-tests (initial and final) were highly predictive of SWPFs for the three healthcare scenarios (repetitions 1, 2, and 3) and three healthcare activities (CPR, MB, and ultrasound) (TABLE XII). When healthcare activity SPWFs were compared to the individual exercise FFs in a multiple linear regression, however, a different picture emerged.

The CPR activity was expected to have the lowest fit because it involved lots of bending over, which would result in heavy breathing. However, respirator fit during the CPR activity was similar to that during MB and lower than ultrasound. Although the MB activity requires subjects to lean over the manikin fewer times and is less rigorous, it appears that the two activities have similar impacts on fit.

The MB activity produced FFs, on average, similar to those of the CPR activity. While bed making is not physically demanding, it does require completing many steps in a specified order, which can require intense thinking. Multiple linear regression showed that in addition to normal breathing and head up-and-down, talking was significantly correlated with respirator fit. Normal breathing and moving head up and down occur throughout this activity but all subjects were asked not to talk. When people think hard, it is common for them to move their jaw or maybe scrunch their face. It appears that some facial movement occurs during bed making that is similar to the jaw movements made when one talks.

I expected the ultrasound activity to have the best fit because it required the smallest amount of complex head motions and had low physical demands. Subjects experienced the best fit during this healthcare activity (Figure 15). It is assumed that the extensive amount of turning the head to the side followed by looking down at the simulated patient does not alter the fit of the respirator or cause the respirator to fail. Surprisingly, the head side-to-side motion was not significantly correlated in the multiple linear regression.

None of the fit-test exercises was predictive individually or in combination of the CPR SWPF. This is surprising, since the exercises used are among the most rigorous of the eight required by OSHA. On the other hand, the normal breathing and moving head up-and-down

exercises were predictive of the MB SWPF, which is more in line with our expectations. It appears that CPR involves a more complex set of head and body motions than captured by the individual fit-test exercises, suggesting that workplace tasks may have some use in determining respirator performance.

Using three simulated healthcare scenarios, Hauge et al. (2012) found that the protection afforded by a respirator varied significantly between subjects and that IV treatment and wound care produced SWPFs that were significantly different from each other (11). The order of the three scenarios was randomized; Hauge et al. found the second scenario SWPFs were significantly different SWPFs compared to those measured in the first and third scenarios. This trend was also observed in my study; the second activity—ultrasound—had a significantly higher SWPF than the first exercise—CPR, or the third exercise—MB. By repetition, however, no difference was observed between repetitions although a difference in the variance was identified.

Simulated workplace protection factors derived from video recordings combined with exercise FFs were not predictive of measured SWPFs. Problems with this methodology included not having a definitive way to count how many times a specific head motion was performed or if only a half motion was made. Best estimates were made regarding the amount of time each activity lasted, but the actual amount of time could not be determined. This effort revealed how complicated head motions can be when performed in small activities compared to how definitive the motion is when constrained during a fit test.

My analyses demonstrate that the fit of an N95 FFR is very person-specific. In general, I observed low within-subject variability for all of the exercises (Figure 12) and high between-subject variability. This trend has been observed in previous studies by all investigators using

this technology (11, 32). This might suggest that the length of fit test might not matter as much as performing a fit test to ensure a respirator fits a subject.

It is important to note that in this study subjects did not remove their respirator between the fit tests and simulated healthcare activities. I assume there might be some change in respirator fit that occurs during redonning. Redonning might affect how a respirator fits during real-work tasks compared to how the respirator fits during the fit test. For a subject to achieve the best fit during this set of experiments, the researcher asked each subject to pinch the nosepiece of the respirator. In general, it was observed that given this instruction, subjects did not pinch the nosepiece tightly enough to obtain a good face-to-facepiece seal. To achieve a better fit, subjects were asked to pinch the nosepiece tighter still, and only after this instruction did subjects achieve a strong fit. It is assumed that in the workplace employees would not pinch the nosepiece this tightly and therefore might not achieve as good a respirator fit as they did during their annual fit test. This is an important aspect of fit to explore in future experiments.

E. **Limitations**

While every effort was made to design a flawless experiment, several limitations should be noted. Due to the size of the subject pool, a full 25-subject BVA panel was not possible. However, we were able to recruit subjects in seven of the ten cells.

The protocol was lengthy and did not included the five-minute comfort assessment recommended by OSHA (26). Subjects wore a respirator for some time period while a preliminary FF was assessed (by visually comparing the two instruments' measurements), so it is more than likely that subjects wore the respirator for a minimum of five minutes prior to

beginning the experiment; this cannot be confirmed and may not be exactly the same for all subjects.

As was observed in chapter III, we found that moisture buildup on the inside-facepiece sampling tube changed the relationship between the two instruments over time. It is assumed that the moisture buildup in the tube collects particles that would otherwise reach the instrument, thus artificially decreasing inside-facepiece concentrations. Since it is unknown when this buildup occurs, the line of best fit between the initial calibration and the final calibration was used to correct the values from the two instruments.

VI. CONCLUSION

This body of work analyzed for the first time the relationship between written RPPs and policies. To conduct this study a tool was developed to quantitatively score how well the written programs followed the OSHA standard. It was found that in acute care hospitals, written RPPs lacked sufficient detail and did not assign RPP policies to a single individual. These written program scores were compared to hospital policies as observed via an in-person interview. Hospital managers were more familiar with the hospital policies than healthcare workers, but no correlation was found between written program scores and employees' self-reported knowledge and practices. We conclude that while programs are poorly written and lack important elements, in particular a program administrator, many hospitals appear to be following most of the policies and practices required by the OSHA respiratory protection standard.

This is the first study with simulated healthcare activities showing that FFs are predictive of SWPFs. Similar work by Hauge et al. (2012) was strongly suggestive that QNFTs would be predictive of fit during a different set of healthcare tasks, but were limited by truncation of FFs over 200 (11). Neither Hauge et al. nor I, however, are able to state that our healthcare task—or activity-based SWPFs—are predictive of respirator fit in real healthcare settings. In order to make this possible, additional experiments are needed with real healthcare workers in actual hospital settings performing real-world activities.

As a first step in developing SWFP methodology, I developed a systematic approach comparing a new real-time fit-testing methodology to traditional OSHA quantitative fit tests. I found that these two methods resulted in equivalent fit factors. I also discovered that the grimace

exercise interferes with such comparisons and should be excluded, because it introduces an unpredictable source of variation.

Using the validated real-time methodology, two studies of SWPF were conducted using a similar respirator with two different types of workers. During the first of these with emergency responders, I discovered that two repetitions of many short workplace activities was useful for observing trends in fit over time. As well, I found that other PPE—in this case the hood of a suit—can impact fit positively or negatively. In the second study, real-time methodology was used to study respirator fit with subjects trained to perform simulated healthcare tasks. Again, I found that performing activities repetitively was useful in discovering trends over time. In addition, I discovered the fit of the respirator was person-dependent and had low within-subject variability and high between-subject variability.

This research provided a first analysis of respirator fit achieved from a quantitative fit test in comparison to respirator fit achieved during simulated workplace activities. In both simulated studies the QNFT was significantly correlated to overall SWPF fit. The small within-subject variability observed might demonstrate that the length of fit test might not matter as much as performing a fit test to ensure a respirator fits a subject.

APPENDICES

APPENDIX A

Written RPP Scoring Protocol

Analysis of Written RPP*

1. Written Program		
Written policies and procedures for respirator use to protect employees from exposures to inhalation hazards. Should address all of the elements described below, with specific details about how each element is accomplished in this hospital		**Met/Not Met**
2. Program Administrator		
Responsibility is assigned to one properly trained individual for ensuring full implementation and evaluation of the RPP		**Met/Not Met**
Specific Items	**Description/Best Practices**	**Was Program Element Met?**
Title	Should indicate at least a title of one individual who is responsible. Should be a single person's title, not a division or department	
Qualifications	Appropriate training or experience to oversee the program and conduct evaluations	
Responsibilities	*Should also indicate a set of responsibilities for this individual*	
	Identifying work areas, processes or tasks that require workers to wear respirators, and evaluating hazards	
	Selection of respiratory protection options	
	Monitoring respirator use to ensure that respirators are used in accordance with their certifications	
	Arranging for and/or conducting training	
	Ensuring proper storage and maintenance of respiratory protection equipment	
	Ensuring that employees receive fit testing	
	Administering the medical surveillance program	

	Maintaining records required by the program	
	Evaluating the program	
	Updating the written program, as needed	
	Ensuring an adequate supply	
3. Respirator Selection/Risk Assessment		
A written description should exist that identifies all jobs and tasks with inhalation hazards and indicates which class of NIOSH-approved respirator will protect employees from each hazard. Where possible, the expected exposure level should be identified and linked with a respirator's assigned protection factor		**Met/Not Met**
Specific Items	**Description/Best Practices**	**Was Program Element Met?**
Selection of participants in RPP	*Identified hierarchy of controls that led to selection of people in the program (typical and emergency situations, e.g., pandemics) and excludes everyone else*	
Who is exposed		
When are they exposed		
Type of exposure	Should also identify levels of hazards by types of exposures (for diseases and procedures)	
	Airborne	
	Influenza	
	aerosol generating	
Which respirator for each exposure	*Should expect to see higher levels of respiratory protection for higher levels of risk (greater hazard or higher exposure)*	
4. Information		
There should be written procedures for informing employees when respirators are required		**Met/Not Met**
Specific Items	**Description/Best Practices**	**Was Program Element Met?**
Medical Determination	Limitation of respirator use related to medical conditions or workplace conditions	
	Need for medical evaluation follow-up	
	Statement that employee got copy of recommendations	

	Provision of powered air purifying respirator if needed	
Training	Basic advisory info on respirators for voluntary use	
Notification of Managers and Employees	*Type and size of respirators*	
	Received and passed fit test	
Employee Information	*Making sure employees can identify and find their respirator (correct mfr. make, model, and size)*	
Trigger	*Making sure employees know when to wear a respirator and what type—how would employees know—signs, labels, etc.*	
5. Medical Evaluation		
Baseline and periodic medical evaluations should be performed to determine employees' ability to safely wear a respirator		**Met/Not Met**
Specific Items	**Description/Best Practices**	**Was Program Element Met?**
Physician or Other Licensed Health Care Professional	*Describe who does this and criteria used*	
Questionnaire	Confidential	
	Normal working hours or convenient	
	No cost	
	Employee understands content	
	Description of when and how often medical evaluation is performed	
Follow-up evaluation for positive questionnaire response	Confidential	
	Additional tests at discretion of PLHCP	
	No cost to the employee	
Opportunity to discuss with PLHCP		

Additional Medical Evaluations provided if:	When employee reports signs or symptoms	
	PLHCP, supervisor, program administrator determines need for reevaluation	
	Information (fit-testing or program evaluation) indicate need	
	Change in workplace conditions with substantial increase in physiological burden	
	Best practice suggests periodic reevaluation of all users	
Supplemental information for PLHCP:	Type of weight of respiratory protection	
	Duration and frequency of respirator use	
	Expected work effort	
	Additional PPE to be worn while wearing the respirator	
	Extreme temperature and relative humidity	
	Written program	
	Medical evaluation section of the OSHA standard	
	How information will be transferred change in PLHCP	

6. Fit Testing		
There should be written procedures for ensuring, on an annual basis, that each employee receives a respirator that provides adequate fit and instructions on proper donning and doffing		**Met/Not Met**
Specific Items	**Description/Best Practices**	**Was Program Element Met?**
Test	Describe qualitative or quantitative; match with the level of protection (air-purifying respirators)	
	Use of OSHA protocol	
	Who does fit testing	
	What to do in case of failure	
	Communicate results to employees	

When	Prior to use	
	With change in respirator	
	Annually	
Additional fit tests	Will be performed when employee, employer, PLHCP, supervisor, or program administrator reports that employee's physical condition has changed (dental surgery, change in body weight, dental, cosmetic surgery, scarring	
	Employee reports respirator is unacceptable	
7. Maintenance and Use		
Describe methods for ensuring proper storage, care and maintenance of respirators		**Met/Not Met**
Specific Items	**Description/Best Practices**	**Was Program Element Met?**
Use	Prohibiting conditions resulting in facepiece leakage (facial hair, other conditions such as scarring, other PPE)	
	Preventing employees from removing respirators in hazardous environments	
	Taking actions to ensure effective operation throughout work shift	
	Ensure employees perform seal check	
Maintenance	Procedures for cleaning and disinfecting	
	Storage (free from damage, dust, sunlight, temperature)	
	Inspection before each use and during cleaning	
Repairs	Powered air purifying respirator specific repairs	
Reuse	*If, when, how*	
	Clear connection between reuse and storage	
8. Training		
The program should describe the training program including training content in requirements of the standard and why, when, and how to use respiratory protection		**Met/Not Met**

Specific Items	Description/Best Practices	Was Program Element Met?
Employee knowledge	Explain what are the hazards and health effects that may result	
	Proper selection and use (reuse)	
	Fit testing—what it does and what means	
	How improper fit, usage, and maintenance can compromise fit	
	Limitations and capabilities of the respirator (IDLH, O_2 deficiency, gases/vapors vs. particulate)	
	How to use respirator in emergency situations including respirator malfunction	
	Inspect, don, doff, seal check	
	Procedures for maintenance and storage	
	Policies and procedures for reuse	
	Medical signs and symptoms that limit effective use; should address medical signs that signal problems with wearing a respirator, such as: shortness of breath, wheezing, local skin irritation, claustrophobia, etc.	
	General requirements of training section of the OSHA standard	
	Description of hospital's RPP	
	Description of OSHA standard	
	Hazards and health effects	
Measuring understanding	*Hands-on exercises and a written exam recommended.*	
Method	Understandable	
When	Prior to first respirator usage	
	Annually	
	Changes in workplace or respirator that makes prior training obsolete	

	Inadequacies in employee knowledge or use indicating that the employee has not retained requisite understanding	
	During work at no cost	
9. Program Evaluation		
The program should describe procedures and frequency of periodic RPP		**Met/Not Met**
Specific Items	**Description/Best Practices**	**Was Program Element Met?**
Evaluation	As necessary to ensure the provision of current written program are being implemented	
	As necessary to ensure that the program is effective	
Employee consultation	Solicitation and review of input from managers, supervisors, and employees	
	Regular feedback solicited and reviewed to assess views on program effectiveness	
	Identify problems	
	Consider respirator fit, respirator selection, proper use in workplace, proper maintenance	
Record review	*Review all program records, medical evaluation, training, fit testing*	
Observations	*Random observations of employee respiratory protection practices*	
	Availability, signage, training content	
Record of Auditing	*Should have a record of auditing that shows problems and fixes*	
10. Recordkeeping		
There should be written procedures for maintaining records of risk assessments, medical evaluations, fit tests, and program audits		**Met/Not Met**
Specific Items	**Description/Best Practices**	**Was Program Element Met?**
Written Program	Keep copy of current program	
Risk Assessment/Respirator Selection		

Medical Evaluation	Following 29 CFR 1910.1020—duration of employment + 30 years	
Fit Testing	Type of fit test	
	Name of employee	
	Make, model, size of respirator	
	Date of test	
	Pass/fail results	
	Kept until next fit test	
Training	*Overall training—who is conducting, content, etc.*	
	Individual training records	
	Individual records kept until next training	
Record Availability	Made available to affected employees, Asst Sec, or designee	
11. Availability		
There should be written policies and procedures to ensure that there is an adequate supply of respirators available to meet the needs of employees during normal and emergency situations		**Met/Not Met**
Specific Items	**Description/Best Practices**	**Was Program Element Met?**
Supply	*Written description that matches supply for normal and emergency situations*	
	Ensure availability and match to need at unit and point of use	
	Written policy about reuse- whether it is allowed and how	
		Overall Score: /22

*Items in italics are considered best practice and are not required by the OSHA standard

APPENDIX B

Correlation between Portacounts

Instrument Setup A: 3M Portacount; 3M Companion

Instrument Setup B: UIC Portacount; 3M GC Companion

Instrument Setup C1: NIOSH Portacount; NIOSH Companion 1

Instrument Setup C2: NIOSH Portacount; NIOSH Companion 2

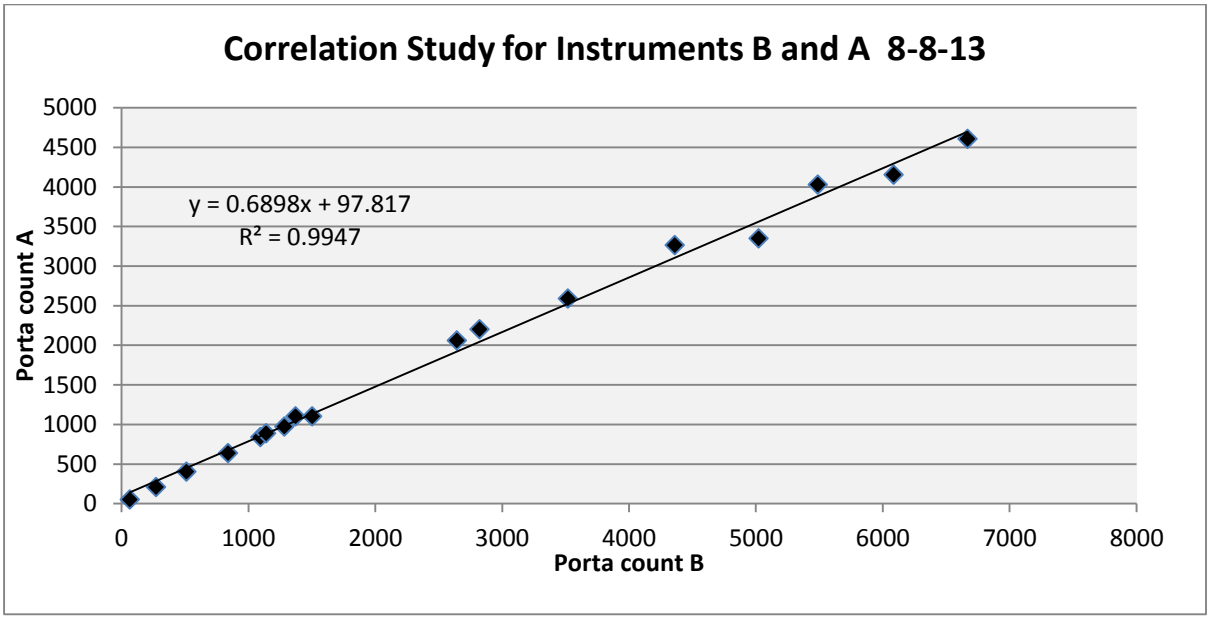

Figure 16. Correlation Between Study Instruments B and A.

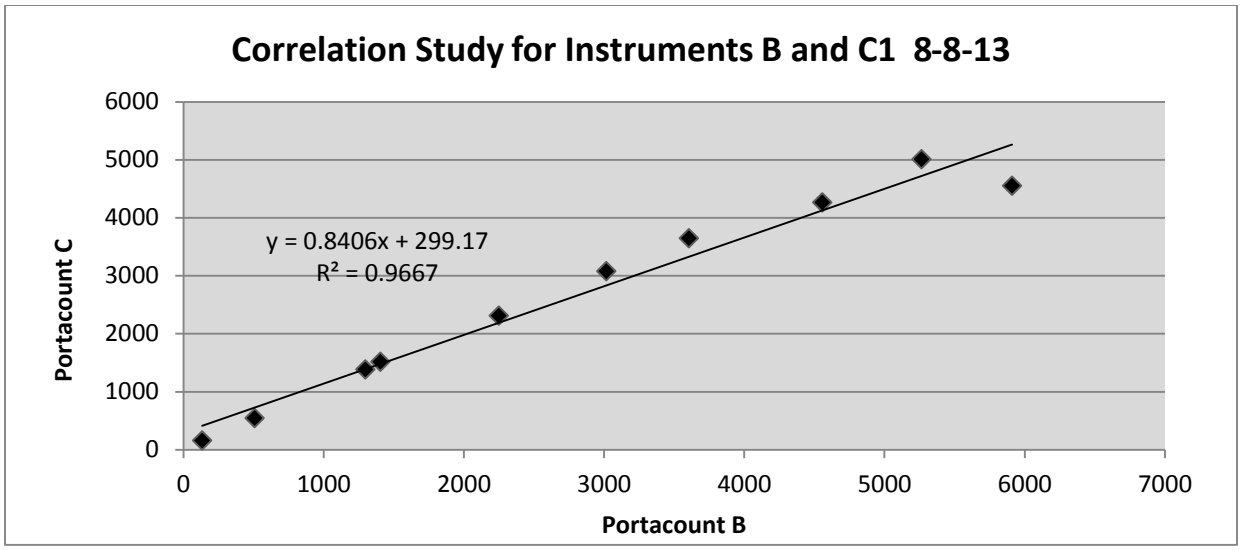

Figure 17. Correlation Between Study Instruments B and C1.

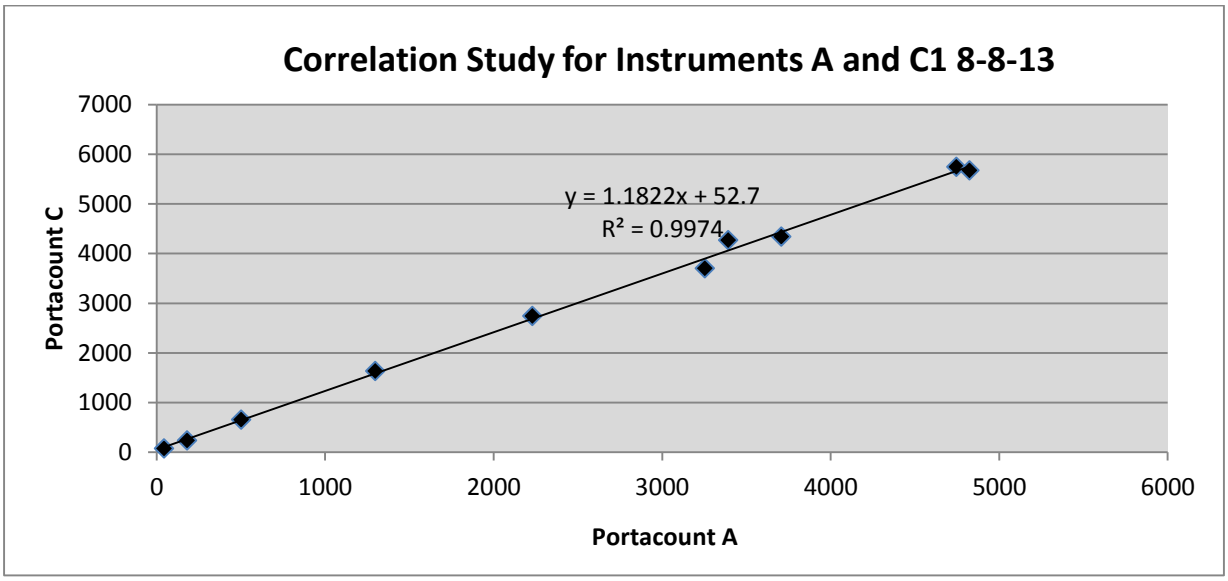

Figure 18. Correlation Between Study Instruments A and C1.

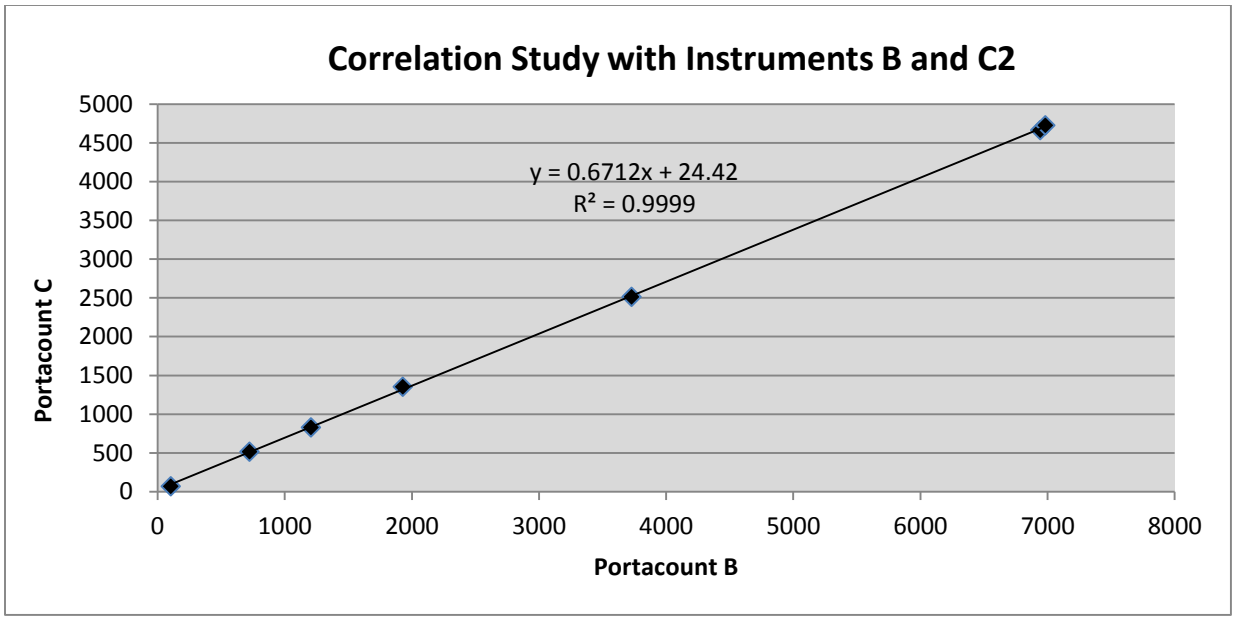

Figure 19. Correlation Between Study Instruments B and C2.

APPENDIX C

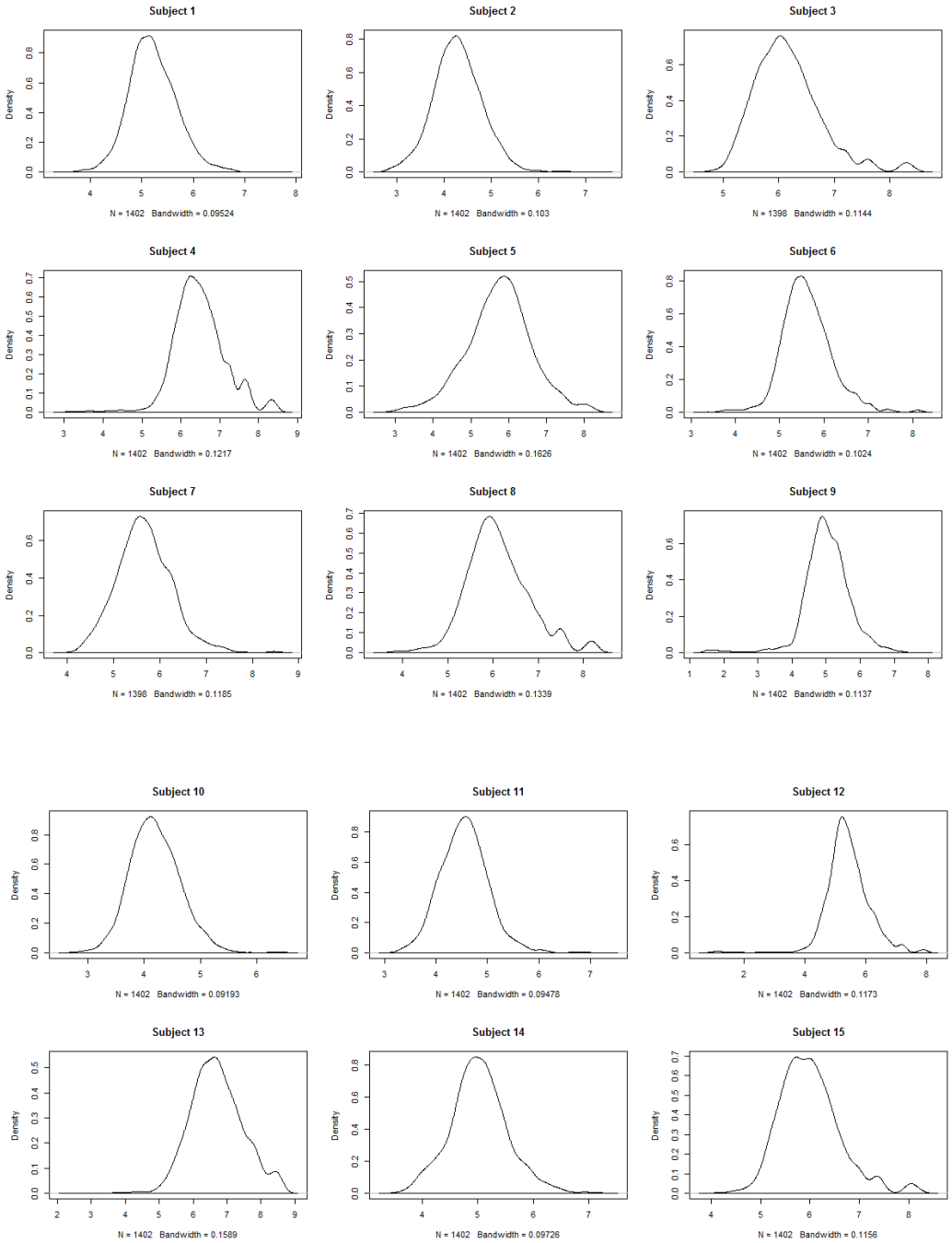

Figure 20. Density plots by subject for all log-transformed FF.

APPENDIX D

Table XV

GM, GSD, LCL, and UCL by Subject

Activity	Subject	GM	GSD	LCL	UCL
Normal Breathing 1	All	247	2.91	30	2011
	1	175	1.42	88	346
	2	108	1.66	40	294
	3	560	2.45	97	3238
	4	1164	2.13	265	5114
	5	194	3.19	20	1878
	6	344	1.75	115	1032
	7	408	1.68	147	1134
	8	662	1.93	182	2410
	9	186	1.57	76	451
	10	96	1.70	34	271
	11	71	1.65	26	189
	12	158	1.71	55	454
	13	672	2.93	81	5540
	14	88	1.51	39	198
	15	357	2.21	75	1696
Bending Over 1	All Subjects	251	2.63	38	1669
	1	237	1.57	98	571
	2	92	1.84	28	304
	3	644	2.02	163	2547
	4	764	2.11	177	3294
	5	343	2.11	79	1488
	6	288	1.51	128	646
	7	306	1.81	96	975
	8	424	2.29	84	2148
	9	207	1.39	108	396
	10	80	1.67	29	218
	11	85	1.51	38	191
	12	211	1.81	66	670
	13	662	1.98	173	2531
	14	80	1.71	28	230
	15	455	1.90	129	1598

GM, GSD, LCL, and UCL by Subject

Activity	Subject	GM	GSD	LCL	UCL
Talking	All Subjects	202	2.47	34	1187
	1	125.2	1.47	59	265
	2	94.6	1.49	43	206
	3	529.0	1.90	151	1854
	4	516.8	1.73	177	1513
	5	294.7	2.05	72	1208
	6	198.8	1.40	103	383
	7	240.5	1.47	113	511
	8	356.9	1.77	116	1094
	9	251.7	1.74	85	748
	10	63.9	1.78	21	199
	11	88.9	1.60	35	223
	12	133.7	1.86	40	450
	13	670.7	1.83	204	2202
	14	67.4	1.38	36	126
	15	262.9	2.05	65	1070
Head Side-to-Side 1	All Subjects	250	2.7	36	1747
	1	120	1.80	38	380
	2	148	1.84	45	491
	3	633	1.82	195	2051
	4	616	1.75	207	1836
	5	205	2.92	25	1677
	6	272	1.98	71	1036
	7	333	1.65	124	892
	8	440	1.79	141	1376
	9	243	1.56	101	583
	10	88	1.68	32	242
	11	90	2.24	19	436
	12	170	1.64	64	449
	13	1420	1.89	408	4947
	14	103	1.65	39	272
	15	349	1.48	162	749
Head Up-and-Down 1	All Subjects	198	2.66	29	1348
	1	135	1.39	71	258
	2	73	2.16	16	331
	3	561	1.63	217	1453
	4	795	1.68	289	2186
	5	56	1.72	20	163
	6	260	1.63	100	678

GM, GSD, LCL, and UCL by Subject

Activity	Subject	GM	GSD	LCL	UCL
	7	407	1.60	162	1022
	8	268	1.69	95	753
	9	179	1.62	70	462
	10	89	1.45	43	184
	11	71	1.77	23	217
	12	149	1.45	72	307
	13	656	2.04	162	2659
	14	110	1.62	43	286
	15	338	1.84	102	1120
Normal Breathing 2	All Subjects	211	2.64	32	1415
	1	171	1.56	72	411
	2	101	1.65	38	269
	3	427	1.62	165	1105
	4	748	1.80	237	2358
	5	148	2.82	19	1125
	6	287	1.41	146	565
	7	460	1.81	144	1470
	8	426	1.74	144	1259
	9	153	1.60	61	383
	10	60	1.67	22	163
	11	79	1.41	40	154
	12	140	1.56	59	333
	13	495	3.73	38	6530
	14	103	1.76	34	313
	15	319	1.74	108	941
CPR 1	All Subjects	201	2.42	35	1135
	1	178	1.56	75	425
	2	42	1.66	16	113
	3	419	1.72	145	1213
	4	636	1.58	259	1560
	5	239	2.27	48	1190
	6	287	1.73	98	839
	7	238	1.64	90	630
	8	328	1.72	113	954
	9	110	1.39	58	211
	10	74	1.56	31	178
	11	98	1.46	47	204
	12	173	1.88	50	596

GM, GSD, LCL, and UCL by Subject

Activity	Subject	GM	GSD	LCL	UCL
	13	387	1.79	123	1216
	14	148	1.36	81	271
	15	400	1.86	118	1354
Ultrasound 1	All Subjects	270	2.63	41	1802
	1	135	1.39	71	258
	2	73	2.16	16	331
	3	561	1.63	217	1453
	4	795	1.68	289	2186
	5	56	1.72	20	163
	6	260	1.63	100	678
	7	407	1.60	162	1022
	8	268	1.69	95	753
	9	179	1.62	70	462
	10	89	1.45	43	184
	11	71	1.77	23	217
	12	149	1.45	72	307
	13	656	2.04	162	2659
	14	110	1.62	43	286
	15	338	1.84	102	1120
Making Bed 1	All Subjects	222	2.59	34	1438
	1	182	1.36	100	332
	2	78	1.43	38	158
	3	397	1.55	168	935
	4	683	1.85	205	2282
	5	418	1.82	130	1351
	6	294	1.59	118	730
	7	202	1.57	84	485
	8	540	1.79	173	1683
	9	204	1.58	83	502
	10	46	1.57	19	112
	11	97	1.33	56	170
	12	120	3.33	11	1260
	13	502	1.80	158	1594
	14	123	1.28	76	199
	15	447	1.83	136	1468
Normal Breathing 3	All Subjects	212	2.45	37	1226
	1	195	1.52	86	446
	2	59	1.68	21	162

GM, GSD, LCL, and UCL by Subject

Activity	Subject	GM	GSD	LCL	UCL
	3	448	1.74	152	1322
	4	388	2.09	91	1648
	5	530	1.80	167	1684
	6	259	1.86	77	873
	7	266	1.67	98	722
	8	276	1.45	133	571
	9	131	1.37	71	242
	10	58	1.60	23	146
	11	102	1.43	50	204
	12	195	1.89	56	684
	13	624	1.95	169	2308
	14	105	1.41	54	205
	15	395	1.59	159	981
CPR 2	All Subjects	207	2.5	34	1249
	1	134	1.70	47	378
	2	56	1.43	28	113
	3	383	1.68	138	1062
	4	454	1.49	207	995
	5	409	1.92	114	1464
	6	263	1.70	93	742
	7	205	1.95	55	758
	8	459	1.77	150	1403
	9	89	3.06	10	795
	10	61	1.41	31	120
	11	107	1.47	51	228
	12	235	1.72	81	684
	13	510	1.69	183	1426
	14	169	1.37	91	314
	15	347	1.82	107	1118
Ultrasound 2	All Subjects	245	2.62	37	1617
	1	191	1.54	82	445
	2	78	1.44	38	160
	3	479	1.75	160	1440
	4	674	2.16	149	3050
	5	231	2.04	57	932
	6	289	1.61	114	732
	7	317	1.64	121	834
	8	526	1.91	147	1875

GM, GSD, LCL, and UCL by Subject

Activity	Subject	GM	GSD	LCL	UCL
	9	132	1.63	50	346
	10	67	1.51	30	151
	11	69	1.61	27	174
	12	268	1.72	93	778
	13	855	1.77	279	2621
	14	178	1.74	60	529
	15	511	1.81	160	1628
Making Bed 2	All Subjects	227	2.38	41	1242
	1	197	1.40	102	380
	2	77	1.39	40	146
	3	336	1.54	145	781
	4	406	2.08	96	1712
	5	483	1.82	149	1568
	6	270	1.48	126	580
	7	222	1.67	81	603
	8	567	1.76	188	1709
	9	145	1.57	60	351
	10	60	1.38	32	114
	11	124	1.41	63	242
	12	164	1.62	64	425
	13	783	1.80	247	2482
	14	123	1.50	56	272
	15	377	1.86	112	1269
Normal Breathing 4	All Subjects	236	2.57	37	1507
	1	188	1.65	71	500
	2	70	1.70	25	198
	3	459	2.12	105	1996
	4	551	2.03	137	2213
	5	341	2.16	75	1542
	6	274	1.61	108	697
	7	342	1.67	125	934
	8	320	2.11	74	1387
	9	111	1.43	55	225
	10	61	1.75	21	183
	11	131	1.51	59	293
	12	265	1.84	80	877
	13	858	2.53	139	5299
	14	147	1.56	62	349

GM, GSD, LCL, and UCL by Subject

Activity	Subject	GM	GSD	LCL	UCL
	15	396	1.69	142	1105
CPR 3	All Subjects	226	2.69	32	1576
	1	147	1.64	56	388
	2	45	1.67	16	122
	3	401	1.72	139	1159
	4	494	1.61	195	1253
	5	378	1.92	106	1352
	6	310	1.87	91	1057
	7	249	1.50	112	552
	8	486	1.82	151	1570
	9	72	2.37	13	388
	10	72	1.48	33	156
	11	103	1.42	51	205
	12	270	1.76	89	820
	13	843	1.73	287	2474
	14	203	1.40	104	394
	15	458	1.86	135	1552
Ultrasound 3	All Subjects	278	2.78	37	2071
	1	201	1.51	89	451
	2	75	1.45	36	153
	3	543	1.84	164	1792
	4	967	1.81	302	3096
	5	258	2.50	43	1551
	6	322	1.63	124	838
	7	401	1.69	144	1119
	8	530	2.07	127	2218
	9	136	1.76	45	409
	10	82	1.47	38	175
	11	84	1.54	36	195
	12	273	1.87	80	931
	13	1525	1.87	445	5222
	14	232	1.68	84	638
	15	375	1.66	138	1017
Making Bed 3	All Subjects	273	2.5	45	1642
	1	227	1.40	117	439
	2	73	1.49	33	159
	3	462	1.67	169	1265
	4	657	1.69	235	1833
	5	433	1.90	123	1517

GM, GSD, LCL, and UCL by Subject

Activity	Subject	GM	GSD	LCL	UCL
	6	269	1.56	113	644
	7	217	1.62	84	560
	8	740	1.95	199	2754
	9	268	1.73	92	782
	10	66	1.43	33	135
	11	111	1.36	61	202
	12	284	1.70	100	804
	13	1011	1.86	298	3429
	14	180	1.51	81	402
	15	366	1.65	136	982
Normal Breathing 5	All Subjects	263	2.75	36	1905
	1	240	1.49	110	521
	2	84	1.61	33	215
	3	668	2.06	163	2742
	4	669	1.96	178	2509
	5	119	2.27	24	593
	6	289	2.03	72	1159
	7	353	1.98	92	1350
	8	419	1.78	135	1304
	9	169	2.05	41	692
	10	66	1.77	21	200
	11	107	1.57	44	257
	12	413	2.08	98	1740
	13	1143	1.99	296	4417
	14	199	1.61	78	506
	15	389	1.78	126	1201
Bending Over 2	All Subjects	266	2.62	40	1758
	1	261	1.60	104	656
	2	87	1.63	34	227
	3	665	1.67	242	1825
	4	737	2.01	187	2900
	5	258	2.03	64	1034
	6	243	1.75	81	730
	7	345	1.59	138	860
	8	404	1.84	122	1333
	9	157	1.71	55	450
	10	74	1.76	24	222
	11	124	1.54	53	287
	12	446	1.74	151	1318

GM, GSD, LCL, and UCL by Subject

Activity	Subject	GM	GSD	LCL	UCL
	13	1116	1.84	339	3673
	14	115	1.84	35	379
	15	289	2.32	55	1511
Talking 2	All Subjects	265	2.52	43	1624
	1	190	1.54	82	442
	2	107	1.46	51	224
	3	560	1.99	145	2157
	4	617	1.56	256	1483
	5	462	1.81	144	1480
	6	188	1.48	87	406
	7	387	1.77	126	1188
	8	304	1.68	110	837
	9	193	2.24	40	936
	10	76	1.44	37	156
	11	119	1.96	32	444
	12	249	2.08	59	1046
	13	1229	2.01	312	4840
	14	128	1.29	78	210
	15	445	1.75	149	1335
Head Side-to-Side 2	All Subjects	303	2.77	41	2238
	1	192	1.51	86	430
	2	159	1.87	46	544
	3	720	1.89	208	2498
	4	896	1.74	303	2654
	5	280	2.36	52	1507
	6	146	1.60	58	366
	7	554	1.82	170	1801
	8	232	2.58	36	1493
	9	254	1.74	86	747
	10	80	1.42	40	160
	11	113	2.35	21	603
	12	360	1.97	95	1361
	13	1723	1.79	552	5379
	14	225	1.56	94	536
	15	494	1.99	129	1901
Head Up-and-Down 2	All Subjects	242	3.29	24	2496
	1	231	1.77	75	707
	2	55	1.70	19	157
	3	790	1.94	215	2897

GM, GSD, LCL, and UCL by Subject

Activity	Subject	GM	GSD	LCL	UCL
	4	1040	1.74	350	3090
	5	121	1.67	44	332
	6	103	2.09	24	434
	7	527	1.69	188	1476
	8	160	1.90	45	566
	9	134	2.24	28	647
	10	68	1.40	35	131
	11	70	1.51	31	156
	12	430	1.91	121	1531
	13	2042	2.02	515	8099
	14	256	1.54	110	596
	15	371	1.55	157	878

APPENDIX E

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- Advanced knowledge of
  - Microsoft Word, Excel, PowerPoint, Access
  - GIS
  - SAS
  - R
- Strong Statistical and Analytical abilities
- Management of research projects
- OSHA 40 Hour HAZWOPER Certified
- Languages: English—fluently; Spanish—proficient

RESEARCH & TRAINING SUPPORT

Funded Support

Grant # TR-83418401-0 Kaplan (PI) Dates: Aug. 2011–Aug. 2012

United States Environmental Protection Agency

Subproject: To identify the public health benefits of redeveloping brownfield sites in a sustainable manner and conduct technical assistance.

Role: Graduate Student Research Assistant

Grant# 254-2010-36476 Brosseau (PI) Dates: Jan. 2011–Dec. 2011

National Institute for Occupational Safety and Health Goals: Describe the extent to which Illinois and Minnesota hospitals have implemented RPPs for influenza in the context of CDC guidelines and recommendations as well as local policies and practices

Determine the usage of respiratory protection for influenza 3exposure among health care workers in MN and IL, in the context of CDC guidelines and local policies and practices.

Role: Graduate Student Research Assistant

Grant # T42\OH008672 Conroy (PI) Dates: Aug. 2009–May 2014

National Institute for Occupational Safety and Health

Goals:Great Lakes Education and Resource Center traineeship program aimed to provide academic and research training in applied occupational health and safety practice and thorough grounding in safety science, engineering, and research.

Role: Trainee

TEACHING

Teaching Assistant

University of Illinois at Chicago, School of Public Health
Environmental Calculations (EOHS 405), Fall 2010, Fall 2014
Principles of Environmental Health Sciences (EOHS 400), Fall 2012, Spring 2013
Fundamentals of Industrial Hygiene (EOHS 421), Fall 2013
Industrial Hygiene Laboratory I (EOHS 428), Spring 2015
Evaluation and Control of Chemical and Biological Agents (EOHS 426), Spring 2015

Purdue University, Biological Sciences
Fundamentals of Biology I (BIOL 110), Fall 2005, Fall 2006, Fall 2007
Fundamentals of Biology II (BIOL 111), Spring 2005, Spring 2006, Spring 2007, Spring 2008

PROFESSIONAL, DEPARTMENTAL, & LOCAL ACTIVITIES

American Industrial Hygiene Association
Member, 2008–Present

American Conference for Governmental Industrial Hygienists
Member, 2012–Present

International Society for Exposure Assessment
Member, 2012–2013

International Society for Respiratory Protection
Member, 2014–Present

Advisory Boards

University of Illinois School of Public Health 2010–2012

Committee on Educational Programs—Advised and worked with faculty to ensure the School of Public Health Curriculum remains of highest quality

Volunteer Work

Chicago Regional Science Bowl Volunteer 2011, 2012

UIC College Prep Case Study Volunteer 2012

PUBLICATIONS

L. M Brosseau, L. M Conroy, **M. Sietsema**, K. Cline. Evaluation of Minnesota and Illinois Hospital RPPs and Healthcare Worker Respirator Use. J Occup Environ Hyg. 2015; 12:1–15.

M. Sietsema, L. M. Conroy, L. M. Brosseau, K. Cline. Scoring Hospital RPPs using Written Programs and Interview Data. J Occup Environ Hyg. 2015. 12(3): 189–198.

M. Sietsema, P. Bodurtha, E. Dickson, L. M. Brosseau. Evaluating Simulated Workplace Protection Factors for a First Responder Low-Level Protective Ensemble. J Int Soc Resp Prot. (accepted).

M. Sietsema, L. M Brosseau. Comparison of Two Quantitative Fit-Test Methods Using N95 Filtering Facepiece Respirators. (in preparation).