AN ALTERNATE APPROACH FOR FIT TEST IN IDENTIFYING RESPIRATORY PROTECTION BY N95 RESPIRATOR

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An Alternate Approach for Fit Test in Identifying Respiratory Protection by N95 Respirator

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Abstract

Background

Global concern over use of N95 respirator has increased recently because of the threat of outbreaks of infectious diseases, such as avian influenza and the novel Influenza A (H1N1). The use of a fitted N95 respirator has been recommended, legislated and implemented in the USA, Canada and other countries. Perception factors or any discomfort may influence the proper use of the respirator by the wearer as the wearer may dislocate the respirator and/or use it in a non-appropriate position. The conventional quantitative fit test instruments, which give an instant measurement, have provided the gold standard for predicting the protection of an N95 respirator in a laboratory environment; however, conventional quantitative fit test instruments cannot deliver real-time measurements of faceseal leakage when the N95 respirator is in use in clinical settings. This study aimed to develop an alternate method to evaluate N95 respiratory protection in real-time, in a clinical setting.

Method

Stage 1 involved developing and validating a new fit test method to evaluate respirator protection. Stage 2 evaluated (a) the performance of the investigator-developed fit test method and (b) the necessity to perform fit check, a subjective self-check method by the wearer to determine whether the respirator he/she has put on is leaking. Eighty-four subjects were selected for this study. All were first-year undergraduate students who had never performed a fit test or a fit check before being recruited for this study. They were divided randomly into four groups. The real-time fit test method was measured by two Portable Aerosol Spectrometers at the same time. The tests were conducted while the subjects were wearing N95 respirators in doing bedside nursing procedures. All subjects were asked to evaluate six perceptions (heat, breathability, tightness, ease in talking, comfort on ear lobe and overall comfort) that they experienced while doing the procedures wearing a respirator in the test.

Results

Results from the work of Stage 1 showed that the two spectrometers were consistent in measuring ambient particle concentration. The one-way intraclass correlation coefficient between the two spectrometers was 0.83. Results of Stage 2 showed significant differences among groups in perception of sensation after wearing N95 respirator in terms of the ease in talking ($p=0.026$). This study achieved an effect size index of 0.866 which made the power analysis of the study 99%.

Discussion

Health care workers are told to perform a fit check whenever donning an N95 respirator, but they often do not know how important the fit check is and do not understand the consequence of not performing the fit check. This study found that performing the fit check minimizes the air particles leaking into the respirator during nursing procedures. Personal perception of respirator, whether their feeling toward wearing respirator can affect health care workers' compliance with rules regarding protective equipment, their personal safety as

well as their morale. Therefore, the respiratory protection and training programme should include thorough training in how to wear the N95 respirator; it should reinforce the importance of performing the fit check whenever donning an respirator in clinical work place, and supervised the compliance of fit check in performance of fit test.

Conclusion

The investigator-developed fit test method to evaluate N95 respirator protection was devised and tested in this study. Results are promising. This investigator-developed fit test method can provide real-time measurement of the effectiveness of respiratory protective devices; it can thereby significantly reduce the risk of health care workers exposed to airborne infectious diseases if consistently used in clinical settings.

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List of Abbreviations

APF	Assigned protection factor
CDC	Centers for Disease Control and Prevention
FF	Fit factor
MPPS	Most-penetrating particle size
OSHA	Occupational Safety and Health Administration
PAS	Portable Aerosol Spectrometer
PF	Protection Factor
PEL	Permissible exposure limit
PRST	Personal Respirator Sampling Test
QLFT	Qualitative fit-testing
QNFT	Quantitative fit-testing
WHO	World Health Organization
WPF	Workplace protection factor

CHAPTER 1

INTRODUCTION

1.1 Introduction

This chapter provides an overview of the problems of the current fit test method for the N95 respirator as used by health care workers in clinical settings. It states the research questions, and outlines the aims and significance of the research.

An N95 respirator requires fit testing before use in health care settings in the United States, Europe and in hospitals in Hong Kong. O ccupational Safety and Health Administration regulations state that, for their own safety, no one should wear an N95 without being fit-tested (Rebmann, 2007). Currently, the fit test is performed by a quantitative fit test instrument (Figure1.1), which delivers instant results. This instrument has provided the gold standard in predicting the protection of an N95 respirator in the laboratory environment. However, quantitative fit test instruments cannot deliver real-time measurements of faceseal leakage when the N95 respirator is in use in clinical settings.

Figure 1.1: A quantitative fit test instrument

This study aimed to develop a method to identify N95 respiratory protection in real-time, in a clinical setting. Such a method could safeguard the health of clinical workers exposed to airborne infectious diseases during their work more effectively than the conventional method now in use.

This study consisted of two stages. Stage 1 involved developing and validating a new fit test method to evaluate respirator protection. In Stage 2 t he performance of the investigator-developed fit test method and the necessity to perform a "fit check", i.e., a self-check performed by the wearer to determine whether the respirator he/she has put on is leaking, were evaluated.

1.2 Background

Debate over the use of the N95 respirator and its respiratory protection in clinical settings began in 1995 with the introduction of the Guidelines for the Prevention of Transmission of Mycobacterium Tuberculosis by the U.S. Centers for Disease Control and Prevention (CDC)'s National Institute for Occupational Safety and Health (NIOSH) (CDC, 1998). According to the Guidelines, health care workers are required to use particulate air-purifying respirators, e.g. N95 respirators, with mandatory annual fit tests to select the right size of respirator for each wearer.

Global concern over the use of the N95 respirator has increased recently because of the threat of outbreaks of infectious diseases, such as avian influenza and the novel influenza A caused by the (H1N1) virus. The World Health Organization (WHO) recommends that any health care worker performing high-risk aerosol-generating procedures (for example, bronchoscopy, or any procedure involving aspiration of the respiratory tract) should use a particulate respirator such as the N95 (WHO, 2009).

The WHO also recommends that every health care worker wear a fitted N95 respirator as a precaution against the pathogens transmitted by air (WHO, 2004; WHO, 2009). Diseases which are spread by airborne transmission and for which airborne precautions should be taken include active pulmonary tuberculosis (TB), measles, chicken pox, pneumonic (pulmonary) plague, and haemorrhagic fever with pneumonia. Fit testing of respirators has been recommended, legislated and implemented in the USA and Canada (Clayton and Vaughan, 2005).

In Hong Kong, a fit test is done when a health care worker joins the workforce, when any registered user has facial contour changes, or when a particular respirator model is discontinued by the manufacturer. The Hong Kong Hospital Authority (HA) recommends use of the N95 respirator as a precaution during high risk aerosol-generating procedures. The Hong Kong Labour Department recommends workers should always perform a seal check after putting on a fit-tested respirator (Labour Department, 2004). In the USA CDC, 1998 advocate a seal check, also called a fit check, when donning a respirator

for each fit test. Whether a respirator serves its purpose, however, depends on its filter efficiency and tightness of the faceseal.

The respirator fitness is determined by “fit factor” and “fit check” in the quantitative fit test. Fit factor is calculated from measurements of ambient particles inside the respirator while the wearer performs exercises in the laboratory environment; it is expressed as the ratio of the mean concentration of ambient particles outside the respirator to the concentration of particles inside the respirator (Crutchfield, 1995). A fit factor greater than or equal to 100 is taken as an indication that the respirator fits the wearer well (Dosman et al., 2000). Fit check is a self-check performed by the wearer to determine whether the respirator he/she has put on is leaking. The fit and seal of a N95 respirator is critical for effective function. A recent literature review (a search of electronic databases MEDLINE, Cochrane, and CINAHL up to March 2013) show no study of the differences in respiratory protection for wearers who performed a fit check and those who did not, upon donning the respirator.

NIOSH studies have shown that the fit test does not predict the protection of the respirator in a work environment. Indeed, most elements of the NIOSH respirator program (i.e., fit factor, protection estimates, etc.) are theoretical using mathematical models and have not been confirmed in clinical work situations. The calculation of fit factor depends on measuring the amount of particulates in the ambient air, which is feasible in a controlled environment, such as in a laboratory environment, but is not feasible in a ward setting. The respirator investigated in this study is the NIOSH-certified N95 respirator which is certified to filter 95% of particles size greater than 0.3μm or a maximum of 5% penetration rate through the respirator filter.

Particle size range of 0.25 to 1μm penetration size was selected to represent the viral and bacterial particles (Hinds, 1999). 0.3μm represents the most penetrating particle size for mechanical filtration. This is problematic for users of N95 respirators because enough ambient aerosols lie in the "most penetrating" size range to affect results. The conventional fit test measured the total amount of air particles inside and outside the N95 respirator. Therefore the present fit

test method identifies if the air particles inside the respirator have entered through the filter material or through the respirator leak.

Particles smaller than 0.3μm that have penetrated the filter may contribute significantly to the total number of air particles measured inside the respirator (Han and Lee, 2005). The number of air particles inside the respirator is affected by (1) particles penetrating directly through filter fiber and (2) faceseal leakage at the interface region where the respirator contacts the wearer's face. The intention of the current fit test is to quantify the ability of the respirator to provide respiratory protection; however, testing of N95 respirator under laboratory conditions does not necessarily reflect the actual performance of the respirator in clinical situations. Because the fit test measures only faceseal leakage, significant filter penetration can result in erroneously low (i.e., unacceptable) fit factors. As a result, adequate fits may be rejected (Janssen, Luinenburg, Mullins, and Danisch, 2003). Analyzing fit test results by comparing individual exercise fit factors can be misleading (Crutchfield, 1995).

The result of fit factors based on the difference of in-respirator aerosol concentration and ambient concentration outside respirator during individual exercise. Fit factor cannot identify the filtering face-piece and face-mask leakage (Fennelly and Nardell, 1998). The fit factor cannot identify whether air particles entered the respirator through filter penetration or faceseal leakage.

Particle concentration by size is a key predictor of the ability of a particulate exposure to cause adverse health effects (Schlesinger, Kunzli, Hidy, Gotschi, and Jerrett, 2006). Some adverse health effects, particularly those related to cardiovascular function, appear to be related to short-term changes in particle concentration by size (Peters, Dockery, Muller, Murray, and Mittleman, 2001; Wellenius, Schwartz, and Mittleman, 2005). However, the conventional fit test only measures particle concentrations inside and outside the respirator, it is not in real-time in a clinical setting. This drawback seriously endangers the health of workers using the N95 respirator. Faceseal leak requires instruments that provide a rapid measure of particle concentration by size distribution in real-time in a clinical setting.

1.3 Research problem

The conventional fit testing method using the Portacount machine cannot predict the protection of the N95 respirator in a work environment. It does not necessarily reflect the expected performance of the respirator in clinical situations and cannot safeguard the health of clinical workers exposed to infectious diseases during their work. The Portacount machine is an instrument that can measure and compare particle concentration inside and outside the respirator; it cannot distinguish between aerosol particles entering the respirator through the face-piece filter and those entering via face-mask leakage. The conventional fit testing method cannot identify the aerosol particles by size distribution. Analyzing fit test results by comparing individual exercise fit factors could be misleading by, overestimating or underestimating the protection of the N95 respirator. Can a precise and real-time method be devised to accurately, quickly evaluate respiratory protection of an N95 respirator in a clinical setting?

1.4 Aims

The aims of this study were: First, to develop and validate a new fit test method for identifying respirator protection, and, second, to evaluate the performance of the investigator-developed fit test method and the necessity to perform a "fit check", i.e., a self-check performed by the wearer to determine whether the respirator he/she has put on is leaking. Grand research questions are raised.

1.4.1 Stage 1

What was the sensitivity of this investigator-developed fit test method in identifying respiratory protection of the N95 respirator?

1.4.2 Stage 2

How well did the investigator-developed fit test method in evaluating the fitness of N95 respirator as compared to conventional fit test method?

1.4.2.1 Research hypothesis of Stage 2

The investigator-developed fit test method has better predictive power in clinical settings than conventional quantitative fit test instrument in detecting face-seal N95 respirator leakage in laboratory settings.

1.5 Significance of the research

The findings of this research should assist health care professionals and researchers by providing a real-time method for performing fit test in clinical settings. The findings of this research should also provide a new direction in explaining the relationship between fit test and fit check.

The method used in this research can help N95 wearers detect faceseal leakage while they perform different nursing procedures in clinical settings. The study is significant because it can identify particle size distribution in determining the leakage of the N95 respirator in a real-time manner. Equally important, this study provides evidence to indicate the necessity of performing a "fit check" before fit test.

1.6 Delimitation

This study intended to develop a novel fit test method for use in clinical settings not in other workplace environments. The materials and different models of the N95 respirator were also not a focus of this study; therefore no attempt was made to identify or distinguish between different models of the N95 respirator.

1.7 Organization of the thesis

This thesis comprises seven chapters. Following this introductory chapter, the thesis is organized as follows:

Chapter 2 presents a review of current types of fit test methods. R elevant to these methods, the performance of N95 respirators and the perception of comfort of those wearing an N95 respirator are discussed. Chapter 3 reviews the relevant literature on respirator leakage measurements associated with respirator protection, the importance of measuring particle size concentration and particle size distribution in fit test measurements, and relevant research in these areas. Different types of aerosol spectrometers are also discussed in this chapter. Chapter 4 introduces Stage One, a study conducted to find a suitable instrument for fit test measurement. Sample size estimation for the main study

is also included in this chapter. Chapter 5 describes Stage Two, the main study, including the research methods and the procedures of data acquisition. The results of both the pilot study and main study are presented. C hapter 6 discusses the implications of the findings, addresses the limitations of the study and provides recommendation for future study. C hapter 7 presents the conclusion of the thesis.

CHAPTER 2

REVIEW OF THE CURRENT STATUS OF FIT TESTING

2.1 Introduction

This chapter discusses the definition and current types of fit test, fit test exercise, as well as calculation of fit factor and fit check. Performance of the N95 respirator is presented. Environmental conditions and perception of comfort in fit testing of an N95 respirator are also reviewed.

2.2 N95 respirator

The N95 respirator is the most common of the seven types of particulate filtering face-piece respirators commercially available to provide protection against airborne particles. "N95" is a generic term used by different manufacturers. The "N" indicates that the respirator provides no protection against oils, and the "95" indicates it removes at least 95% of airborne particles (CDC, 2010). Thus, by definition, any N95 respirator has a minimum 95% filtration efficiency or a maximum of 5% penetration rate through the respirator

filter using a challenge aerosol consisting of particles in the most penetrating particle size range, i.e. test particles of approximately 0.3μm diameter, which is a threshold smaller than the influenza virus particle (Barclay, 2009). Any N95 respirator has three layers; each layer is made of soft Polypropylene (P.P.). The inner layer reduces the fiber drops and increases the wearing comfort; the middle filter layer which is made of high efficient melt blown web resists dust and oil-free particles; the outer layer provides smooth lining and avoids loose fibers. The typical respirator has latex-free cloth head straps to keep the respirator in place, an adjustable nose clip, and a soft foam nosepiece to ensure a comfortable custom fit.

The N95 respirator is a respiratory protective device. As a type of personal protection equipment, it acts as a p hysical barrier between airborne microorganisms and the wearer. World Health Organization (WHO, 2004) states that personal protective equipment is the first of two tiers of standard precautions specified for infection prevention and control. "Standard Precautions" applies to working with all patients regardless of diagnosis or infectious status, while "Transmission-based Precautions" apply to working

with patients harboring pathogens that are transmitted by air, droplets or physical contact. Airborne precautions prevent transmission of pathogens that are transmitted by air; such pathogens remain infectious over long distances when suspended and disseminated in the air (CDC, 2007). Microorganisms carried in this manner can be widely dispersed via air currents and can remain in the environment for long periods before being inhaled by or deposited on the susceptible host (WHO, 2006). The N95 respirator has a significant role in preventing both droplet nuclei (≤5μm) and dust particles from reaching the wearer through airborne transmission.

The Centers for Disease Control and Prevention (CDC) June 23, 2010 recommends that health care workers conducting the highest exposure risk activities (i.e., aerosol-generating procedures) should wear only fit-tested N95 respirators to reduce the risk of infection. Aerosol-generating procedures are procedures that stimulate coughing and promote generation of aerosols. Fit testing of respirators has been recommended, legislated and implemented in the USA, according to Occupational Safety and Health Administrations (OSHA) Standard 29 CFR 1910.134.

N95 respirators are designed to form a tight seal against the wearer's face. When properly fitted and worn as recommended, they provide respiratory protection. The N95 respirator manufactured by 3M, certified by NIOSH, is the model most commonly used in hospitals in Hong Kong to protect health care workers against airborne transmission diseases such as tuberculosis, measles and chickenpox. How well a respirator provides respiratory protection is critical. Three factors determine the protection of the respirator: (1) material of the filter; (2) design of the respirator and (3) tightness of the seal. The first two factors are determined and guaranteed by the manufacturers; only the third factor, tightness of the seal, can be influenced by the wearer. But often this factor determines whether the N95 actually does its job. Therefore, checking the tightness of the faceseal and being able to adjust the respirator before use is crucial for the wearer. The tightness of the seal is affected by adequacy of training and of fit testing (CDC, 2010). A recent study by Graveling, Sanchez-Jimenez, Lewis, and Groat (2011) concludes that adequate information and suitable training are needed. It is, however, necessary to further define what kinds of information and training are needed.

2.2.1 Respirator performance

In recent years, an increased effort has been undertaken to evaluate the performance of the N95 respirator in the workplace. Up until 2008, respiratory protection was usually evaluated by determining the protection factor (PF), a term coined by the Bureau of Mines in Respirator Approval Schedule 21B in 1965 as a measure of the degree of protection provided by a respiratory protective device (Revoir and Bien, 1997). PF is the ratio of the concentration of airborne contaminants outside the respirator to the concentration inside the respirator (inverse penetration efficiency). As the ratio increases, the level of the protection provided by the respirator also increases. PF depends on the conditions under which the aerosol concentration measurements are conducted. The PF is intended to be used in industrial not clinical settings.

The term PF has been replaced by Fit Factor (FF), Workplace Protection Factor (WPF) and Assigned Protection Factor (APF) (Anonymous, 2008). FF is a quantitative estimate of how well a particular respirator fits a specific individual, and typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn (Occupational Safety and Health Administration, OSHA). WPF is used to estimate the respiratory protection level in a laboratory while the wearer does test exercises designed to simulate work activities. APF is the expected level of respiratory protection that would be provided by a properly functioning respirator or a class of respirators properly fitted to trained users in a workplace (American National Standards Institute [ANSI], 1988).

There is no standardized method to calculate the respiratory protection at work. Therefore, it is necessary to use a method that can evaluate how well the N95 protects a w earer performing actual bedside nursing procedures, not estimating from simulation or assumption.

2.3 Environmental conditions

The high temperature and high moisture content of exhaled air can cause water vapor to condense in the respirator because of the temperature difference between air inside the respirator and the external ambient air. T he breathing action will mechanically reinforce thus affect the penetration. In particular, high humidity may cause measurement error (Lee et al., 2005). Revoir and Bien (1997) found that high temperature and humidity could degrade the performance of the respirator. Therefore, it is necessary to measure the temperature and humidity when performing the fit test because both factors can affect the functioning of the respirator as well as the accuracy of the test.

2.4 Perception of comfort

Temperature and humidity may not only affect performance and fitness of respirator, they also affect the perception of comfort. In other words, when wearers find the respirator uncomfortable, they may adjust it to make it comfortable without regard to its protective function, or in the worst case, they may not wear it a t all. Thermal discomfort is expected when wearing N95 respirator as the tight fit of the respirator causes moist warm air to build up inside the respirator. Pain or discomfort is experienced especially from tight

fitting respirators and after prolonged use. The elastic head straps of the respirator required for tight fit may cause headache and facial pain and ear lobe discomfort (Szeinuk, Beckett, Clark, and Hailoo, 2000).

Clinical studies show that acceptability to wearing a N95 respirator is a crucial factor that limits the ability of respirators to provide protection against inhalation hazards (Harber et al., 1996). The discomfort of wearing a respirator arises from various factors: increased temperature inside the respirator, pressure on the face and ear due to the respirator's elastic straps, perception of inspiratory resistance, odour and effects on hearing. Discomfort may result in reduction of the fractional protection factor offered by the respirator as the worker may dislocate the respirator and/or use it in a non-appropriate position. Perception factors or any discomfort may influence the acceptability and thus the proper use of the respirator by the wearer (Li et al., 2006).

2.5 Fit test

An N95 respirator requires fit testing before use in health care settings in the United States, Europe and Hong Kong hospitals. Fit testing ensures that the respirator fits the wearer, particularly that there is no leakage around faceseal (Morbidity and Mortality Weekly Report [MMWR] CDC, 1998). Fit factor is used to express or quantify the tightness of the N95 respirator as worn by an individual in the fit test. OSHA regulations state that, for his or her own safety, no one should wear an N95 without being fit-tested (Rebmann, 2007). However, there is no recommended standard fit test method or training suggested by WHO or CDC to check the tightness of the seal before use in the clinical settings.

2.5.1 Types of fit test

Two types of fit test are currently performed in health care settings: qualitative and quantitative. Studies have showed that none of the fit test methods adequately screen out poorly fitting respirators (Coffey, Lawrence, Zhuang, Campbell, Jensen, and Myers, 2002; Janssen, Luinenburg, Mullins, and Nelson, 2002).

The qualitative fit test is a pass or fail test relying on the subject's voluntary responses to a challenge agent, that is, taste, smell or irritation (ANSI, 1988). Using 3M FT-10 Qualitative Fit Test (QLFT) Apparatus, fitness testing comprises a threshold (sensitivity) test and a pass/fail test of facial fit. In the test, a test agent is injected through a hole in the hood's face screen using a nebuliser. The test is terminated when the subject detects the taste of the test agent as this indicates a leaking respirator (a failure). If the subject does not detect the taste of the test agent, the test is recorded as successful and the respirator is deemed to fit satisfactorily (a pass). The problem is that the only test agent being used is saccharin and

NIOSH does not recommend its use due to its potential carcinogenicity (Coffery et al., 2004).

The quantitative fit test is an objective test performed by a testing machine (e.g. Fit tester 3000, O HD; Portacount Respirator Fit Tester, TSI) that provides numerical test results. The Portacount Respirator Fit Test is the most common type of testing machine being used in worldwide hospitals. It was developed and commercialized more than 25 years ago. The fit test instrument uses ambient air particles as the challenge agent (CDC, 1998). T he Portacount machine is connected to a personal computer for recording and storing results using Fit Plus for Windows Fit Test Software (Han, 2000).

On January 8, 1998, OSHA released a long-awaited revision to the Respiratory Protection Standard 29CFR 1910.134 which replaced the standard with the same name and number that was released in 1971. This standard was based on a study conducted by CDC's NIOSH in 1994. T he

CDC's NIOSH first evaluated particulate air-purifying respirators (e.g. N95 respirators) in health care facilities using the fit test. NIOSH evaluated the performance of N95 respirator models on a panel with 25 people. The report indicated that a fit test is needed to ensure at least the minimum level of protection, that is, the concentration of airborne contaminants inside the respirator is less than or equal to 10% of ambient levels (CDC, 1998). However, the panel had only 25 people, and they all had experience of wearing respirators and of performing the fit test; their experience may have affected the fit test results (Johnston, Myers, Colton, Birkner, and Campbell, 1992).

A cluster randomized clinical trial comparing fit-tested and non-fit-tested N95 respirators to medical masks (surgical masks) to prevent respiratory virus infection in health care workers was conducted by MacIntyre et al. (2011). Their study showed no s ignificant difference in fit-tested and non-fit-tested N95 respirators in preventing respiratory virus infection in health care workers. In this study, subjects wore respirators on entire and every shift which did not follow the WHO or CDC guidelines which

recommend wearing N95 when perform high risk procedures or take care patients with airborne precautions. The study did not mention whether subjects had performed fit check before fit test or not. R esults showed that fit testing did not improve the efficacy of N95 respirators.

MacIntyre et al. (2011) used the qualitative fit test method but not the quantitative method. It is necessary to evaluate the performance of fit-tested and non-fit-tested N95 respirator using quantitative fit test method. In Loeb (2009)'s study, they compared surgical mask and N95 respirator for preventing influenza among health care workers. T hey noted that the surgical mask could not achieve as tight a seal as did the N95 respirator. However the surgical mask is not designed to create a faceseal; its purpose is to prevent droplets not aerosol from reaching the wearer.

2.5.2 Fit test exercise

Crutchfield and colleagues (1999) suggested that respirator donning affects respirator fit to a greater degree than fit test exercises. In both qualitative and quantitative fit test methods, the wearer is asked to perform a series of exercises that entail: normal breathing, deep breathing, turning head from side-to-side, moving head up-and-down, talking and normal breathing. Quantitative fit test protocols are defined by a series of fit test exercises (OSHA, 1998).

There is limited information available to describe the effectiveness of the fit test exercises in terms of respiratory protection standards. A study by Grinshpun (2009) showed that movement has a detrimental effect on faceseal protection. Six exercises performed during the fit test cannot represent the actual work activities. Only three movement exercises are included in the conventional fit test and these exercises simulate industrial work place activities but they are not continuous body movement and not similar to actual clinical work activities. The conventional fit test method only considers the overall fit factor; that is if the respirator failed as the

wearer performed one of the up and down head movement exercises, but the overall fit factor was greater than 100, the fit test results could be considered as pass. In other words, the present fit test can overestimate the level of protection of a respirator (Clayton and Vaughan, 2005). Crutchfield and colleagues (1999) showed that one particular exercise, the bend-over fit test exercise, could reveal poor respirator fit. Leak measurement over the sampling period of 30 seconds and calculate a mean leakage for entire fit test. An instantaneous leak or relatively high leakage during a single exercise can be offset by longer periods of lower leakage in that single exercise, resulting in an overall passing fit factor in a single exercise (Janssen, Luinenburg, Mullins, and Nelson, 2002).

Results of the tests are used to select the respirator with the best fit for the wearer. The activities performed by the respirator wearer in the workplace involve many body movements (Revoir and Bien, 1997). However, these activities are not accurately simulated in the current fit test being administered to health care workers. The fit test was originally designed for use in industrial settings. For example, many of the

exercises entail repeated body motions; however, health care workers regularly and more characteristically perform bedside procedures that require bending forward, and these motions are not included in the test motions. T he exercises for the fit testing are performed with limited body movements. C rutchfield and colleagues (1999) modified fit test exercise with quick head shake designed to assess the potential shifting of the respirator but this exercise is not relevant to clinical jobs. T herefore, it is necessary to modify the fit test exercise for health care workers so that they mimic or simulate actual movements health care workers are likely to perform.

2.6 Fit factor

Fit factor is calculated from all simulated exercises and represents the total penetration through the respirator and leakage around the faceseal. As originally conceived, it was not intended for use in calculating the wearer's actual exposure to hazardous substances in clinical settings (Operation and Service Manual TSI 2008).

Fit factors have historically been expressed as the results of quantitative fit tests. A fit factor is calculated from all exercises and is expressed as the ratio of the mean concentration of ambient particles outside the respirator to the concentration of particles inside the respirator (Crutchfield, 1995)

$$FF = \frac{\text{Concentration of ambient particles outside the respirator}}{\text{Concentration of ambient particles iniside the respirator}}$$

$$Overall\ Fit\ Factor = \frac{N}{\frac{1}{FF1} + \frac{1}{FF2} + \cdots \frac{1}{FFN}}$$

Where: N = number of exercise

FF1 = fit factor from the first exercise

FF2 = fit factor from the second exercise

FFN = fit factor from the N^{th} exercise

The quantitative fit test measures total aerosol penetration, i.e. leakage that has occurred both through the filter medium and through the faceseal. No method clearly differentiates between the two pathways under actual breathing conditions (Grinshpun, Haruta, and Eninger, 2009).

The Portacount machine takes the average of the ambient concentrations measured before and after the respirator sample is taken, and then divides by the concentration measured in the respirator to produce a fit factor. It is necessary

to measure the required additional ambient concentration sample before the first fit factor can be calculated. Both the ambient and respirator concentrations are determined by integration. The overall concentrations are determined by the total number of particles counted during the sample periods. If no particles are counted in the respirator sample, the Portacount machine automatically adds one particle, to prevent dividing the ambient concentration by zero. The measurement provided by the Portacount machine is an assessment of respirator fit during the stimulation fit test exercises only. Therefore, respirator fit at other times may vary. A fit factor of greater than or equal to 100 would be taken as an indication that the respirator fits the wearer well (Dosman et al., 2000). Fit factor protection estimates are theoretical using mathematical models and have not been confirmed in clinical work situations.

Any respirator having faceseal leakage greater than 1% is considered to have failed the fit test. The 1% criterion is the standard value used by OSHA and ANSI to assess faceseal leakage because it provides a 10-fold safety factor between laboratory-based assessments of leakage and leakage in a workplace environment (i.e. less than 1% leakage in the laboratory should assure less than 10% leakage in the workplace). 10-fold is considered suitable to protect workers at exposure concentrations up to 10 times the OSHA's permissible

exposure limit (PEL) (Johnston et al., 1992). 10 times is the proposed assigned protection factor for filtering face-piece respirators (Lee et al., 2005).

However, this safety factor may overestimate or underestimate workplace protection because during inhalation, concentration inside the respirator can be decreased because of respirator dead space and lung retention. Therefore, the accuracy of the fit test in health care settings has been challenged (Coffey, Lawrence, Campbell, Zhuang, Calvert, and Jensen, 2004). In Coffey et al.'s study, the respirators were tested on a panel of 25 subjects; respirator performance was determined on the basis of four procedures and all results were determined by calculation without correlation with actual work activities in a clinical setting.

2.7 Fit check

In addition to the fit test, infection control personnel and the CDC commonly advocate a fit check, which is a self-check the wearer performs to detect air leaks of the respirator. The fit check is a positive-and-negative pressure test by which a wearer can determine subjectively if his/her respirator is leaking. To perform the test, the wearer places both hands over the front of the respirator

and exhales sharply; if there is no leakage, is the wearer will experience pressure inside the respirator. For a negative seal check, the wearer covers the front of the respirator with both hands and inhales deeply. If there is no leakage, negative pressure will make the respirator cling to the wearer's face. Leakage will result in loss of negative or positive pressure in the respirator due to air entering through gaps in the seal. Performing either of the tests enables a wearer ensures his/her respirator fits correctly, both before and during use.

A successful fit test implies that chosen respirator has the potential to provide an adequate fit but only by performing the fit check can a wearer ensure that the respirator fits at that time (Clayton and Vaughan, 2005). Although explanation of fit check lengthens the fit test appointment, it is crucial that the wearer understand the importance of conducting the fit checks to ensure that the anticipated level of protection is achieved (McMahon, Wada, and Dufresne, 2008). Coffrey et al. (2004) demonstrated that fit test is an important component of a respirator protection programme; however, they did not evaluate whether the fit check makes any difference in terms of respiratory protection. A search of electronic databases MEDLINE, Cochrane, and CINAHL up to

March 2013 show no study investigating the differences in respiratory protection between donning the respirator with and with and without fit check.

2.8 Summary

N95 respirators are designed to form a tight seal against the wearer's face. When properly fitted and worn as recommended, they provide protection from airborne aerosol. Fit testing ensures the respirator fits the wearer, particularly that there is no leakage around the faceseal. While fit testing adequately ensures that a respirator seals the wearers face during simulated exercises, there is no standardized method to calculate the respiratory protection during actual work. T herefore, for nursing staff, it is necessary to devise and use a method to calculate the respiratory protection in performing actual bedside nursing procedures, not by estimation or assumption.

In this chapter, problems and limitations of the current fit test method have been presented and discussed. In the next chapter, respirator leakage, particle size dependency, measurement of respirator leakage will be discussed.

CHAPTER 3

REVIEW OF RESPIRATOR FITNESS AND FACE-SEAL LEAKAGE

3.1 Introduction

Adequate fit of a respirator means no face-seal leakage; this chapter discusses respirator leakage, including the size and shape of potential leaks. T he measurement of respirator leakage and particle size will be explained. The importance of including the measurement of particle size concentration and particle size distribution in fit testing of an N95 respirator will be reviewed.

3.2 Respirator leakage

Respirator leakage is also called face-seal leakage; it refers to leakage where the respirator comes in contact with the wearer's face (Shaffer and Rengasamy, 2009). Several factors can affect respirator leakage in a fit test, particularly facial movements during the fit test exercise. Several studies (Myers el al., 1996; Jannssen et al., 2007) have qualitatively shown that large particles (5-20μm) may enter the respirator through leaks, but the penetration of these larger particles was not quantitatively determined.

Particles in the size range from 2.3 to 4.4μm are generally lost inside the respirator because of settling (particles that experience a force and settle to the bottom of a surface) and inertial impaction. Aerosol particles can be deposited onto a fiber in a filter of an N95 respirator through any of three mechanisms: impaction, interception and diffusion. Impaction is a curvilinear motion that applies in the collection and measurement of aerosol particles (Hinds, 1999). Particles smaller than a certain size can pass through the outer material. Interception is a collection mechanism in the particle size range of minimum efficiency, and it does not depend on flow velocity (Hinds, 1999). Diffusion is net transport of aerosol particles in a concentration gradient, from a region of higher concentration to a region of lower concentration (Hinds, 1999).

Particle size would affect the number of particles inside a respirator. The conventional fit test method measures only the concentration of particles inside and outside the respirator thus affecting the assessment of respirator fit in the fit test. Because different sized particles have different biological impact (the smaller particles tending to be more pathogenic), it is necessary to measure not only the concentration but also the size of air particles inside and outside the respirator during fit test.

Particles above 0.6µm in diameter may be captured by interception and inertial impaction. Inertial impaction occurs when a particle cannot follow a streamline around a fiber because of the inertia and instead impacts into the fiber. Aerosol particles larger than 0.3µm are collected most efficiently by impaction, interception and electrostatic attraction accordingly to single-fiber filtration theory. Particles smaller than 0.2µm are collected most efficiently by diffusion or electrostatic attraction. The most-penetrating particles (MPPS) are of intermediate size, where none of the mechanisms are dominant (Shaffer and Rengasamy, 2009).

The MPPS was 0.1-0.3µm, above which the filtration efficiency increases with size and reaches 99.5% or higher at about 0.75. The MPPS was below 0.2µm at 85 liters/minute (L/min). Particle penetration levels decline as particle size decreases below the MPPS. Diffusion takes place in this size region, and particles are trapped by the fibers. Therefore, viruses may be able to penetrate through the respirator in the form of liquid diffusion by a capillary effect. Capillary effect is a function of the ability of the liquid to wet a particular material (Hinds, 1999). Thus, diffusion of liquid will affect the number of

particles penetration through the respirator. The internal environment (relatively humidity and temperature) of the respirator will generate liquid diffusion when the respirator is being worn.

3.3 Particle size concentration

Particle concentration by size is a key predictor of the ability of a particulate exposure to cause adverse health effects (Schlesinger, Kunzli, Hidy, Gotschi, and Jerrett, 2006). Particle size is also a major determinant of respirator leakage. Size-dependent leakage and face-seal leakage are related to particle size (Holton, Tackett, and Willeke, 1987). However, in Holton (1987)'s study, test subjects sat quietly during the testing; thus his study results might not reflect the respirator leakage in an actual workplace situation. Lee (2005) showed that particle size affects penetration through filter materials and face-seal leaks. Other factors like higher breathing rate may increase penetration and influence face-seal fit (Reponen et al., 2011).

None of the three fit test methods (Portacount Fit test, Fit tester 3000 and qualitative fit test apparatus) meet ANSI sensitivity criterion of 0.95 when compared with either of the other two methods (Janssen, Luinenbury, Mullins, and Nelson 2002). Table 3.1 shows a comparison of the three fit test methods.

Table 3.1: Comparison of the three fit test methods

Model	Features	Test protocol (dynamic or static measurements)	Measurement period	Failure response (integrated or instantaneous)
Condensation Nuclei Counter (CNC) e.g. Portacount Fit test.	Counts condensation nuclei (submicrometer particles) outside and inside the subject's respirator.	Dynamic (detect face-seal leakage during entire exercise period)	30 seconds	Integrated
Controlled Negative Pressure (CNP) e.g. Fit Tester 3000	The instrument draws air from within the facepiece until a fixed negative pressure (typically -15mm water column) is obtained.	Static (take short duration samples after each exercise period)	8 seconds	Integrated
Bitrex Qualitative fit test	Subject are required to detect taste of a Bitrex solution aerosol to indicate unacceptable face seal leakage	Dynamic (detect face-seal leakage during entire exercise period)	30 seconds	Instantaneous

Source: Janssen, L., Luinenbury, M.D., Mullins, H., & Neslon, T. (2002). Comparison of three commercially available fit-test methods. *Industrial Hygiene Association Journal, 63*(6), 762-767.

One study showed that no fit test method met the criteria to screen out poorly fitting respirators (Coffey, Lawrence, Zhuang, Campbell, Jensen, and Myers, 2002). The conventional fit test is an assessment of the performance of total penetration of respirator in laboratory environment. It requires instruments that provide a real-time measurement to identify face-seal leakage of the respirator in clinical settings with bedside nursing procedures.

3.4 Measurement of particle size distribution

There are different instruments to measure aerosol particle size distribution such as the electrical aerosol spectrometer, the condensation nuclei counter, and the laser light scattering photometer. An electrical aerosol spectrometer (Airel Ltd, Tahe 4, 51010 T artu, Estonia) can perform real-time measurement of aerosol particle size distribution, can measure a wide range of particle sizes (3nm to 10μm), and the measurement cycle can be set at intervals from 1 second to several tens of minutes; however, it needs a power source supply during the measurement and it is heavy (60kg). The Portacount fit test instrument (TSI, 8020) is an example of a c ondensation nuclei counter. During operation, it causes alcohol to condense onto particles in the sample flow, creating aerosol droplets large enough to be detected using a light-scattering technique. Although it is light in weight (1.5kg) it requires a power supply during the measurement and requires sufficient ambient aerosol concentration during operation. T herefore it cannot operate in a large room. The results are expressed in total concentration of aerosol particles, and it cannot distinguish between different sized particles (Table 3.2).

Table 3.2: Particle sizes measurement by different particle spectrometers

Model	Weight	Power supply during measurement	Particle size range
Electrical aerosol spectrometer	60 kg	Need	3nm to 10µm
Condensation nuclei counter	1.5 kg	Need	Cannot distinguish between different sized particles
Laser light scattering	2.5 kg	Not necessary	0.25-32µm

In the third type of instrument, the scattered signal from particles passing through the laser beam are collected at approximately 90 degrees by a mirror and transferred to a recipient-diode. A pulse height analyzer then classifies the signal transmitted in 31 size channels with sample flow rate of 1.2L/min. It gives real-time measurements, it can measure particle size (0.25-32µm). It weighs 2.5kg, and can operate by battery. Its results can be stored on a removable data logger card and showed in terms of particle size concentration or particle mass distribution.

Particles sizes between 0.3 and 1µm are removed by several mechanisms like deposition that the shape of leak may have a difference (Grinshpun et al., 2009). These size ranges were selected because ultrafine particles are captured

primarily by diffusion and electrical polarization forces and particles size differences in protection factors persisted (Reponen et al., 2011). Several studies (Myers et al., 1996; Janssen et al., 2007) have qualitatively shown that large particles (5-20μm) may enter the respirator during use but did not quantitatively determine the percent penetration of these larger particles. Therefore, two identical laser light scattering aerosol spectrometers were used in the study.

3.5 Measurement of respirator leakage

The average velocity through a small leak hole allows particles larger than 0.9μm to follow the flow streamlines into the leak. There was a shift in the peak leakage to larger particle sizes for the small hole sizes. Settling losses of particles within the respirator will occur if particles are larger than 1μm in diameter; if particles are smaller than 0.2μm, particles will be lost due to diffusion. Thus total aerosol leakage is related to particle size and size of the leakage is called particle-size dependence of faceseal leakage. This characteristic of face-seal leakage is called particle-size dependence. A study has showed that as the hole size decreases, a greater percentage of larger particles enter through the faceseal leak (Holton, Tackett, and Willeke, 1987). The conventional fit test method cannot identify the size of particles inside the

respirator, it can only count the number. Air filter efficiency is expressed as the ratio of upstream particle concentration to downstream concentration after the air has passed through a filter. In formula form:

$$\frac{C_{down}}{C_{up}} \times 100\%$$

where

Cdown is the aerosol concentration downstream of the respirator filter; and
C_{up} is the aerosol upstream entering the respirator.

Air velocity is greater through larger holes. This indicates that higher inertial entry losses may be removing more particles, larger than 0.9μm from large and medium size holes. Chen et al., (1992) studied face-seal leakage and filter penetration characteristics during inhalation and suggested that the slope of the aerosol size-dependent penetration curve may differentiate face-seal leakage from filter penetration.

Therefore, in this study, particle count of aerosol size distribution was chosen as the means to measure and evaluate respirator face-seal leakage.

3.6 Leak size and shape

More aerosol penetrates through circular leak holes than long slits of equal cross-sectional area because the shape of a leak affects the leak flow. The effective diameter dependency is strong in low sampling flows because the leak flow fraction is higher at low sampling flows.

In normal respiration, particles between 0.1-1μm in diameter are deposited by gravitational sedimentation and diffusion within the alveoli of the lungs. Aerosol particles between 0.2 μm and 1.0μm are the size on the lung deposition (Woolman, Coutts, Dendy, and Highenottam, 1989). In an average human at rest, about 0.5L of tidal air is inhaled and exhaled with each breath. During heavy work, the tidal volume may exceed three times that amount. OSHA's modeled breathing rate is 53.8L/min. A leak rate less than or equal to 53.8L/min corresponds to the minimum fit factor of 100. The lower the number of breaths per minute is, the greater the fractional deposition is for the reason that there is more time for settling due to gravity (Hinds, 1999). The OSHA fit test protocol allows leak rates to exceed 53.8L/min during one or more exercise if the overall fit factor is greater than or equal to 100 (Janssen and

Weber, 2005). Breathing flow rates are 30L/min, 60L/min and 85L/min under light, moderate, and heavy workloads, respectively (Huang, Willeke, Qian, Grinshpun, and Ulevicius, 1998). NIOSH regulation requires a flow rate of 85L/min for the certification test of a respirator because high flow rate (85L/min) will decrease filtration efficiency against smaller particles.

A disposable half-mask respirator contains filter media of about 170 cm^2. For a respirator with an effective filtration area of 120cm^2, the average filtration velocities are 4cm/sec, 8cm/sec and 12 cm/sec for light, moderate and heavy workloads, respectively. At lower filter velocities, the penetration values are lower because the submicrometer particles have more time to be removed by the electrically charged fibers. T herefore, filter media are more efficient in removing aerosol particles at flow rates below the certification flow rate of 85L/min which corresponds to light or moderate workloads. No study has evaluated the difference between performance of the respirator in light and heavy workloads in clinical settings.

3.7 Airflow resistance of respirator

Given a leak with fixed dimensions, for the highest flow rate, the amount of aerosol penetration through the leak relative to the aerosol penetration through the filter material is the lowest (Chen and Willeke, 1992). Flow through both leak and filter material are laminar at a low pressure differential. At high pressure differential the flow through the filter material is still laminar but the flow through the leak hole is in transition between laminar and turbulent flow.

Outer pressure of the respirator is greater than half of the inner pressure of the respirator that is low pressure drop while high pressure drop depends on inner pressure of the respirator. Pressure drop increases in breathing resistance level i.e. inhalation and exhalation of the wearer (Shaffer and Rengasamy, 2009). A high pressure drop (inner pressure less air molecular or increase temperature, particles move faster and collide with the side more often) air at a given flow rate pulls in more aerosols through a leak of a given size. Aerosol penetration increases as leak size increases. When pressure drop which is due to the structure of a filter creates a resistance to the air flowing through it, the pressure drop is directly proportional to the flow rate (Hinds, 1999), and it decreases with

increasing leak size, as flow through the leak channel offers less flow resistance. A large leak allows more aerosol to pass than does a small leak that induces a low pressure drop. Airflow rates of 1-2L/min have been used in most workplace sampling to avoid significant pressure changes inside respirator face-pieces (Johnston, Myers, Colton, Birkner, and Campbell, 1992). In actual work situations, pressure changes are related to workload performed by the wearer. Respirator studies mostly use constant flow rates ranging from 20 to 85L/min to characterize filter penetration based on the airflow rates at normal and heavy working conditions (Rengasamy, Zhuang, and BerryAnn, 2004).

No published study has investigated the relationship between clinical workload performed by the wearer and the performance of the respirator. Low pressure drop is similar to light workload (low breathing rate). The percentage of aerosol penetration at low flow rates is higher than at high flow rates because the fraction of leak flow decreases with increasing sampling flow.

A respirator may have excellent filter media but particles will go around the sides of the face-piece unless there is an adequate facial seal. Air will pass through facial leaks because resistance is lower. Thus, a respirator with a higher filtration efficiency rating that leaks may offer less protection than a properly fitted respirator with a lower filtration efficiency rating. A respirator with proper fit is more crucial than its filtration efficiency rate.

3.8 Summary

A respirator protects the wearer when it fits and has no face-seal leakage. Particle size affects the measurement of respirator fit in the fit test. As a result, it is necessary to measure not only the concentration but also the size of air particles inside and outside the respirator during fit test. Different instrument of aerosol spectrometers were discussed. The Portable Aerosol Spectrometer was chosen for this study. Result of testing its sensitivity and reliability are presented in the next chapter.

CHAPTER 4

DEVELOPING A NOVEL FIT TEST METHOD (STAGE ONE)

4.1 Introduction

A novel fit test method was developed based on the conventional fit test setup for measuring the concentration of air particles inside and outside the respirator. In this chapter, the aim of the study and the hypothesis to be tested will be outlined. The method and experimental setup will be described in detail, and the reliability and sensitivity of the method will be demonstrated.

4.2 Aim of the study

This study aimed to develop a novel fit test method called Personal Respirator Sampling Test (PRST) to evaluate N95 respiratory protection in real-time, in a clinical setting. This study was divided into two stages. The aim of Stage 1 was to develop and validate the PRST for evaluating respirator protection of N95 respirator. The aim of Stage 2 was to evaluate the performance of the PRST and the necessity to perform a "fit check", i.e., a self-check performed by

the wearer to determine whether the respirator he/she has put on is leaking. Therefore, the following three objectives guided this study:

1. Evaluate the new (investigator-developed) fit test method, named "Personal Respirator Sampling Test (PRST)" in identifying respiratory protection of N95 respirator.

2. Compare the difference between conventional fit test method and the investigator-developed PRST method in assessing the respiratory protection of N95 respirator.

3. Compare the difference in the respiratory protection of N95 respirators worn by people who have performed a fit check and those who have not performed a fit check in clinical settings.

Objectives could be fulfilled after determining answers to the following research questions.

1. Could PRST method detect respirator face-seal leakage?

2. Was there any difference in the respiratory protection of N95 respirators worn by people who have been trained to perform a fit check and those worn by people who have not been trained to perform a fit check?

3. Was there any difference in the respiratory protection of N95 respirators worn in clinical settings by people who have performed a fit test and those who have not performed a fit test?

4. Was there any difference in respiratory protection of N95 respirator under light and heavy working conditions by investigator-developed fit test method?

4.3 Research hypothesis

1. The investigator-developed fit test method had better predictive power in clinical settings than conventional quantitative fit test instrument in detecting face-seal N95 respirator leakage in laboratory settings.

2. There was a difference in identifying the effectiveness of respiratory protection between those wearers who perform trained fit check and those who performed untrained fit check.

4.4 Procedure

Two Portable Aerosol Spectrometers 1.109 (Grimm Technologies, Inc) were used for continuous measurement of the size distribution of various aerosol particles. Aerosol spectrometers did not required a power supply or sufficient ambient aerosol concentration during machine operation. While the conventional fit test was performed in a laboratory setting using a Portacount fit test instrument (TSI, 8020); it evaluated total aerosol particles inside and outside the respirators without investigating respiratory protection for individual particle size ranges (Myers et al., 1996; Zhuang et al., 1996).

4.4.1 New sampling method

The new sampling method, PRST, was designed as follows:

Two Portable Aerosol Spectrometers were put into a backpack to be worn by the experimental subject. A sampling probe (Adaptor Kit 8025-N95, TSI Inc., St. Paul, MN, USA) punctured the respirator and was secured with a push nut on from the other side of the respirator. One 60 cm-long cylindrical plastic tube was used to connect the exposed end of the sampling probe to the spectrometer for measuring size distribution of aerosol particles in the respirator, and one 60cm-long cylindrical plastic tube was anchored to the outer surface of the respirator near the nose region to measure ambient concentration. N 95 respirators of Models 1860, 1860s, and 1862 of 3M were used in this study. A schematic presentation of the PRST is illustrated in Figure 4.1.

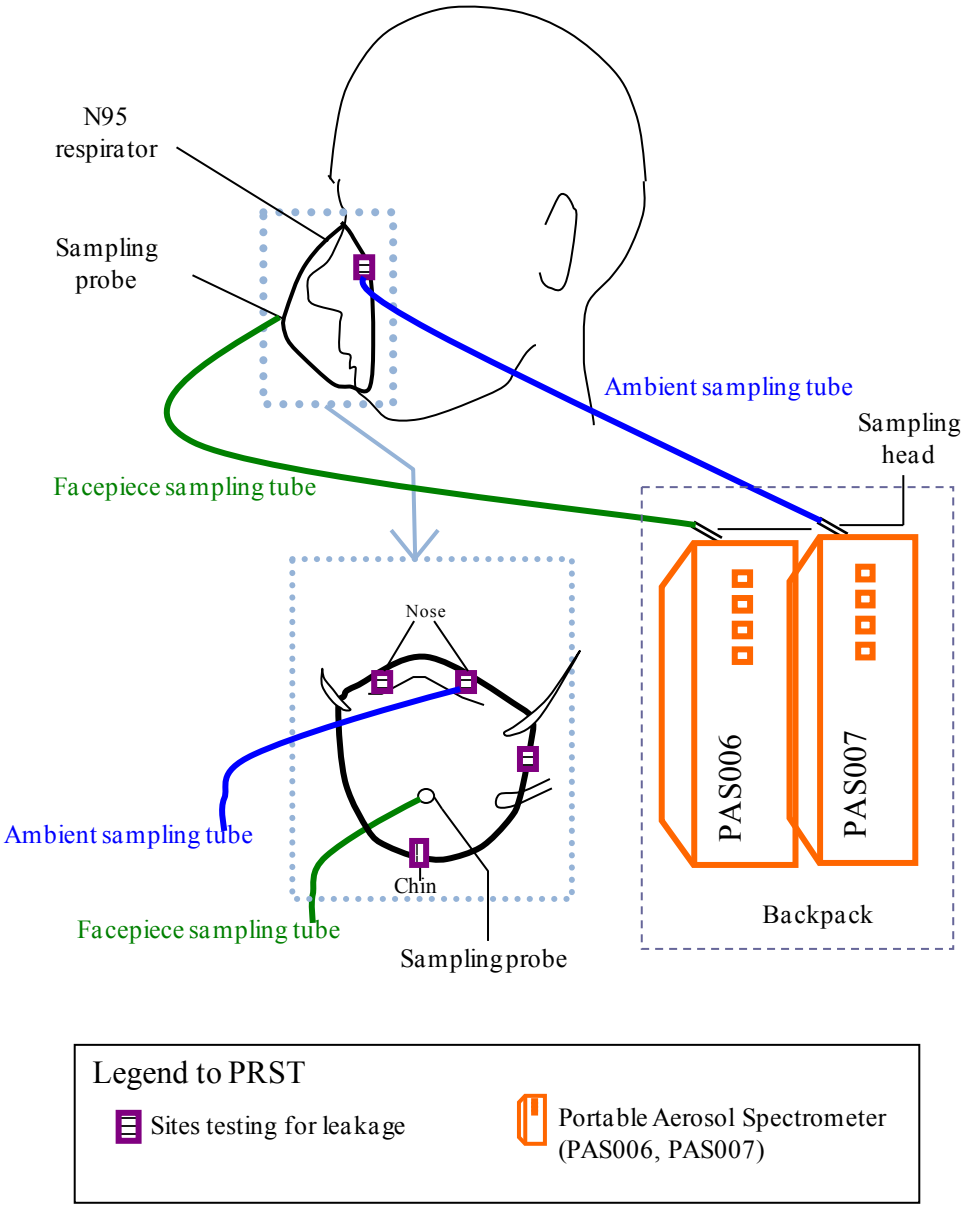

Figure 4.1: Schematic presentation of the PRST

The setup consisted of five components: (i) sampling probe (Adaptor Kit 8025-N95, TSI Inc., St. Paul, MN, USA); (ii) two Portable Aerosol Spectrometers 1.109 (PAS006 and PAS007) (Grimm Technologies, Inc); (iii) one facepiece sampling tube and one ambient sampling tube, each 60 cm long cylindrical plastic tube; (iv) N95 respirators (Model 1860, 1860s, 1862, 3M); and (v) one backpack.

The real-time concentration of air particles was monitored simultaneously by two Portable Aerosol Spectrometers, one (PAS007) measured the ambient air particles outside the respirator while another (PAS006) measured the air particles inside the respirator. The total weight of the PRST fit test setup was about 5kg. P ortable Aerosol Spectrometers provide rapid measurement of particle number concentration by optical size from 0.25-32μm with thirty-one size channels. The fully charged Portable Aerosol Spectrometer can operate continuously for six hours. Results can be stored on a removable data logger card, and the sampled aerosol can be collected on a removable 47mm filter.

This set up is modified from Lee et al. (2005) in several aspects. (a) Ambient sampling line was attached (with adhesive) to leak locations on the respirator rather than to the helmet; (b) ambient air particle sizes of 0.25 to 32µm instead of 0.7 to 10µm were measured. This study tracked a much wider range of particles especially the size of 0.3µm, the most penetration particle size which can evaluate the fitness of the N95 respirator; (c) different leak locations. This study also tracked more sites of potential leakage; namely at both sides of the bridge of nose, at chin and at left cheek (Figure 4.2) instead of three locations (nose, left cheek and chin).

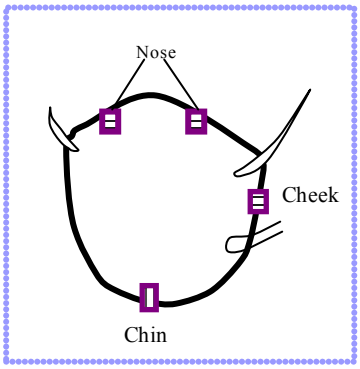

Figure 4.2: Four leaks locations on N95 respirator

Myers, Allender, Iskander and Stanley (1988)'s study showed that 85% of leakage occurred at the nose, 20% leakage at the chin, and 19% at the cheek. Leak sites at the chin area seem to pose a more serious hazard than those at the nose (Holton, Tackett, and Willeke, 1987). Therefore, both sides of the nose, chin and cheek were also selected for monitoring as sites of higher potential of leakage in this study.

Other aspects in this study that are differed from Lee et al. (2005)'s study involved tube attachment and particle size tracking. In the setup the cylindrical plastic tube was directly attached (with adhesive) to leak locations on the respirator rather than to the helmet. It is inconvenient to wear the helmet to perform nursing care in clinical setting because the helmet prevents the head from moving freely particularly when performing bedside nursing procedures. Ambient air particle sizes of 0.25-32μm instead of 0.7 to 10μm were measured. The total aerosol leakage and faceseal leakage were related to particle size (Holton, Tackett and Willeke, 1987). This study tracked a range of particle sizes from 0.25 to 1μm, which is much wider than Lee et al. This range was selected to include

viral and bacterial particles (Hinds, 1999). In particular, 0.3μm size was measured, which is the most penetrating particle size, in the N95 respirator fitness evaluation.

To obtain the facepiece samples from the respirator, a sampling probe was mounted on the respirator body while the ambient sampling line was fixed to the four leaks locations on the surface of the respirator. The aerosol was detected with a sampling probe imbedded in the respirator body in the breathing region between nose and mouth. Plastic tubes were placed along the sealing edges of the respirator approximate 60mm from the facepiece sampling probe, at both sides of the bridge of the nose; at the chin; and at the left cheek to monitor potential facepiece leakage (Figure 4.2).

Two Portable Aerosol Spectrometers were contained in the backpack; this put the spectrometers close to the breathing zone yet out of the way, so that health care workers could perform their routine work without hindrance.

4.5 Equipment preparation

4.5.1 Reliability test

To evaluate the reliability of the Portable Aerosol Spectrometers in measuring number concentration of ambient particle and particle size of ambient particle, an inter-instrument reliability test was performed in the laboratory (Figures 4.3 - 4.5).

The experiment was set up in an enclosed environment with an average air speed of 0.1775m/s, using a low velocity flow analyzer type 54N50, Dantec Type 54R10 with a low velocity transducer, at a temperature of 20.39^{o}C and relative humidity 77.05% (HoBo data logger). The aerosol was measured by two real-time Portable Aerosol Spectrometers, PAS007 and PAS006 (Grimm Technologies, Inc.). The PAS006 and PAS007 provide size range from 0.25-32μm in 31 size channels. A stainless steel tube (4mmOD × 3mmID), provided by the manufacturer was used as the inlet for the PASs. A particle generator Model 8026 (TSI Incorporated, Shoreview, MN, USA) was used to spray a suspension of polydisperse into a box chamber placed at one end of the chamber, and it was then mixed

with a fan. The reservoir jar of particle generator was filled with clean tap water with one salt tablet added. The output adjustment screw was turned completely clockwise to maximize aerosol flow. The flow rate inside the box was maintained at 0.17m/s, and was measured by a flow analyzer (TSI Incorporated, Shoreview, MN, USA).

Particles were measured in the chamber in real-time with two PAS 1.109 instruments. PAS 1.109 were set to report a size distribution every minute. Particle concentration in the chamber was kept constant. The instruments measured the aerosol particles in the chamber three times: at five minutes, fifteen minutes and thirty minutes, in order to estimate measurement precision.

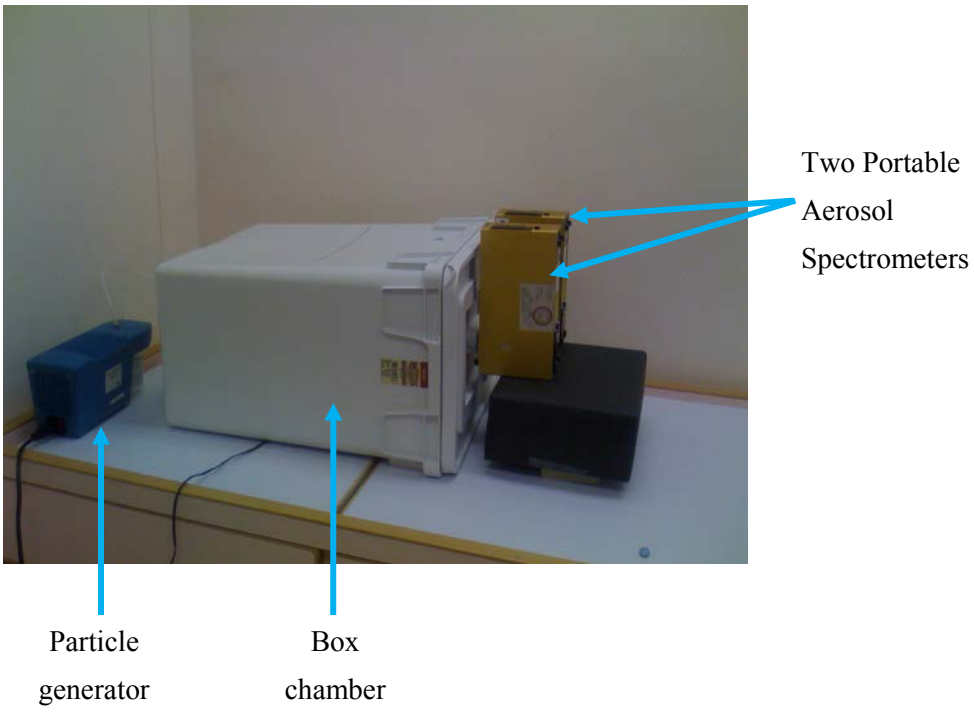

Figure 4.3: Investigator-developed fit test method for inter-instrument reliability test

Figure 4.4: Portable Aerosol Spectrometers

Figure 4.5: Two sampling probes

4.5.1.1 Results

Two sample T-test was used to evaluate and compare the two spectrometers. In the five minute intervals, there was no significant difference in the particle number concentration measured in >0.25 - >0.40µm and >0.58 - >3.00µm size ranges. In the fifteen minute intervals there was no significant difference in the particle number concentration measured in >0.25 - >0.40µm and >0.70 - >3.00µm size ranges. In the thirty minute intervals there was no significant difference in the particle number concentration measured in >0.25 - >0.40µm, >0.70µm and >1.0 - >3.0µm size ranges. Particle size distributions measured by the two instruments decreased from 910000 particles cm^{-3} at 0.28µm to below 1 p article cm^{-3} at 2.5µm. Thus, the particle size distributions measured by the two instruments showed no significant difference in the particle number concentration measured in >0.25 - >0.40µm and >0.7 - >3.0µm size ranges.

Correlation analysis was used to examine the relationships between spectrometers and particle generator, and the relationship between the two spectrometers. Table 4.1 displays the correlation of spectrometer 1, spectrometer 2 and the particle generator.

Table 4.1: Correlations of Spectrometer 1 and particle generator; Spectrometer 2 and particle generator; Spectrometer 1 and Spectrometer 2 (N=156)

	Spectrometer 1	Spectrometer 2	Particle generator
Spectrometer 1	1.00		
Spectrometer 2	0.71**	1.00	
Particle generator	0.72**	0.71**	1.00

**p<0.001.

Results show strong positive correlation between spectrometer 1 and spectrometer 2 ($r = 0.71$, $p = 0.00$) and the p-value was 0.00, <0.05, indicating that the relationship of measuring particle size distribution between spectrometer 1 and spectrometer 2 was statistically significant.

The intraclass correlations (ICC) coefficient indicates reliability of a single trial of multiple instruments. ICC values range from 0.00 to 1.00 with values greater than 0.80 considered highly reliable. The one-way intraclass correlation coefficient between the two spectrometers was 0.83. This showed that the two spectrometers measured ambient particle concentration consistently.

4.5.2 Sensitivity test

Sensitivity refers to the test's ability to obtain a positive test when the target condition is really present. The sensitivity test was used to evaluate the aerosol spectrometers in term of their ability to accurately assess the presence of aerosol particles (Portney & Watkins, 1993).

Aerosol spectrometer 1: The sensitivity was calculated as follows:

$$\frac{\text{True positive}}{\text{True positive} + \text{False negative}} \times 100$$

Where True positive: number of aerosol particles measured by aerosol spectrometer 1

True positive + False negative: total number of aerosol particles in box chamber

Therefore,

Sensitivity of aerosol spectrometer 1 was:

$$= \frac{224.409}{224.409 + 25.591} \times 100\%$$

=89%

Aerosol spectrometer 2: The sensitivity was calculated as follows:

$$\frac{\text{True positive}}{\text{True positive} + \text{False negative}} \times 100$$

Where True positive: number of aerosol particles measured by aerosol spectrometer 2

True positive + False negative: total number of aerosol particles in box chamber

Therefore,

Sensitivity of aerosol spectrometer 2 was:

$$= \frac{190}{190 + 60} \times 100\%$$

=76%

The sensitivity of spectrometers 1 and 2 were 89% and 76%, respectively. The sensitivity of the investigator-developed fit test instruments were more than 60%. T hus these two spectrometers had satisfactory detection of target condition. Results indicated that this new personal sampling system is sensitive to identifying respiratory protection of N95 respirator.

4.6 Summary

The development and validation of the investigator-developed fit test (PRST) setup with two spectrometers was described in this chapter. Results show that there is strong positive correlation between spectrometer 1 and spectrometer 2 ($r = 0.71$, $p = 0.00$) suggesting that spectrometer 1 and spectrometer 2 are highly correlated. The one-way intraclass correlation coefficient between the two spectrometers was 0.83. This figure confirms that the two spectrometers measured ambient particle number concentration consistently. The sensitivity of spectrometers 1 and 2 were high; results for spectrometers 1 and 2 were 89% and 76%, respectively. This evidence indicates that the new personal sampling system was sensitive in measuring the particle size distribution and concentration inside and outside of the respirator as a means to evaluate the protection of N95 respirator. The performance of the investigator-developed fit test method will be discussed in the next chapter.

CHAPTER 5

THE PERFORMANCE OF THE INVESTIGATOR-DEVELOPED FIT TEST METHOD (STAGE TWO)

5.1 Introduction

This chapter discusses the setup of the investigator-developed fit test method, Personal Respirator Sampling Test (PRST) in performing aerosol-generating procedures and routine bedside nursing care. It also describes subject selection and the instruments (including questionnaires and apparatus) used in both the pilot and main study. The data analysis used in both pilot and main study is also described.

5.2 Subjects

Subjects were recruited through convenience sampling. We put up a poster to recruit subjects at the Hong Kong Polytechnic University.

5.2.1 Inclusion and exclusion criteria

Subjects were students 18 years of age or older, and all were Year 1 nursing students. To minimize the confounding effects resulting from prior clinical experience and training in how to wear a N95 respirator, the exclusion criteria were that a subject had learned how to perform fit test and fit check before. Subjects who were pregnant, who had a beard, who had been diagnosed with respiratory problem within the past five years, or who had a back injury were excluded.

The purposes and procedures of the study were explained to the subjects. Written consent was obtained from each subject before the researcher recorded any personal information. T he ethics was approved by the Human Subjects Ethics Sub-committee of the Hong Kong Polytechnic University.

5.2.2 Randomization and blinding

This study was single-blinded. Subjects were blinded in that they did not know any of the other subjects in the groups. Each subject was assigned a subject code. Randomization was implemented by sealing the subject codes inside a paper bag. Drawing was performed by an individual who was not associated with the study. Random assignment means each subject has an equal chance of being assigned to any group, that assignments will reduce systematic bias. During the assignment, investigator concealed the allocation list to safeguard the assignment sequence before and until allocation, thus preventing selection and confounding biases.

5.3 Instrument

5.3.1 Questionnaires

5.3.1.1 Subject information questionnaire

A subject information questionnaire (Appendix C) was used to obtain demographic data of subjects including their age, gender, race, height, weight, smoking habits, drinking habits and medical history. The questionnaire was adopted from Respiratory Protection Standard 29CFR 1910.134 developed by the Occupational Safety and Health Administration (OSHA, 1998) which has been used in previous study (Grinshpun, Haruta, Eninger, Reponen, McKay, and Lee, 2009).

5.3.1.2 Usability questionnaire

A usability satisfaction questionnaire (Appendix E) was used to record each subject's evaluations of six perceptions (heat, breathability, tightness, ease in talking, comfort on ear lobes and overall comfort) when wearing an N95 respirator. E ach

parameter was recorded on a 5-point scale from 1 (unsatisfactory), 3 (average) to 5 (very satisfactory). R ecording perception factors is important because they influence the acceptability and thus can affect how a person wears the respirator. In this study, researcher used a modified version of the usability questionnaire of Li et al. (2006). The questionnaire has been validated (Meyer, Hery, Herrault, Hubert, Francois, Hecht, and Villa, 1997). It shows a multiple correlations between each subjective response and air temperature. The validity and reliability of the usability questionnaire have been confirmed in a number of studies (e.g., Lee et al., 2005; Reponen et al., 2011).

The results showed that the responses recorded are all in relatively good agreement and can be compared without bias. The subjective results in the field are in good accordance with those of a previous laboratory study (Meyer et al., 1997) in which the same questions about breathing discomfort. D ry air temperature is the main factor of subjective response variation. Air temperature has an important influence on almost all the

subjective responses (Meyer et al., 1997). The ratings for humidity, heat, breath resistance and overall discomfort increased gradually with time and increase of workload (Li et al., 2005).

5.3.1.3 Fit check checklist

A Centers for Disease Control and Prevention (CDC) checklist (Appendix D) was used to record how subjects performed the fit check. The checklist record whether subjects have performed fit check properly according to these steps: (1) place hands over outside of the respirator; (2) forcefully exhale several times (the respirator should expand), and (3) forcefully inhale several times (the respirator should collapse). If the respirator does not expand and collapse as noted, it means the faceseal is not tight, and must be adjusted.

5.3.2 Apparatus

Two pieces of equipment used in the study were: the Portacount Plus machine, and Portable Aerosol Spectrometer, as described below:

5.3.2.1 Portacount Plus

The Portacount Plus (Model 8020, TSI, Inc., Shoreview, Minnesota, USA), a fit test instrument, uses ambient air particles as the challenge agent. The Portacount Plus was connected to a personal computer for recording and storing results using Fit Plus for Windows Fit Test Software. The instrument was calibrated in 2010. Portacount Plus has been accepted and recognized by OSHA respiratory protection standard 29 C FR1910.134 for compliance with all fit testing regulations since 1988.

5.3.2.2 Portable Aerosol Spectrometer

The Portable Aerosol Spectrometer 1.109 (Grimm Technologies, Inc) is a unit used for continuous measurement of various aerosol particles size distribution. It is operated without connection. Instead, its results are stored on a removable data logger card, from which the data can be later downloaded to a computer. The sampled aerosol can be collected on a removable 47mm filter. Portable Aerosol Spectrometers provide rapid

measurement of particle number concentration by optical size from 0.25-32μm with thirty-one size channels. The fully charged Portable Aerosol Spectrometer can operate continuously for six hours. Two spectrometers of the same model were used in this study.

Particles of 0.3μm, 1μm, and 4μm in diameter were measured in this study. Particle size range of 0.25 to 1μm penetration size was selected to represent the viral and bacterial particles (Hinds, 1999). 0.3μm representing the most penetrating particle sizes for mechanical filtration; also adopted in the present NIOSH respirator certification protocol. 1μm, the largest particle size tested and a representative size for most airborne bacterial particles. 0.3 -1μm particles are moved by several mechanisms including inertial deposition so the shape of leakage can make a more substantial difference in this particle size range. At the high airflow of 95L/min, about 95% of the 4μm particles enter through the leak site, but only 30% of the 0.8μm particles.

Most submicrometer particles enter through the filter material even in the presence of a sizable leak hole (Chen, Ruushanen, Pilacinski, and Willeke, 1990). Therefore 3 particle sizes were being selected to study.

5.4 Procedure

This study aimed to validate a Personal Respirator Sampling Test (PRST) to determine the level of protection of N95 respiratory in clinical settings. PRST performance was evaluated by the conventional methods, i.e. fit test, fit check or both. The two grand research questions addressed were as follows:

Stage 1. What was the sensitivity of this investigator-developed fit test method in identifying respiratory protection of N95 respirator?

Stage 2. How well did the investigator-developed fit test method in evaluating the fitness of N95 respirator as compared to conventional fit test method?

This study had a 2 x 2 experimental design with two consecutive sessions. The objectives and procedures of this stage are described in subsequent sections of this chapter.

5.5 Personal Respirator Sampling Test (PRST) Setup

Components

The setup consisted of five components: two Portable Aerosol Spectrometers 1.109 (Grimm Technologies, Inc) sampling probe (Adaptor Kit 8025-N95, TSI Inc., St. Paul, MN, USA), 60 cm cylindrical plastic tubes, N95 respirators (3M) and one backpack. Figures 5.1 to 5.3 show the setup of the portable fit test instrument. At the same time, one spectrometer (PAS007) measured the ambient air particles outside the respirator while another (PAS006) measured the air particles inside the respirator. The total weight of the setup was about 5kg. Two Portable Aerosol Spectrometers were located in the backpack which was closer to the breathing zone and convenient for health care workers to perform routine work.

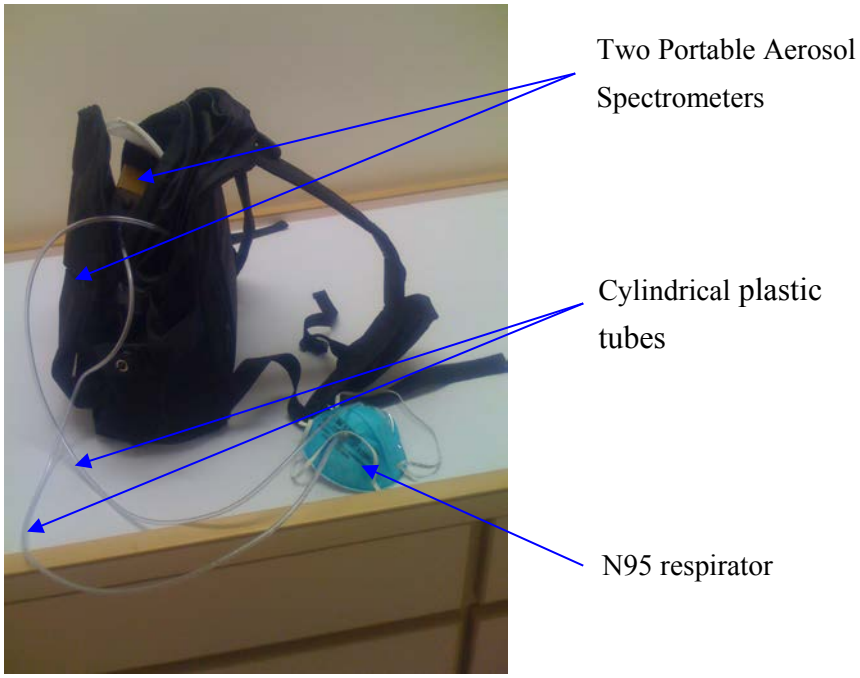

Figure 5.1. Portable fit test instrument

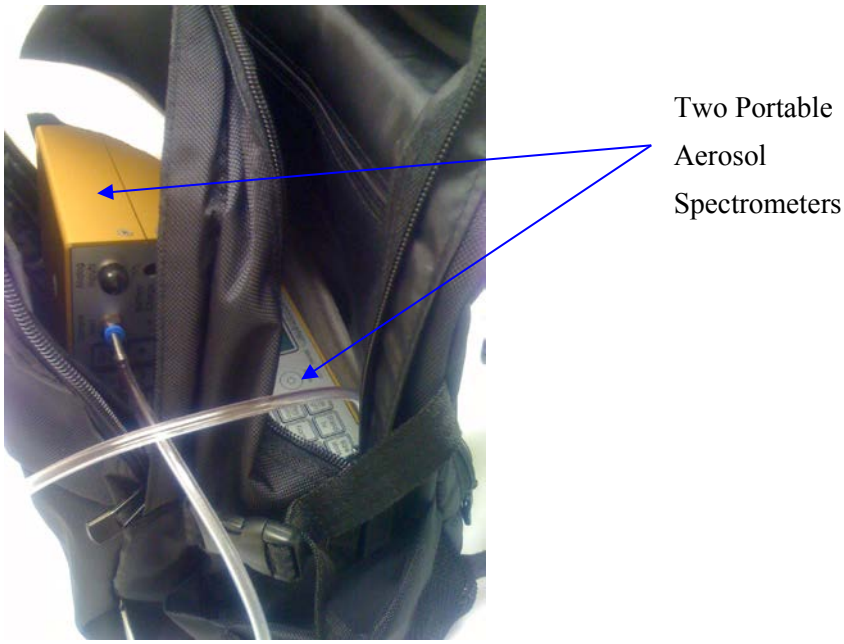

Figure 5.2. Portable Aerosol Spectrometers in the backpack

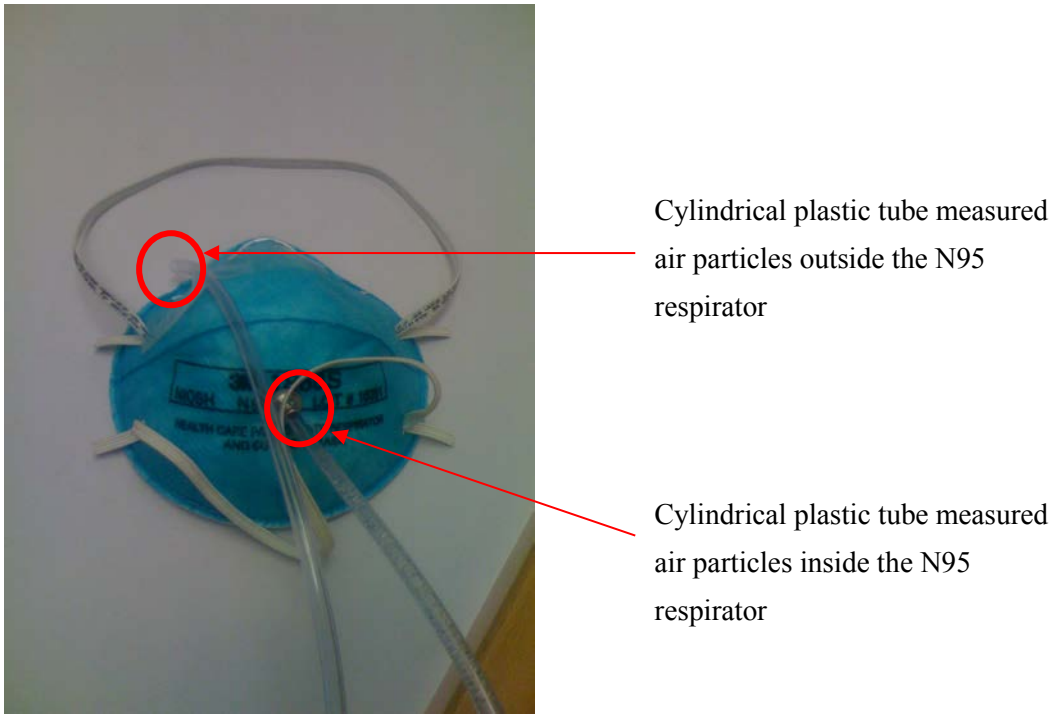

Figure 5.3: N95 respirator with two cylindrical plastic tubes to measure air particles inside and outside the respirator

5.6 Workplace simulation

The workplace test simulated the physical work that workers experience in clinical settings. It was conducted in a nursing laboratory. Subjects wore an N95 respirator in doing one of the aerosol-generating procedures, e.g. napkin changing. The average of the total particle concentration was measured by the Portable Aerosol Spectrometer (GRIMM model 1.109 G ermany) for 31 size channels. Measurement was conducted continuously for 15 minutes with particle concentrations averaged over 1 minute. Subjects were required to close their mouths and breathe through their noses during the experiment to

minimize water vapor generated from their mouth entering the sampling system. This prevented the mixing of particles that had leaked in around the face-seal with those that had been generated by the wearer. The plastic tubing was changed after each subject to prevent water content generated by the subject's exhalation from entering the instrument.

Upon completion, subjects, still wearing their N95 respirators, were asked to breathe normally. They were then asked to record the six perceptions (heat, breathability, tightness, ease in talking, comfort on ear lobe and overall comfort). Room temperature and relative humidity in each fit test session were recorded.

5.7 Measures and data analysis

The completed questionnaires, room temperature and relative humidity of each fit testing sessions were coded with a serial number for further analysis. All the data including the questionnaires and air particle concentration required statistical analysis to explore the relationships between demographic characteristics, particle size distribution and respirator leakage. The Statistical

Package for Social Sciences version 17.0 (SPSS 17.0) was used for the statistical analysis of the particle size distribution. T he demographic distributions of all subjects were examined and all numeric data were presented as means and standard deviations (mean ± SD). One way Analysis of Variance (ANOVA) was used to analyze differences between groups to determine if there were any significant differences in terms of each outcome variable among the four groups. T he confidence level was set at 95% and the significant level for the p value less than 0.05.

5.8 Pilot study

5.8.1 Introduction

The pilot study tested the study method specifically, recruitment, the questionnaire, and methods of determining face-seal leakage. The procedure and outcome parameters in the pilot study mimiced those in the main study. This pilot study also provided a set of data for statistical analysis from which the sample size required for the main study could be estimated.

5.8.2 Objectives

The objectives of the pilot study were as follows:

1. Evaluate the proposed study procedure for face-seal respirator leakage measurement.
2. Provide preliminary statistical results for sample size estimation for the main study.

5.8.3 Procedure

Ethical approval was obtained from the Human Subjects Ethics Sub-Committee, set up under the University Research Committee of The Hong Kong Polytechnic University before recruiting subjects.

5.8.3.1 Subject recruitment

All first-year undergraduate students were invited to participate in the pilot study. S ubjects were recruited by convenience sampling. S ubjects who had never performed a fit test or fit check before were eligible. Subjects with history of smoking or

alcohol were excluded because alcohol and smoking have negative effects on exercise performance and breathing capacity (El-Sayed, Ali N, and E1-Sayed Ali, 2005). Subjects who were pregnant, who had a beard, diagnosed with respiratory problem or back injury were excluded. T he purposes and procedures of the study were explained to the subjects and an information sheet (Appendix A) was given to each. Written consent (Appendix B) was obtained from each subject.

5.8.3.2 Demographic Questionnaire

A questionnaire was used to record the demographic data of subjects including their gender, age, race, height and weight and smoking and drinking habits and past medical history (Appendix C).

5.8.3.3 Experimental Procedure

This study was designed to comprise two consecutive sessions. In Session 1 (15 minutes) subjects were required to perform the quantitative fit test conducted with a Portacount Plus machine. A fit factor (FF) of 100 or above was considered an acceptable passing value. Fit test exercises were performed according to the OSHA fit test protocol specified in 1910.134. T hese exercises include normal breathing, deep breathing, turning head from side-to-side, moving head up-and-down, talking, grimacing, bending over and returning to normal breathing (OSHA, 1998). Each exercise was performed for 2 minutes. P article concentrations inside and outside the respirator were measured and averaged for 1 minute. In Session 2 (15 minutes), subjects performed fit testing by the investigator-developed fit test method (PRST) in performing bedside nursing procedures.

Subjects were divided into four groups as follows: Upon arrival in the waiting area, all subjects were asked to complete the demographic questionnaire. Subjects in groups A and B were asked to enter a room where the researcher demonstrated how to perform a fit check. A supervised return demonstration (with verbal feedback) was carried out. S ubjects were allowed to practice until the researcher was satisfied with their performance. Then group A subjects performed the fit test while group B subjects did not.

Subjects in groups C and D did not receive instructions nor training on the fit check procedure; therefore they were not required to perform the fit check demonstration. G roup C subjects were asked to perform the fit test, while group D subjects did not perform the fit test and fit check. Researcher assessed all their performance in doing their fit check by using a fit check checklist developed by the researcher, the checklist was based on the CDC guideline. Subjects in Group A and C were

told about the recommended type of N95 respirators after performing the fit test.

N95 particulate respirator model 1860S (3M, St Paul, MN) was offered to subjects first. If it did not fit, then the researcher chose either N95 particulate respirator1860 (3M) or model 1862 (3M) (Table 5.1).

Table 5.1: A comparison of different respirator types

Respirator types	Size	Shape	Valved/Unvalved	Minimum total efficiency %	Disposable
1860s	small	Cup-shaped	Unvalved	95	Yes
1860	standard	Cup-shaped	Unvalved	95	Yes
1862	standard	Flat fold	Unvalved	92	Yes

Subjects who passed the conventional fit test (fit factor of 100 or above) could proceed to Session 2. To simulate the physical work that subjects would experience in the clinical settings, Session 2 was conducted in a nursing laboratory at The Hong Kong Polytechnic University. Researcher reminded subjects of groups A and C to wear the recommended N95 respirators as in Session 1.

Subjects were required to wear N95 respirator in doing nonmoving exercise (normal breathing) and moving exercises: one of the aerosol-generating procedures (suction) and one routine bedside care procedure (napkin changing). A total of 4 exercises were performed, and 64 samples were taken. The average of the total particle concentration was measured by the Portable Aerosol Spectrometers (GRIMM model 1.109 Germany) for 31 size channels. Measurements were conducted continuously for 15 minutes with particle concentrations measured averaged over 1 minute. One (PAS007) measured the ambient air particles outside the respirator while another (PAS006) measured the air particles inside the respirator.

Upon completion of each session, all subjects were asked to evaluate six perceptions (heat, breathability, tightness, ease in talking, comfort on e ar lobes and overall comfort) that they experienced. Room temperature and relative humidity in each fit test session were recorded. A ll the procedures were performed in a consistent manner.

The flowchart of the research procedure as shown in Figure 5.4.

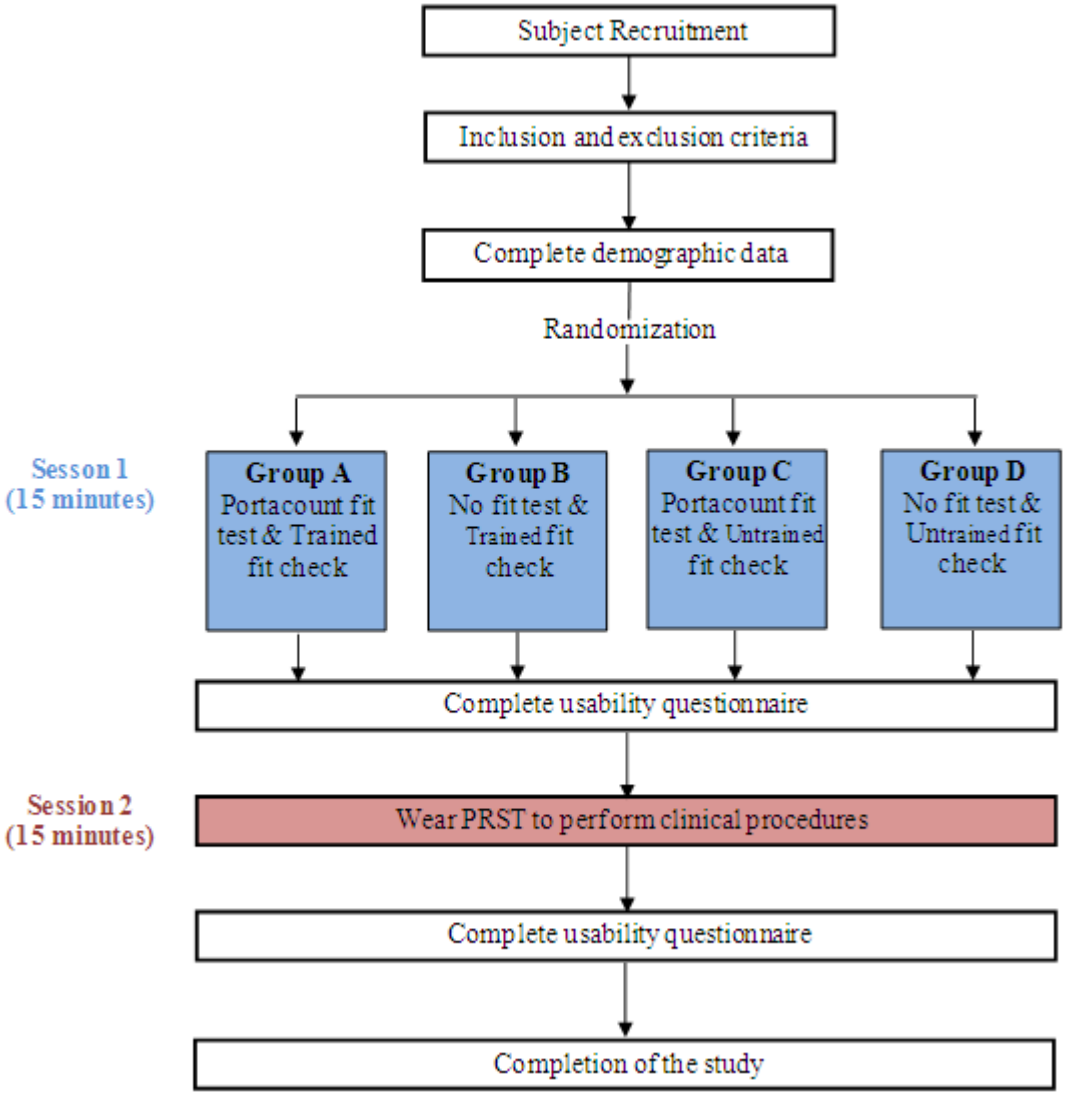

Figure 5.4: Flowchart of the research procedure for main study

5.8.4 Results

5.8.4.1 Statistical analysis

Sixteen first year undergraduate students participated in the pilot study. Three subjects (18.75%) were male and 13 (81.25%) were female; with mean age of 19 ± 0.96 year. Their height ranged between 152 to 171cm and weight ranged between 40 to 68kg. They were all Chinese, and all of them were non-drinkers and non-smokers.

5.8.4.2 Subject perception

Perception of sensation was expressed as the mean value ± standard deviation (SD) (Table 5.2). Subjects were compared using Analysis of variance (ANOVA). A p value less than 0.05 was considered statistically significant. There was no statistical significance between subjects among different groups.

Table 5.2: Perception of sensations of wearing N95 among the four groups (N=16)

Sensations	Group A (mean ± SD) (n=4)	Group B (mean ± SD) (n=4)	Group C (mean ± SD) (n=4)	Group D (mean ± SD) (n=4)	p* (<0.05)
Heat	3.00 ± 0.82	3.50 ± 1.29	3.75 ± 0.50	3.25 ± 0.96	0.71
Breathability	3.50 ± 0.58	4.00 ± 0.00	3.75 ± 0.50	4.00 ± 0.00	0.25
Tightness	3.25 ± 0.96	3.25 ± 0.50	4.00 ± 0.82	4.00 ± 0.82	0.35
Ease in talking	3.50± 1.00	3.50 ± 0.58	4.00 ± 0.00	4.50 ± 0.58	0.14
Comfort on ear lobe	4.00 ± 0.00	4.00 ± 0.00	4.50 ± 0.58	4.50 ± 0.58	0.17
Overall comfort *	3.25 ± 0.50	3.75 ± 0.50	4.00 ± 0.00	3.75 ± 0.50	0.15

*Significant when p<0.05.

Group A was 3.25 (± 0.50); Group B was 3.75 (± 0.50); and Group D was 3.75 (± 0.50). The mean of overall comfort perception was the highest 4.00 (± 0.00) in Group C. T his finding indicated subjects in Group C have higher overall comfort perception scores during fit test.

5.8.4.3 Fit factor

With analysis of variances in the data, there was a s ignificant difference of fit factor of normal breathing before performing nursing procedure among the four groups (p value = 0.03). The results of assessing fit factor while subjects performed nursing procedures are summarized in Table 5.3.

Table 5.3: Fit factor of investigator-developed fit test method in performing nursing procedures with N95 respirator among the four groups (N=16)

Exercise	Group A (mean ± SD) n=4	Group B (mean ± SD) n=4	Group C (mean ± SD) n=4	Group D (mean ± SD) n=4	ANOVA F ratio	p* (<0.05)
Normal breathing	1.32±0.08	1.27±0.11	1.46±0.11	1.25±0.06	3.89	0.03
Performed suction	1.31±0.10	1.24±0.11	1.38±0.13	1.23±0.04	1.74	0.21
Changed napkin	1.28±0.10	1.24±0.13	1.37±0.08	1.24±0.04	1.69	0.22
Normal breathing	1.30±0.10	1.24±0.14	1.40±0.17	1.22±0.08	1.58	0.25

*Significant when p<0.05.

5.8.4.3 Sample size estimation

In the pilot study, four groups (n=4) with equal sample size in each group, representing a total of 16 subjects, were evaluated.

The mean fit protection factors of the four groups were used for the calculation of the effect size. The mean fit protection factors of group A, B, C and D were 16.07, 29.54, 24.13, and 9.84, respectively. Equations below were used to guide the calculation of effect size.

$$f = \frac{Sm}{s}$$

where f represents the effect size

S_m represents the standard deviation of the means

s represents the common standard deviation of the scores (i.e. 8.69)

$$S_m = \sqrt{\frac{\sum_{i=1}^{4} n_i(\bar{X}_i - \bar{X}_G)^2}{N}}$$

where n_i represents the number of subjects in each group

N represents the total of sample size for all groups combined (i.e. 16)

$\bar{X}_i$ represents the individual group mean ($\bar{X}_1 = 16.07$, $\bar{X}_2 = 29.54$, $\bar{X}_3 = 24.13$ and $\bar{X}_4 = 9.84$ were the mean fit protection factors of group A, B, C and D in the pilot study respectively.)

$\bar{X}_G$ represents the grand mean for this total sample

$$= \frac{\bar{x}_1(n_1) + \bar{x}_2(n_2) + \bar{x}_3(n_3) + \bar{x}_4(n_4)}{N}$$

$$= \frac{16.07(4) + 29.54(4) + 24.13(4) + 9.84(4)}{16}$$

$$= 19.90$$

Therefore,

$$S_m = \sqrt{\frac{4(16.07-19.90)^2 + 4(29.54-19.90)^2 + 4(24.13-19.90)^2 + 4(9.84-19.90)^2}{16}}$$

$$= \sqrt{\frac{906.78}{16}}$$

$$= 7.53$$

$$f = \frac{7.53}{8.69}$$

Effect size 0.86

Effect size was 0.86, means of fit factor of Group A, B, C and D were 16.07, 29.54, 24.13, a nd 9.84 r espectively (SD=8.69). This study suggested a choice for sample size estimation, that is, 4 in each group when the effect size was 0.86 with an achieved power of 62% and alpha was 0.05. Sample size for the main study was then obtained from the power table (Table 8.3.14, p.

315, Cohen, 1988). The minimum required sample size was 18 in each group when the effect size was 0.40 and power was 80%.

5.8.5 Discussion

This pilot study was designed to test the study method and determine the significant sample size. In the pilot study, data collection procedures were practiced to ensure good data collection. Based on feedback from participants in the pilot study, procedures were standardized. Items in usability satisfaction questionnaire were clearly defined.

5.8.5.1 Subject perception

The results of this pilot study showed that there was statistical insignificance between subjects in the different groups. The mean of overall comfort perception of Group C was 4.00 (± 0.00) and Group A was 3.25 (± 0.50); Group B was 3.75 (± 0.50); and Group D was 3.75 (± 0.50). The mean of overall comfort perception of Group C was the highest among the four groups.

5.8.5.2 Fit factor

In Table 5.3, the results showed that the fit factors were the lowest in Group D (no fit test and no fit check). The lowest fit factor means low protection provided by the respirator and, conversely, the wearer exposed to higher risk from particle contamination. T he fit factors were the lowest in groups without fit testing; thus, their respiratory protection was less than the other groups with fit testing in terms of fit factor. The result suggested significant difference of fit factor of normal breathing before performing nursing procedure among the four groups (p value 0.03).

The lower fit factors were found more frequently in moving exercises demanding heavy work or lifting (i.e., napkin changing). Results showed that air leakage occurred to a measurable degree during nonmoving exercise (normal breathing) after heavy working condition (napkin changed).

In these cases, the fit factor was low as compared to other exercises. Therefore, it indicated that respirator protection was lower in wearer during or after heavy work conditions.

Power analysis revealed that the power of this study was 62%. T he power of generating significant results was consistent and achieved a higher power for the benefit of a respiratory protection outcome. T herefore, the results from the pilot study indicate that this method could be used for the main study.

The sample size required for the main study was calculated based on the effect size achieved from the pilot study. It was sufficient to fulfill the statistical requirements of this research design. In the main study, the minimum sample size of 18 was determined in each group with the power table based on effect size being 0.40 and power being 80%. A sample size of 21 per group (n=84) was used to achieve a large effect size in the main study to examine the difference among the four groups (Cohen, 1992). The larger the effect size, the greater the effective difference between groups. With a large expected effect size, fewer subjects' pairs will be needed to cross a boundary. Fewer subjects were strong enough to show consistent preferences (Portney and Watkins, 1993). Therefore, a sample size of 21 per group was chosen in this study.

5.8.6 Summary of the pilot study

The pilot study was a rehearsal of the data acquisition procedure and experimental testing procedure for the main study. The results of the pilot study showed that the proposed method was feasible for the main study. T he power of this pilot study was 62%. T he sample size required for the main study was determined to be 21 subjects in each group. The data acquisition and analysis methods were used in the main study based on their satisfactory performance in this pilot study.

5.9 Main study

5.9.1 Introduction

Subjects in main study were divided into four groups as pilot study. The following paragraphs discuss the results of the main study and its methodology. It is divided into three parts. The first part depicts the characteristics of subjects. The second part presents relationship between environmental factors and subjective perception of wearing N95 respirator when doing bedside nursing care procedures; fit factors in performing

different nursing procedures among four groups are compared. In the last part, power analysis of this study is discussed

5.9.2 Results

5.9.2.1 Background of subjects

Eighty-four subjects ranging in age from 18 to 21 years old were recruited for the study. All subjects were asked to complete a questionnaire that captured demographic data and data pertaining to any symptoms of pulmonary illness. Results are described in the following paragraphs.

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5.9.2.2 Demographic distribution

Forty-three subjects (51.20%) were female, ranging in height from 150 to 179cm (SD=5.48) and in weight from 38 to 75 kg (SD=8.16). Forty-one subjects (48.90%) were male, ranging in height from 161 to 188cm (SD=6.06) and in weight from 44.70 to 78kg (SD=7.60). Mean ages (SD) for males and females

were 19.37 (0.99%) and 19.28 (0.80%), respectively. All were ethnically Chinese. Sixty-five subjects (77.40%) were born in Hong Kong, 17 (20.20%) were born in Mainland China and 2 (2.30%) were born in Macau. They were all non-drinkers and non-smokers. Three subjects (3.57%) had a history of asthma, and 2 (2.38%) had a history of pneumonia. Five subjects with respiratory problems were included, 3 subjects had history of asthma when they were young and were treated. Two subjects had had one episode of pneumonia. All of them were monitored during the experiment, and none of them expressed breathing difficulties or exhaustion. None were allergic to latex.

All were first-year undergraduate nursing students. 78 subjects (93%) were general nursing students and 6 (7.10%) were mental health nursing students. They had not attended clinical placement and did not know how to perform the fit test or fit check. In Group A, the average height was 166.57cm, and the average weight was 56.45kg; in Group B, the average height and

weight were 168.95cm and 60.17 kg, respectively. In Group C, the average height was 165.76cm and the average weight was 56.11kg; in Group D the average height and weight were 165.81cm and 54.05kg, respectively.

One-way ANOVA was performed to compare the means of age, height and weight between subjects among the four groups, and no significant difference was found. C hi-square tests were performed for the other demographic variables, and no significant differences were found (Table 5.4).

Table 5.4: Demographic distribution (N=84)

		Group A	Group B	Group C	Group D		
		n=21 n(%)	n=21 n(%)	n-21 n(%)	n=21 n(%)	Chi-square	p* (<0.05)
Sex	Male	12(57.14)	14(66.67)	6(28.57)	9(42.86)	7	0.07
	Female	9(42.86)	7(33.33)	15(71.43)	12(57.14)		
Age		19.33(0.66)[a]	19.57(1.08)[a]	19.1(0.83)[a]	19.29(0.96)[a]	1[b]	0.39
Height		166.57(8.17)	168.95(7.86)[a]	165.76(6.18)[a]	165.81(9.44)[a]	0.738[b]	0.53
Weight		56.45(9.52)[a]	60.17(9.60)[a]	56.11(8.10)[a]	54.05(9.46)[a]	1.61[b]	0.19
Place of birth	Hong Kong	16(76.19)	13(61.90)	19(90.50)	17(81.00)	6.62	0.36
	Mainland, China	5(23.80)	7(33.30)	2(9.50)	3(14.30)		
	Macau	0	1(1.20)	0	1(1.20)		
Programme studied	General	19(90.10)	19(90.10)	21(100)	19(90.10)	8.76	0.46
	Mental	2(9.50)	2(9.50)	0	2(9.50)		

[a] mean (SD)

[b] ANOVA

*Significant when p<0.05.

5.9.2.3 Subjective perception of wearing the N95 respirator

For the study, subjects were asked to put on N95 respirators and perform bedside nursing procedures alternating with periods of normal breathing according to a timed schedule. The sequence was: normal breathing (2 minutes), napkin changing (5 minutes), performing open suction (5 minutes), and normal breathing (2 minutes).

All 84 subjects (100%) rated overall comfort of wearing N95 respirator during bedside nursing care procedures as “quite satisfactory” to “satisfactory”. In Group A, no subject felt hot or had difficulty in breathing during the experiment. In this group, however, four (19%) felt the respirator to be tight, 3 (14.29%) felt discomfort on ear lobes, and 2 (9.52%) rated ease in talking as “unsatisfactory”. In Group B, 1 (4.76%) subject felt hot and 2 (9.52%) subjects had difficulty in breathing. Two (9.52%) subjects felt tightness of the respirator and rated ease in talking and comfort on ear lobes as “unsatisfactory”. In Group

C, 2 (9.52%) subjects felt hot, and 1 (4.76%) subject felt tightness of the respirator. All 21 (100%) subjects in Group C rated breathability, ease in talking and comfort on ear lobes as "satisfactory". In Group D, 5 (23.81%) subjects were not satisfied with the breathability of the respirator; 2 (9.52%) felt hot and reported tightness while 1 (4.76%) subject was not satisfied with the ease of talking.

The mean of overall comfort perception of Group C (Portacount fit test and untrained fit check) was 4.24 ± 0.63,and for Group A(Portacount fit test and trained fit check), 3.95 ± 0.67; while for Group B (No fit test and trained fit check) it was 3.86 ± 0.91, and for Group D (No fit test and untrained fit check) it was 3.71 ± 0.85. Comparing the means of overall comfort perception, Group C felt most comfortable (mean=4.24± 0.63) while Group D felt least comfortable (mean=3.71 ± 0.85).

Analysis of variance (ANOVA) was performed to compare differences in perception among subjects of different groups. Results showed significant differences among groups only in terms of the ease in talking ($p=0.03$). Subjects of Group C (Portacount fit test and untrained fit check) felt most satisfied with ease in talking while members of Group B (no fit test and trained fit check) felt least satisfied with ease in talking during nursing procedures. No significant differences were found among groups of subjects in terms of heat, breathability, tightness comfort on ear lobes or overall comfort (Table 5.5).

Table 5.5: Perception of sensations of wearing N95 among the four groups (N=84)

Sensations	Group A (mean ± SD) (n=21)	Group B (mean ± SD) (n=21)	Group C (mean ± SD) (n=21)	Group D (mean ± SD) (n=21)	p* (<0.05)
Heat	3.81 ± 0.68	3.9 ± 0.89	3.86 ± 1.01	3.76 ± 0.95	0.96
Breathability	3.76 ± 0.77	3.76 ± 1.0	4.05 ± 0.67	3.38 ± 1.12	0.14
Tightness	3.43 ± 1.12	3.95 ± 0.92	4.41 ± 0.85	3.67 ± 0.97	0.09
Ease in talking	4 ± 0.89	3.62 ± 0.12	4.43 ± 0.51	3.9 ± 0.77	0.03
Comfort on ear lobes	4.19 ± 0.81	4.41 ± 1.06	4.48 ± 0.60	4.19 ± 0.68	0.53
Overall comfort	3.95 ± 0.67	3.86 ± 0.91	4.24 ± 0.63	3.71 ± 0.85	0.17

*Significant when p<0.05.

5.9.2.4 Environmental factors

In the room, the ambient temperature ranged from 20°C to 24°C, with a mean of 21.05°C. R elative humidity (RH) ranged from 76% to 96% with a mean of 83.81%.

5.9.2.5. Room temperature and humidity

Correlation was used to measure the relationship between room temperature and personal sensations of subjects after performing the fit test. Results showed the overall comfort was positively related to room temperature with a coefficient of r= 0.23, which is significant at p=0.04 ($p<0.05$). In other words, the warmer the room the more comfortable the subjects felt in the range tested. The relationship between relative humidity and sensation of overall comfort of subjects after performing the fit test was measured. There was no correlation between overall comfort and the room's relative humidity with a coefficient of r= -0.13, which is statistically insignificant p=0.23 ($p>0.05$). There was a positive correlation between temperature and comfort, within the range tested.

MANOVA was used to test the difference of room temperature across subjects' perceptions of heat, breathability and overall comfort. Fo r temperature, Wilks' lambda is 0.87, F(12, 204) = 0.89 p=0.55 which is insignificant at p. >0.05. Temperature was statistically insignificant among perceptions of heat, F-ratio 1.22, p=0.31; breathability F-ratio 0.59, p= 0.67; and overall comfort F-ratio 1.37, p=0.25. The critical value was 1.96 with the alpha level set to p<0.05. The relative humidity Wilks' lambda is 0.62, F(30, 209) = 1.24, p=0.20 which is insignificant at p. >0.05.

The ANOVA tests were performed on t he three dependent variables, namely, sensation of heat, breathability, and overall comfort. Temperature had no significant effect on the sensation of comfort experienced by subjects. There was no statistically significant relationship between relative humidity and sensation of heat, F-ratio 0.88, p=0.55, nor of breathability, F-ratio 0.76, p=0.66 but there was a statistically significant difference between relative humidity and overall comfort, with F-ratio 2.25, p= 0.02,

alpha level at 0.05. There was a probability of 0.02 t hat an F-ratio of this size would occur by chance as 0.05 as criterion for statistical significance, therefore the result can be considered significant ($p<0.05$).

5.9.2.6 Fit factor

The mean value of overall fit factor of Group A (Portacount fit test and trained fit check) was 1.37 (±0.17) compared with 1.37 (±0.13) for Group C (Portacount fit test and untrained fit check). The mean value of respirator overall fit factor of Group B (no fit test and trained fit check) was 1.41 (±0.16) compared with 1.33 (±0.16) for Group D (no fit test and untrained fit check). Analysis of variances in the data showed no s ignificant differences of fit factor measured during performance of nursing procedures among the four groups. The F-ratio of normal breathing 0.61, after performed napkin changed was less than 1, which indicates fit factor was not statistical significant. The fit

factors for all groups while performing nursing procedure are summarized in Table 5.6.

Table 5.6: Fit factor during the performing of nursing procedures for the four groups (N=84)

Exercise	Group A (mean ± SD) (n=21)	Group B (mean ± SD) (n=21)	Group C (mean ± SD) (n=21)	Group D (mean ± SD) (n=21)	ANOVA F ratio	p* (<0.05)
Normal breathing	1.39±0.18	1.43±0.18	1.39±0.15	1.32±0.17	1.80	0.15
Performed suction	1.38±0.17	1.43±0.15	1.38±0.11	1.32±0.16	1.96	0.13
Changed napkin	1.37±0.16	1.39±0.15	1.35±0.11	1.31±0.16	1.29	0.28
Normal breathing	1.35±0.15	1.39±0.17	1.35±0.15	1.36±0.16	0.61	0.61
Overall fit factor	1.37±0.17	1.41±0.16	1.37±0.13	1.33±0.16	--	--

*Significant when $p<0.05$.

Note. Dashes indicate the ANOVA and p value were not estimated.

5.9.2.7 Fit factor under different work conditions

A fit factor less than 10 was found more frequently in subjects doing moving exercise under heavy working conditions (i.e., napkin changing). During the experiment, subjects performed the nursing procedure without adjusting or manipulating the respirator. Measurements during nonmoving exercise (normal breathing) after heavy work (e.g., napkin changing) often showed that air leakage had occurred. The fit factor in these cases was typically less than 10, very low, as compared to other exercises. The higher concentrations of large particles > 4.0μm were found in Group D doing all exercises, and in all groups doing heavy work. These findings correspond to those reported by Grinshpun, Haruta, Eninger, Reponen, McKay and Lee (2009).

5.9.2.8 Detection of face-seal leakage

ANOVA was performed to compare the performance of the respirator in terms of the concentration of different sized particles

inside the respirator. S ignificant differences in concentrations of particles >4.0μm were found in respirators worn by subjects of different groups during suctioning procedure (p=0.04, F-ratio 2.83). There were no significant differences in concentrations of particles of 0.3 and 1μm diameter found during the performance of other bedside nursing procedures. R esults indicate that, during moving exercise, large particles (i.e. >4.0μm, which is penetration size) leaked into the respirators of subjects of all groups.

For group A, the mean value of fit factor of particle sizes of 0.3μm and 1μm was lowest during the most vigorous exercise, and was highest during the nonmoving exercise. Head movement and breathing patterns were different during moving and nonmoving exercises. The mean value of fit factor of particle size of 0.3μm was lowest 24.91 with a standard deviation of 19.87 in normal breathing (a nonmoving exercise) after napkin changing (the most vigorous exercise). The fit factor was

highest (36.23, with a s tandard deviation of 30.89) in normal breathing (nonmoving exercise) before suctioning (the least rigorous exercise) and napkin changing (the most vigorous exercise). Fit factor may explain that the respirator leakage was existed after moving exercise, particularly in heavy working conditions (napkin changing). The mean fit factor of particle size of 1μm was lowest (6.15 ±6.63) during napkin changing, and was highest (13.7±24.51) in normal breathing before vigorous exercises. Particles >4μm diameter were found most frequently when subjects performed suction (the least vigorous exercise). In other words, larger particles tended to lead into the respirator during any kind of moving exercise.

For group B, the mean value of fit factor of 0.3μm and 1μm was lowest during the most vigorous exercise, and was highest during the nonmoving exercise. T he mean fit factor of 0.3μm was lowest (36.95 ±35.22) during napkin changing (the most vigorous exercise), and was highest (52.12 ±53.85) in normal breathing

before moving exercise. Respirators leaked more frequently in moving exercise, especially heavy exercise (e.g., napkin changing). The mean fit factor of 1μm was lowest (7.34 ±6.84) during performing suction (the least vigorous exercise) and highest (10.76 ± 18.16) during normal breathing. Particles of 4μm in diameter entering the respirator were found more frequently during napkin changing than nonmoving exercise.

For group C, the mean value of fit factor of 0.3μm and 1μm was lowest during the most vigorous exercise, and was highest during the nonmoving exercise. T he mean fit factor of 0.3μm was lowest (20.91 ±14.85) during napkin changing (the most vigorous exercise), and was highest (35.8 ±34.36) in normal breathing (a nonmoving exercise). The mean value of fit factor of 1μm was lowest (6.45 ±9.4) during napkin changing (the most vigorous exercise) and was highest (12.99 ±17.8) in normal breathing (a nonmoving exercise). Particles >4.0μm in diameter were found more frequently during napkin changing.

For Group D, the mean value of fit factor of 0.3μm and 1μm was lowest during the most vigorous exercise, and was highest during the nonmoving exercise. T he mean fit factor of 0.3μm was lowest (19.84 ±24.12) during napkin changing (the most vigorous exercise), and was highest (24.02 ±31.31) in normal breathing (a nonmoving exercise). The respirator leaked more frequently in moving exercise especially during heavy working conditions (e.g., napkin changing). The mean fit factor of 1μm was lowest (3.84 ±3.98) during performing napkin changing (the most vigorous exercise) and highest (7.27 ± 11.28) during normal breathing (in nonmoving exercise). Particles of 4μm in diameter were found entering the respirator more frequently during normal breathing (a nonmoving exercise) after napkin changing (a vigorous exercise). The results of the fit factor tests for concentrations of different particle sizes among different groups are summarized in Table 5.7.

Table 5.7: Fit factor of different particle sizes among different groups (N=84)

Exercises performed in different size channel	Group A (mean ± SD) (n=21)	Group B (mean ± SD) (n=21)	Group C (mean ± SD) (n=21)	Group D (mean ± SD) (n=21)	ANOVA F ratio	p* (<0.05)
>0.3 µmNB	36.23±30.89	52.12±53.38	35.80±34.36	23.12±27.59	2.08	0.11
>0.3 µmS	31.95±27.79	44.08±42.56	26.70±22.84	21.68±28.40	1.95	0.13
>0.3 µmN	27.40±23.33	36.95±35.22	20.91±14.85	19.84±24.12	2.08	0.11
>0.3 µmNB1	24.91±19.88	38.25±36.82	22.98±19.03	24.02±31.31	1.54	0.21
>1.0 µmNB	13.70±24.51	10.76±18.16	12.99±17.48	5.28±8.55	0.93	0.43
>1.0 µmS	9.89±18.37	7.34±6.83	7.62±7.41	3.94±6.94	1.09	0.36
>1.0 µmN	6.15±6.63	9.55±9.94	6.45±9.40	3.84±3.98	1.89	0.14
>1.0 µmNB1	7.11±9.53	10.26±10.84	10.63±16.22	7.27±11.28	1.02	0.39

* Significant when $p<0.05$.

NB : normal breathing
S : suction
N : napkin changing
NBI : normal breathing after napkin changing

Table 5.8: Number of particles measured inside N95 respirator (N=84)

	GroupA (n=21)	GroupB (n=21)	GroupC (n=21)	GroupD (n=21)	ANOVA F ratio	p* (<0.05)
>4.0 µmNB	2	3	2	3	0.79	0.50
>4.0 µmS	5	1	1	3	2.83	0.04
>4.0 µmN	3	4	5	4	0.15	0.93
>4.0 µmNB1	5	2	3	5	1.10	0.36

*Significant when p<0.05.

There was a significant difference in numbers of 4.0µm particles inside the N95 respirator measured in groups performing suctioning (the least rigorous exercise). The highest number of particles was measured in Group A and the lowest in Groups B and C (Table 5.8). Groups A and C (with portacount fit test) had fewer >4.0µm particles in the first exercise (normal breathing) than Groups B and D (no fit test). T here was a significant difference in number of 4.0µm particles inside the N95 respirator measured in groups performing suctioning (the least rigorous exercise). The highest number of particles was measured in

Group A and the lowest in Groups B and C. N umber of particles size of 4.0μm inside the N95 respirator measured in Group A performing napkin changing (the most rigorous exercise) decreased but increased for all other groups.

5.9.2.9 Evaluation of investigator-developed fit test method-PRST

The Kruskal-Wallis test was performed to compare the conventional fit test and the investigator-developed fit test method (PRST) as a means of evaluating how well the N95 respirator fits and, thus, how much protection it provides. There was no significant difference in the respiratory protection of N95 respirator between conventional portacount machine ($H(3)=2.87$, $p=0.41$) with a mean rank of 37.67 for Group A, 45.29 for Group B, 41.52 f or Group C and 45.43 f or Group D and the PRST method in terms of fit tested N95 respirator type among the four groups ($H(3)=5.31$, $p=0.15$) with a mean rank of 40.00 for Group A, 48.00 for Group B, 44.00 for Group C and 38.00 for Group D.

These results indicate that the PRST method and conventional Portacount fit test are equally reliable to evaluate respiratory performance of N95 respirator.

5.9.3 Power analysis

The power analysis of this study was conducted based on the statistical analysis results of the particle concentration measurements. The mean fit protection factors of the four groups were used for the calculation of the power. The calculation of the power was based on effect size and the number of subjects per group in the experiment. There were 21 subjects in each group (n=21), with a total number of 84 (N=84). The equations below were used to guide the calculation. With the effect sizes available, the power was determined from the power table (Table 8.3.14, p. 315, Cohen, 1988). Given the effect size was 0.86, sample size and sample size of 21 in each group, and alpha = 0.05 (2 tailed). which made the power was determined at least 99%.

$$f = \frac{Sm}{s}$$

where f represents the effect size

S_m represents the standard deviation of the means

s represents the common standard deviation of the scores (i.e. 8.05)

$$S_m = \sqrt{\frac{\sum_{i=1}^{4} n_i(\bar{X}_i - \bar{X}_G)^2}{N}}$$

where n_i represents the number of subjects in each group

N represents the total of sample size for all groups combined (i.e. 84)

$\bar{X}_i$ represents the individual group mean ($\bar{X}_1$ =32.73, $\bar{X}_2$ =42.96, $\bar{X}_3$ = 29.74 and $\bar{X}_4$ =23.77 were the mean fit protection factors of Group A, B, C and D in the main study respectively.)

$\bar{X}_G$ represents the grand mean for this total sample

$$= \frac{\bar{x}_1(n_1) + \bar{x}_2(n_2) + \bar{x}_3(n_3) + \bar{x}_4(n_4)}{N}$$

$$= \frac{32.73(21) + 42.96(21) + 29.74(21) + 23.77(21)}{84}$$

$$= 32.30$$

Therefore,

$$S_m = \sqrt{\frac{21(32.73-32.30)^2 + 21(42.96-32.30)^2 + 21(29.74-32.30)^2 + 21(23.77-32.30)^2}{84}}$$

$$= \sqrt{\frac{4055.84}{84}}$$

$$=6.95$$

$$f = \frac{6.95}{8.05}$$

Effect size 0.86

In conclusion, this study achieved an effect size of 0.86 which made the power of the study 99%. The results provide encouragement for further discussion of the new fit test method in the next chapter.

CHAPTER 6

DISCUSSION

6.1 Introduction

This chapter discusses the demographic distribution of the subjects, the results of fit factor among the four groups during nursing care procedures and the respirator fitness between trained fit check and untrained fit check measured by the investigator-developed fit test method. Subject perception on r espirator fitness will also be discussed.

6.2 Subject characteristics

No significant differences were found in demographic characteristics among the four groups. All the subjects were undergraduate full-time first year nursing students. None of them had had any training in how to perform a fit test or fit check. This is important because experience may have a significant impact on fit test results (Johnston, Myers, Colton, Birkner, and Campbell, 1992).

6.3 Environmental factors

The room temperature had positive correlation with overall comfort. Within the range tested, as room temperature increased so did the overall comfort of the subjects with statistical significance, which indicates that the observed value is unlikely to be the result of chance. T he room temperature would affect subjects' ratings of perceptions of sensations while wearing N95 respirator during bedside nursing procedures. Subject felt more comfortable at warmer temperatures (20^{o}C to 24^{o}C).

6.4 Subjective perception

All twenty-one (100%) subjects in Group C (conventional fit test and untrained fit check) rated respirators as satisfactory in terms of breathability, temperature, ease in talking and comfort on ear lobes of the respirator during the experiment. In other words, subjects who performed the fit test and were trained in fit check did not feel hot and did not have difficulty in breathing but they did feel that the respirator was tight, and they experienced discomfort on ear lobes.

The results demonstrated significant differences among groups in perception of sensation in terms of talking while wearing fit tested N95 respirators. This at least partially, explains why health care workers wear the N95 respirator only when it is necessary, that is when they perform high-risk aerosol-generating procedures to minimize the wearing discomfort.

6.5 Particles size measurement

In this study, optical particle counters were selected because they are an instrument that measures particle number concentration in 31 di fferent size fractions. T he size ranges were selected to coincide with the size ranges of different types of biological particles targeted in the study. In this way the number of particles in a specific size range could be determined. T he sample line flow rate is 1.2L/min of optical particle counters.

During moving exercise, large particles >4μm leaked most frequently into the respirators of subjects in Groups A, B, C and D which includes the fit-tested and fit check group. Particles of 4μm diameter fall in the size range between droplet nuclei and bacteria-containing dust aggregates and thus have capability of carrying infectious particles (Hatch, 1961). Particles of 4μm in diameter entering the respirator were found more frequently during suctioning after normal breathing in Group A (fit-tested and fit check group) and were decreased during vigorous exercise. T his anomalous situation did not happen in any of the other three groups. In Group D (no fit test and untrained fit check) respirator leakage even happened in non-moving exercise. T herefore, performed trained fit check can affect the degree of respirator leakage especially in non-moving exercise.

Penetration decreased with increasing particle size. U nder constant flow conditions, face-seal leakage increases with increase in particle size. In Chen et al's study (1990) with larger particles, 0.5-5µm, they found increased impaction losses in the faceseal leaks for larger particles. Particle flux through face-seal leakage of the N95 respirator generally exceeded the flux through the filter medium by approximately one order of magnitude. Flux was 20 fold for 1µm particles; in other words, 1 out of every 20 particles found inside the respirator came through the filter, whereas the other 19 came through a face-seal leak.

6.6 Fit factor

The sensitivity of the analytical methods (fit factor) application are generally well defined and presented in the published literature (Myers, Allender, Plummer, and Stobbe, 1986).

Burgess and Mashingaidze's (1999) study (qualitative fit test) showed that the number of subjects passing the fit test was significantly greater for those who had performed a fit check before than for those who had not. In this study (quantitative fit test), subjects of the groups without either a fit test or trained fit check had the lowest fit factor. While these results were not statistically significant but they have clinical importance. Without trained fit check, almost half of the subjects had poor fit test results and needed to repeat the fit test. This demonstrates the value of having wearers perform the fit check before the fit test. Passing a fit test does not guarantee that every time a wearer dons a facepiece an adequate fit will be achieved. The respirator has the potential to provide an adequate fit only when the wearer fits the respirator correctly. This means, each time a person dons the respirator, he/she should check the fit by performing the user fit check as described in the CDC instructions.

In Clayton and Vaughan's (2005) commentary, a successful fit test implies that the chosen respirator has the potential to provide an adequate fit but it will actually do so only if the wearer performs the user fit check each time that he/she dons a respirator. In a CDC study performed in 2005, without fit testing, subjects were liable to have poor face-seals, resulting in excessive leakage and exposure.

6.7 Light and heavy working conditions

It was assumed that normal breathing would be the most appropriate reference exercise. Movement increases leakage; this assumption is in agreement with earlier results presented by Chen et al. (1990); Chen and Willeke (1992), which show that the fraction of particles leaking through the face-seal decreases when the constant flow rate through the respirator increases from 5 to 95 $Lmin^{-1}$. In this study the type of exercise had more pronounced effect than respiratory flow rate on the fraction of particles penetrating through the filter. Respiratory flow rate can be higher under heavy work load that tends to increase faceseal leakage (Grinshpun Haruta, Eninger, Reponen, McKay, and Lee, 2009). The faceseal leakage-to-filter ratio of N95 respirator was more sensitive to body movements and variations in breathing pattern than to facial dimensions. More exercise

produced higher face-seal leakage-to-filter ratios than nonmoving ones. The results of this study are consistent with those of Grinshpun et al.

At the very low airflow of 5L/min, about 95% of all aerosols enter the respirator cavity through a leak site, irrespective of particle size. At the high airflow of 95L/min, about 95% of 4µm particles enter through the leak site (Chen, Ruushanen, Pilacinski, and Willeke, 1990). Results in this study indicate that large particles entered the respirator through leak sites. 4µm particles are not the penetration size; thus, the concentration of 4µm particles inside the respirator indicates numbers of particles entering the respirator through a leak. 4µm particles entered the respirator more frequently in heavy working conditions/moving exercise (i.e. suction and napkin changed). When this happens, respirator protection is compromised. The greater the number of particles inside the respirator, the lower the respirator fitness. Again, this study corroborates Grishpun et al.'s results.

In the study, without trained fit check, subjects had poor fit test results and needed to repeat the fit test. Results show that a successful fit test cannot be performed without trained fit check. The results demonstrate the potentially dangerous consequences of not performing fit check. By performing PRST, each wearer can know when his respirator is likely to be leaking so that he/she can adjust and refit the respirator as appropriate at any time during his or her work. Results show that the conventional fit test and PRST are equally reliable in evaluating respirator fitness; however, the conventional fit test cannot be used on the job. This is crucial, because faceseal leakage is most likely to occur spontaneously and unexpectedly during work. T hus, all N95 respirator wearers should be trained in performing PRST so that they can use it whenever and as often as they need to.

6.8 Implications

Concern about the proper use and function of the N95 respirator has increased since the SARS outbreak of 2003. In 2004, the Hong Kong Government allocated considerable resources to purchase N95 respirators, install expensive Portacount fit test machines and employ staff to perform fit tests for their health care workers. Much money was spent, but possibly not on the most crucial factor in the use of N95 respirators, which is ensuring that they fit properly while the wearer is working. There has been little published research on the proper wearing of N95 respirators and interpreting fit test results.

Health care workers are told to perform a fit check whenever donning an N95 respirator, but there has been limited published research on the consequences of not performing the fit check. WHO 2006 International Health Regulations only recommend that a respirator should be fit tested. In Hospital Authority hospitals of Hong Kong, health care workers are told to perform a fit check whenever donning an N95 respirator but the consequences of not performing the fit check is not mentioned. Therefore no one supervises or monitors the compliance of the fit check.

Even when the overall fit factor is deemed to pass (i.e., is greater than 100), the fit factor of an individual exercise may be failing (i.e., below 100.) In this case, the respirator is leaking. In this case, even though the health care worker is wearing a respirator and has passed the fit test, the leakage means that the health care workers is at risk of exposure to infectious agents during work. If the fit test result indicates that the health care worker has respirator leakage when performing napkin changing, we can recommend that he or she adjusts the N95 respirator before and after performing this procedure in a ward. That is, once a specific person knows the respirator leaks when he/she does a procedure, every time he/she does that same procedure, he/she should check and adjust the respirator. Therefore; through PRST, health care workers can fully understand the strengths and weaknesses of the N95 respirator when they themselves perform any nursing procedure. Through PRST, each health care worker can acquire specific individual knowledge about when and where his/her respirator is likely to leak so that he/she can refit the respirator as appropriate during his/her clinical work.

PRST was developed to provide information about the respiratory protection of the N95 respirator when used in actual nursing procedures and to give a clear picture to health care workers of the importance of the fit check. Good fit test results mean the respirator will protect the wearer if it fits properly. The respirator is likely to fit more comfortably, which in turn means health care workers are more likely to use it, hence complying with occupational health and safety regulations. The correct selection of an N95 respirator, including consideration of the subjective requirements of the wearer, is therefore a crucial issue to be taken into account by occupational health and safety specialists (Petrowski, 2010).

Personal perceptions of the comfort of wearing the N95 respirator can affect health care workers' compliance with rules regarding protective equipment and, possibly even more important, their morale. Considerations of comfort, however, should not outweigh considerations of safety. Therefore, a training programme should be implemented to (1) monitor the compliance of health care worker's in performing a fit check whenever donning respirator; (2) teach PRST as a valuable means to ensure continuous proper functioning of the respirator; and (3) emphasize the importance of performing the fit check together with the

fit test. Through such a programme, wearers can understand proper wearing of N95 respirator and the consequences of faceseal leakage.

6.9 Limitations

This study achieved a satisfactory power of 99% with the sample recruited, which provides sufficient scientific evidence to confirm the results concluded from this study are promising. Subjects were required to wear the spectrometer of 5kg in weight and to close their mouths and breathe through their noses during the experiment to minimize water vapor generated from their mouth entering the sampling system. These experiments under such requirements would not totally reflect the real working situation. This prevented the mixing of particles that have leaked in around the face-seal of the face-piece with those that have been generated by the wearers. All the subjects recruited in this study were between 18 to 20 years of age and had no working experience in a health care setting. The results may not be generalizable to health care workers of other age groups, particularly because different age groups may have different facial contours.

6.10 Future recommendations

One area for future research is the development of an aerosol spectrometer that is lighter, more easily attached to different types of N95 respirator, easy to use, and low-cost. Future effort could focus on developing software to present the fit test results in terms of particle size and degree of fitness of the respirator. The sampling for future studies should recruit health care workers from different rank and different age groups. Future studies should investigate other bedside procedures like chest physiotherapy by physiotherapist or other high risk aerosol generating-procedures.

6.11 Summary

This chapter discussed the findings of the main study. Results presented in this chapter show that the room temperature and relative humidity affect subject's perceptions while wearing the N95 respirator during bedside nursing procedures. Without trained fit check, subjects had poor fit test results and needed to repeat the fit test. It is believed that the investigator-developed fit test method, PRST, could replace the conventional fit test in identifying respiratory protection in the work environment.

This chapter discussed the potential implication of PRST in clinical settings. A larger data set with more N95 respirators and different bedside procedures was recommended for future research.

CHAPTER 7

CONCLUSION

7.1 Introduction

This chapter revisited the research questions, summarized the approaches used by the researcher, and concluded with the interpretation of results, study implications and recommendations for future study. This study employed convenience sampling to develop a real-time novel fit test method, called the Personal Respirator Sampling Test (PRST), to evaluate the respiratory protection of the N95 respirator in clinical settings.

Current methods for respirator fit testing cannot truly estimate the protection of N95 respirator in clinical settings while wearer: health care workers are performing their duties. Active work can cause the respirator to shift, thus, wearers need some way to test and check whether their respirator fits properly, and whether it continues to protect them from air-borne pathogens.

7.2 Revisit research questions

To develop a novel real-time fit test method to evaluate the respiratory protection of N95 respirator in clinical settings, the following research questions were raised:

1. What was the sensitivity of this investigator-developed fit test method in identifying respiratory protection of the N95 respirator?

2. How well did the investigator-developed fit test method in evaluating the fitness of N95 respirator as compared to conventional fit test method?

7.3 Summary of approaches and findings

This research was divided into two stages. Stage 1 involved developing and validating a new fit test method to evaluate respirator protection called the Personal Respirator Sampling Test (PRST). Stage 2 evaluated the performance of the investigator-developed fit test method and the necessity to perform a "fit check", i.e., a self-check performed by the wearer to determine whether the respirator he/she has put on is leaking. It also tested the effect of training.

In the pilot study, 16 subjects were recruited, and divided into four groups. There were two variables: Performing/not performing the Portacount fit test; training/not training fit check. After going through the baseline measurement, all subjects have to wear PRST to perform clinical procedures. The proposed method was found to be feasible for the main study, and power analysis yielded a series of satisfactory outcomes of 99%.

In the main study, 84 subjects were recruited. A ll were first-year undergraduate nursing students who had never performed a fit test or fit check before. They were divided randomly into four groups, as in the pilot study. No significant differences were found among the four groups in terms of age, sex, height and weight, or place of birth.

Environment (relative humidity and room temperature) were important factors because it is known that these factors affect comfort in wearing the N95 respirators, which in turn affects work morale and compliance of wearing Personal Protective Equipment (PPE). Despite limited scientific evidence to support the statement that subjects without trained fit check had the lowest fit

factor, it has clinical importance that these subjects had poor fit test results and needed to repeat the fit test. It demonstrates the clinical importance of wearers performing the trained fit check before putting on a respirator.

7.4 Implication and recommendation

The novel fit test method PRST was developed as a means to evaluate the respiratory protection of N95 respirator during actual nursing procedures and to give respirator wearers a clear sense of the importance of the fit check. Results here indicate PRST can quickly wearers' immediate feedback on how well their respirator is protecting them, at any time in their workday. Therefore, any respiratory protection and training programme should include instruction in proper wearing of N95 respirators; it should reinforce the importance of performing a fit check whenever donning a respirator in clinical work place..

Areas for future research include investigating other bedside procedures like chest physiotherapy by physiotherapist or other high risk aerosol generating-procedures.

7.5 Summary

A novel fit test method (PRST) to evaluate N95 respirator protection was devised and tested in this study. Results indicate that PRST can provide real-time, on-the-job assessment of the effectiveness of respiratory protective devices that people are wearing. If implemented, PRST can enable health care workers to significantly reduce their exposure to infectious airborne pathogens in clinical settings.

Appendices

Appendix A: Information Sheet

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香港理工大學

INFORMATION SHEET

TITLE OF RESEARCH PROJECT

You are invited to participate on a study conducted by Or Pui Lai, Peggy, who is a research student of the School of Nursing in The Hong Kong Polytechnic University.

The aim of this study is to evaluate fit test in identifying N95 respirator with the best respiratory protection for health care workers, compared with a f it check. The study will involve completing a questionnaire, which will take you about 15 minutes. You will then be asked to take part in a fit test measurement. Measurements will be taken by Portable Aerosol Spectrometer (GRIMM model 1.109 Germany) for thirty-one size channels. Two particle counters are located in the backpack; they measure the concentration of ambient particles inside and outside a respirator. It is hoped that this information will help to understand the alternate fit test method and to evaluate fit test practice in order to provide the best respiratory protection for health care workers.

The testing should not result in any undue discomfort, but you will need to wear N95 respirator in doing the bedside routine work. All information related to you will remain confidential, and will be identifiable by codes only known to the researcher.

You have every right to withdrawn from the study before or during the measurement without penalty of any kind. The whole investigation will take about 1 hour.

If you have any complaints about the conduct of this research study, please do not hesitate to contact Mr. Eric Chan, Secretary of the Human Subjects Ethics Sub-Committee of The Hong Kong Polytechnic University in person or in writing (c/o Human Resources Office of the University).

If you would like more information about this study, please contact Or Pui Lai, Peggy on telephone number 9469 or Prof. Joanne Chung on telephone number 2766 6548.

Thank you for your interest in participating in this study.

Prof. Joanne Chung

Principal Investigator/Chief Investigator

Appendix B: Consent Form

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香港理工大學

CONSENT TO PARTICIPATE IN RESEARCH

TITLE OF RESEARCH PROJECT

I _____ hereby consent to participate in the captioned research conducted by Or Pui Lai, Peggy.

I understand that information obtained from this research may be used in future research and published. However, my right to privacy will be retained, i.e. my personal details will not be revealed.

The procedure as set out in the attached information sheet has been fully explained. I understand the benefit and risks involved. My participation in the project is voluntary.

I acknowledge that I have the right to question any part of the procedure and can withdraw at any time without penalty of any kind.

Name of participant: _____

Signature of participant: _____

Name of researcher: _____

Signature of researcher: _____

Date: _____

Appendix C: Subject Information Questionnaire

Subject Information Questionnaire

Code_____

Demographic data:

1. Age_____
2. Sex _____ 3. Place of birth_____ 4. Race_____5. Occupation_____
6. Height_____(cm) 7. Weight_____(kg)
8. Smoking: None_____Ex-smoker_____Smoker_____
9. Drinking: None_____Ex-consumer___Consumer_____

Medical history

Please tick the most appropriate ones:

1. Have your ***ever had*** any of the following pulmonary or lung problems?
   a. Asbestosis: Yes/No
   b. Asthma: Yes/No
   c. Chronic bronchitis: Yes/No
   d. Emphysema: Yes/No
   e. Pneumonia: Yes/No
   f. Tuberculosis: Yes/No
   g. ilicosis: Yes/No
   h. Pneumothorax (collapsed lung): Yes/No
   i. Lung cancer: Yes/No
   j. Broken ribs: Yes/No
   k. Any chest injuries or surgeries: Yes/No
   l. Any other lung problem that you've been told about: Yes/No

2. Do you ***currently*** have any of the following symptoms of pulmonary or lung illness?
   a. Shortness of breath: Yes/No
   b. Shortness of breath when walking fast on level ground or walking up a slight hill or incline: Yes/No
   c. Shortness of breath when walking with other people at an ordinary pace on level ground: Yes/No
   d. Shortness of breath that interferes with your job: Yes/No
   e. Coughing that wakes you early in the morning: Yes/No
   f. Coughing that occurs mostly when you are lying down: Yes/No
   g. Wheezing: Yes/No
   h. Chest pain when you breathe deeply: Yes/No
   i. Any other symptoms that you think may be related to lung problems: Yes/No

3. Have you had allergic to latex: Yes/No
4. Have you ***ever had*** a back injury: Yes/No

Appendix D: Checklist of Proper Fit Check

Checklist of proper fit check

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Source of picture: http://www.cdc.gov/ncidod/dhqp/ppe.html

Please tick the appropriate one

Items	Performed	Not performed	N/A
Place hands over outside of the respirator			
Forcefully exhale several times, the respirator should expand			
Forcefully inhale several times, the respirator should collapse			

Appendix E: Usability Satisfaction Questionnaire

Please circle the appropriate choices:

Usability Satisfaction Questionnaire

	Unsatisfactory		Average		Very Satisfactory
Heat	1	2	3	4	5
Breathability	1	2	3	4	5
Tightness	1	2	3	4	5
Ease in talking	1	2	3	4	5
Comfort on ear lobe	1	2	3	4	5
Overall comfort	1	2	3	4	5

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Usability Satisfaction Questionnaire (after Experiment)

Please circle the appropriate choices:

	Unsatisfactory		Average		Very Satisfactory
Heat	1	2	3	4	5
Breathability	1	2	3	4	5
Tightness	1	2	3	4	5
Ease in talking	1	2	3	4	5
Comfort on ear lobe	1	2	3	4	5
Comfort on backpack	1	2	3	4	5
Overall comfort	1	2	3	4	5

REFERENCES

American National Standards Institute, Inc (1988). *Respirator fit methods* Z88.10-1988. New York, U.S.

Anonymous (2008). *Fit factor vs protection factors.* Retrieved from http://www.tsiinc.fr/documents/ITI-023.pdf

Barclay, L. (2009). Surgical mask may be comparable to N95 respirator in halting flu transmission. *Medscape Medical News.* Retrieved October 8, 2009, from http://www.medscape.com/viewarticle/709810

Burgess, G.L., & Mashingaidze, M.T. (1999) Respirator Leakage in the Pharmaceutical Industry of Northwest England. *The Annals of Occupational Hygiene, 43*(8), 513-517.

Centers for Disease Control and Prevention (1994, October 28). *Guidelines for the Prevention of Transmission of Mycobacterium Tuberculosis in Health Care Facilities.* Retrieved from http://www.cdc.gov/mmwr/preview/mmwrhtml/00035909.htm

Centers for Disease Control and Prevention (1998, December 11). Laboratory performance evaluation of N95 filtering facepiece respirators, 1996. *Morbidity and Mortality Weekly Report (MMWR).* Retrieved from http://www.cdc.gov/mmwr/preview/mmwrhtml/00055954.htm

Centers for Disease Control and Prevention (2007). *Guideline for isolation precautions: Prevention transmission of infectious agents in healthcare settings.* Retrieved from http://www.cdc.gov/hicpac/2007IP/2007ip_part3.html#b

Centers for Disease Control and Prevention (2010, July 15). *Interim guideline on infection control measures for 2009 H1N1 influenza in health care settings, including protection of healthcare personnel.* Retrieved from http://www.cdc.gov/h1n1flu/guidelines_infection_control.htm

Centers for Disease Control and Prevention (2010, December 1). *Respirator trusted-source information page.* Retrieved from http://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/RespSource.html

Chen, C.C., Ruuskanen, J., Pilacinski, W., & Willeke, K. (1990). Filter and leak penetration characteristics of a d ust and mist filtering facepiece. *American Industrial Hygiene Association Journal, 51*(12): 632-639.

Chen, C.C., & Willeke, K. (1992). Characteristics of face seal leakage in filtering facepieces. *Advances in Industrial & Environmental Hygiene, 53* (9), 533-539.

Clayton, M., & Vaughan, N. (2005). Fit for purpose? The role of fit testing in respiratory protection. *The Annals of Occupational Hygiene, 49* (7): 545-548.

Coffery, C.C., Lawrence, R.B., Campbell, D.L., Zhaung, Z., Calvert, C.A., & Jensen, P.A. (2004). Fitting characteristics of eighteen N95 filtering-facepiece respirators. *Journal of Occupational and Environmental Hygiene, 1*(1), 262 -271.

Coffery, C.C., Lawrence, R., Zhuang, A., Campbell, D.L., Jensen, P.A., & Myers, W.R. (2002). Comparison of five methods for fit-testing N95 filtering-facepiece respirators. *Applied Occupational and Environmental Hygiene, 17*(10), 723-730.

Cohen, J. (1992). A power primer. *Psychological Bullein*, 112, 155-159

Cohen, J. (1988). *Statistical power analysis for the behavioral sciences* (2nd ed.). Hillsdale, N.J.: Lawrence Erlbaum Associates.

Crutchfield, C.D., Murphy, R.W., & Van Ert, M.D. (1993). A comparison of controlled negative and aerosol quantitative respirator fit test systems by using human subjects. *American Industrial Hygiene Association Journal*, *54*(1), 10-15.

Crutchfield, C.D., Park, D.L., Hensel, J.L., Kvesic, M.K., Marty, D., & Flack, M.D. (1995). Determinations of Known Respirator Leakage Using Controlled Negative Pressure and Ambient Aerosol QNFT Systems. *American Industrial Hygiene Association Journal, 56*(1), 16-23.

Crutchfield, C., Fairbank, E., & Greenstein, S. (1999). Effect of test exercises and mask donning on measured respirator fit. *Applied Occupational and Environmental Hygiene, 14*(2), 827-837.

Dosman, J., Senthilselvan, A., Kirychuk, S., Lemay, S., Ernest, M., Wilson, P., & Cormier, Y. (2000). Positive human health effects of wearing a respirator in a Swine Barn. *Chest, 118*(3), 852-860.

El-Sayed, M.S., Ali, N., & El-Sayed Ali, Z. (2005). Interaction between alcohol and exercise. *Sports Medicine, 35*(3), 257-269.

Fennelly, K.P., & Nardell, E.A. (1998). The relative efficacy of respirators and room ventilation in preventing occupational tuberculosis. *Infection Control & Hospital Epidemiology, 19*(10), 754-759.

Graveling, R., Sanchez-Jimenez, A., Lewis, C. & Groat, S. (2011). Protecting respiratory health: what should be the constituents of an effective RPE programme? *The Annals of Occupational Hygiene, 55*(3), 230-8.

Grinshpun, S.A., Haruta, H., Eninger, R.M., Reponen, T., McKay, R.T., & Lee, S.A. (2009). Performance of an N95 filtering facepiece particulate respirator and a surgical mask during human breathing: Two pathways for particle penetration. *Journal of Occupational and Environmental Hygiene, 6*(10), 593-603.

Han, D.H. (2000). Fit factors for quarter masks and facial size categories. *The Annals of Occupational Hygiene, 44*(3), 227-234.

Han, D.H., & Lee, J. (2005). Evaluation of particulate filtering respirators using inward leakage (IL) or Total Inward Leakage (TIL) testing-Korean experience. *The Annals of Occupational Hygiene, 49*(7), 569-574.

Harber, P., Barnhart, S., Boehleckc, B.A., Gerrity, T., McDiarmid, M.A., Nardbell, E., Repsher, L., Brousseau, L., Hodous, T., & Utell, M.L. (1996). Respiratory protection guidelines. *American journal of respiratory and critical care medicine, 154*, 1153-1165.

Hatch, T.F. (1961). Distribution of inhaled particles in respiratory tract. *Bacteriol Rev 25*(3), 237-240.

Hinds, W.C. (1999). *Aerosol technology: Properties, behavior; and measurement of airborne particles* (2nd ed.). New York: John Wiley & Sons, Inc.

Holton, P.M., Tackett, D.L., & Willeke, K. (1987). Particle size-dependent leakage and losses of aerosols in respirators. *American Industrial Hygiene Association Journal, 48*(10), 848-854.

Huang, C., Willeke, K., Qian, Y., Grinshpun, S., & Ulevicius, V. (1998). Method for measuring the spatial variability of aerosol penetration through respirator filters. *American Industrial Hygiene Association Journal, 59*(7), 461-465.

Janssen, L., Luinenburg, M. D., Mullins, H., Danisch, S.G., & Nelson, T.J. (2003). Evaluation of a quantitative fit testing method for N95 filtering facepiece respirators. *American Industrial Hygiene Association Journal, 64*(4), 480-486.

Janssen, L., Luinenbury, M.D., Mullins, H., & Neslon, T. (2002). Comparison of three commercially available fit-test methods. *Industrial Hygiene Association Journal, 63*(6), 762-767.

Janssen, L.L., Nelson, T.J., & Cuta, K.T. (2007). Workplace protection factors for an N95 filtering facepiece respirator. *Journal of Occupational and Environmental Hygiene, 4,* 698–707.

Johnston, A.R., Myers, W.R., Colton, C.E., Birkner, J.S., & Campbell, C.E. (1992). Review of respirator performance testing in the workplace issues and concerns. *Industrial Hygiene Association Journal, 53*(11), 705-712.

Labour Department, Occupational Safety and Health Branch (2004). Doctors' guide to medical examinations for workers engaged in hazardous occupations in industrial undertakings. Retrieved from http://www.labour.gov.hk/eng/public/oh/DoctorsGuide.pdf

Lee, S.A., Grinshpun, S.A., Adhikari, A., Li, W., Mckay, R., Maynard, A., & Reponen, T. (2005). Laboratory and field evaluation of a new personal sampling system for assessing the protection provided by the N95 filtering facepiece respirators against particles. *The Annals of Occupational Hygiene, 49*(3), 245-257.

Li, Y., Li, F., & Zhu, Q. (2005). Numerical simulation of virus diffusion in facemask during breathing cycles. *International Journal of Heat and Mass Transfer 48*(19-20), 4229-4242.

Li, Y., Wong, T., Chung, J., Guo, Y.P., Hu, J.Y., Guan, Y.T., Yao, L., Song, Q.W., & Newton, E. (2006). In vivo protective performance of N95 respirator and surgical facemask. *American Journal of Industrial Medicine, 49,* 1056-1065.

Loeb, M., Dafoe, N., Mahony, J., John, M., Sarabia, A., Glavin, V., Webby, R., Smieja, M., Earn, D.J., Chong, S., Webb, A., & Walter, S.D. (2009). Surgical mask vs N95 respirator for preventing influenza among health care workers: a randomized trial. *The Journal of the American Medical Association, 302*(17), 1865-71.

MacIntyre, C.R., Wang, Q., Cauchemez, S, Seale, H., Dwyer, D.E., Yang, P., Shi, W., Gao, Z., Pang, X., Zhang, Y., Wang, X., Duan, W., Rahman, B., & Ferguson, N. (2011). A cluster randomized clinical trial comparing fit-tested and non-fit-tested N95 respirators to medical masks to prevent respiratory virus infection in health care workers. *Influenza Other Respi Viruses. 5*(3), 143-5.

McMahon, E., Wada, K., & Dufresne, A. (2008). Implementing fit testing for N95 filtering facepiece respirators: Practical information from a large cohort of hospital workers. *American Journal of Infection Control, 36*(4), 298-300.

Meyer, J.P., Hery, M., Herrault, J., Hubert, G., Francois, D., Hecht, G., & Villa, M. (1997). F ield study of subjective assessment of negative pressure half-masks. Influence of the work conditions on c omfort and efficiency. *Applied Ergonomics, 28*(5-6), 331-8.

Myers, W.R., Allender, J.R., Plummer, R., & Stobbe, T. (1986). Parameters that bias the measurement of airborne concentration within a respirator. *Journal of American Hygiene Association, 47*(2), 106-114.

Myers, W.R., Allender, J.R., Iskander, W., & Stanley, C. (1988). Causes of in-facepiece sampling bias - 1. Half-facepiece respirators. *The Annals of Occupational Hygiene, 32*(3), 345-359.

Myers, W.R., Zhang, Z., & Nelson, T. (1996). Field performance measurements of half-facepiece respirators—foundry operations. *American Industrial Hygiene Association Journal*, 57, 166–74.

Occupational Safety and Health Administration (1998). Respirator protection 1910.134. R etrieved from http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=12716

Operation and Service Manual (2008), St. Paul, MN: TSI.

Peters, A.D., Dockery, W., Muller, J.E., Murray, M.D., & Mittleman, M.D. (2001). Increased particulate air pollution and the triggering of myocardial infarction. *Circulation, 103*, 2810-5.

Petrowski, P. (2010). Filtering respiratory protection devices-tools against hazardous particles. *Health and Safety International, 33*, April. Retrieved from http://www.hsimagazine.com/article.php?article_id=423

Portney, L.G., & Watkins, M.P. (1993). *Foundations of Clinical Research: Applications to Practice* (pp.651). New Jersey: Prentice Hall.

Rebmann, T. (2007). Protect yourself, protect your patients: The essentials of PPE. *Nursing made incredibly easy,* Jan/Feb, 30-39.

Rengasamy, A., Zhuang, Z., & BerryAnn, R. (2004). Respiratory protection against bioaerosols: literature review and research needs. *American Journal of Infection Control, 32*(6), 345-54.

Reponen, T., Lee, S.A., Grinshpun, S.A., Johnson, E., & Mckay, R. (2011). Effect of fit testing on the protection offered by N95 filtering facepiece respirators against fine particles in a laboratory setting. *The Annals of Occupational Hygiene, 55*(3), 264-71

Revoir, W.H., & Bien, C.T. (1997). *Respiratory protection handbook.* B oca Raton : CRC Press.

Schlesinger, R.B., Kunzli, N.G., Hidy, M., Gotschi, T., & Jerrett, M. (2006). The health coherence of toxicological and epidemiological inferences. *Inhal Toxicol, 18*(2), 95-125.

Schulz, K.F. (2000). A ssessing allocation concealment and blinding in randomised controlled trials: why bother? *Evidence-Based Medicine, 5,* 36-38.

Shaffer, R.E., & Rengasamy, S. (2009). R espiratory protection against airborne nanoparticles: a r eview. *Journal of Nanoparticle Research, 11*(7), 1661-1672.

Szeinuk, J., Beckett, W.S., Clark, N., & Hailoo, W.L. (2000). Medical evaluation for respirator use. *American Journal of Industrial Medicine, 37*(1):142-57.

Wellenius, G.A., Schwartz, J., & Mittleman, M.A. (2005). Air pollution and hospital admissions for ischemic and hemorrhagic stroke among medicare beneficiaries. *Stroke, 36,* 2549-53.

World Health Organization (WPRO Region, 2004). *Practical guidelines for infection control in healthcare facilities.* Geneva: WHO (SEARO Regional Publication No. 41).

World Health Organization (2006, February 9). *Interim Infection Control Guidelines for Health Care Facilities.* Retrieved from http://www.who.int/csr/disease/avian_influenza/guidelines/infectioncontrol1/en/

World Health Organization (2009, May 21). *Clinical management of human infection with new influenza A (H1N1) virus: initial guidelines.* Retrieved from http://www.infekce.cz/Docasne/DoporWHO0609.pdf

World Health Organization (2009, November). *Clinical management of human infection with pandemic (H1N1) 2009: revised guidelines.* Retrieved from http://www.who.int/csr/resources/publications/swineflu/clinical_management_h1n1.pdf

Woolman, P.S., Coutts, C.T., Mole, D.R., Dendy, P.P., & Higenbottam, T.W. (1989). S ites of deposition of aqueous aerosols: a study of efficiency of delivery systems for lung ventilation imaging in man. *Nuclear Medicine Communications, 10*(3), 171-180.

Zhuang, Z., & Myers, W.R. (1996). Field performance measurements of half-facepiece respirators -paint spraying operations. *American Industrial Hygiene Association Journal, 57,* 50-57.