

**THE EFFECT OF MULTIPLE DONNING ON RESPIRATOR FIT
IN NATIONAL HEALTH LABORATORY SERVICE EMPLOYEES
DURING 2016**

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Master of Public Health (Occupational Hygiene).*

Johannesburg,

DECLARATION

I, Cynthia Dansile Vuma, declare that this research report is my own, unaided work. It is being submitted for the degree of Master of Public Health (Occupational Hygiene) at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other university.

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C.D. Vuma

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ABSTRACT

Introduction

Healthcare providers, laboratories and other industries in South Africa use N95 filtering face-piece respirators to reduce or protect themselves against exposure to airborne diseases such as tuberculosis. This is despite the fact that the use of personal protective equipment such as respirators is the least preferred means of exposure control in the occupational hygiene hierarchy of controls. The National Health Laboratory Service (NHLS) provides diagnostic laboratory services to all national and provincial health departments in South Africa. Thus, NHLS employees are potentially exposed to infectious agents such as *Mycobacterium tuberculosis* and are provided with N95 respirators to protect themselves. NHLS employees in some laboratories tend to take one respirator and use it for the whole shift or multiple shifts. These practices raise some concerns of damage due to multiple respirator donnings that can result in poor fit. A study in the United States of America (USA) recommended that re-using of a respirator should be limited to not more than five times to ensure a continued good seal.

Study aim

The aim of this study was to determine if multiple donnings of the same respirator could influence the face seal resulting in poor fit of respirators worn by the National Institute for Occupational Health (NIOH) employees during 2016.

Study objective

To measure and describe the effect on respirator fit following multiple donning and doffing of the N95 respirator by NIOH employees using the same respirator.

Materials and methods

This was a cross-sectional qualitative experimental study with descriptive components. NHLS employees from one institute, namely the National Institute for Occupational Health (NIOH) were invited to participate in the study. Study participants involved both respirator users exposed to hazardous biological agents and non-respirator users. Non-respirator users refer to non-exposed personnel to hazardous biological agents i.e. administration office, librarian. Data were collected on 25 employees who participated in this study. All participants underwent six consecutive fit tests using the same respirator each time whilst performing dynamic movements.

Quantitative respirator fit testing was conducted using the PortaCount fit testing equipment. A fit factor of ≥ 100 was considered satisfactory following OSHA protocol. STATA version 14 was used to perform data analysis.

Results and discussion

The 25 study participants all passed the fit test on the first donning. The fit test results on average gradually deteriorated after multiple consecutive donnings but the average fit factor remained above the cut off 100. A significant difference in mean fit factor was seen between the first and sixth donning but not between the second and sixth donnings suggesting that the donning method deteriorated after the first donning. The proportion of participants achieving a fit factor below 100 were eight percent for fit test two, 24% for fit test three, 32% for fit test four and five, then decreased to 28% for fit test six; although 13 (52%) achieved an overall fit factor of above 100 for all six consecutive fit tests. Four participants achieved a good overall fit factor of above 200 after six donnings. This experimental study results are in agreement with the findings of a National Institute for Occupational Safety and Health (NIOSH) study, which investigated the impact of multiple consecutive donnings on filtering face-piece respirator fit, and recommended five donnings of one respirator. The NIOSH study also established that the fit of the filtering face-piece respirator gradually decreased after multiple donnings and the best levels of fit were observed for donnings one to five. Some participants (6.25%) of this study showed an increased fit after six donnings.

Respirator fit was demonstrated to vary over the consecutive donnings for most participants suggesting that the method used to don the respirator is very important to achieving a good fit. A third of participants failed a fit test and then passed in a subsequent fit test indicating the mask retained the ability to fit while the donning skill of the participant varied with each donning. The best overall fit factors were observed for donnings one and two (Table 3.5). Occurrences of two or more consecutive fit test scores of less than 100 were observed on eight participants. Persistent fit tests failures were observed on four participants. Head strap and nosepiece breaks were not witnessed in this study.

Conclusion

A satisfactory fit test score was found in the sixth fit test in 72% of the study participants. Variability in the donning technique was demonstrated by the 30% of participants who passed a fit test after failing a previous fit test. The consecutive multiple donnings of respirators carried out in this study demonstrated that while the respirator retains the ability to form a seal, not all respirator users will maintain acceptable levels of respirator fit following multiple donnings and doffings of the same respirator. Users and employers need to be aware of the increasing risk of unsatisfactory fit following multiple donnings and doffing of these devices and invest in regular training and other control measures.

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NOMENCLATURE

CDC:	Centers for Disease Control and Prevention
FFRs:	Filtering Face-piece Respirators
FDA:	Food and Drug Administration
HBA:	Hazardous Biological Agents
IOM:	Institute of Medicine
MHI:	Moist Heat Incubation
MGS:	Microwave-Generated Steam
NHLS:	National Health Laboratory Service
NICD:	National Institute for Communicable Diseases
NIOH:	National Institute for Occupational Health
NIOSH:	National Institute for Occupational Safety and Health
OSHA:	Occupational Safety and Health Administration
PPE:	Personal Protective Equipment
QLFT:	Qualitative Fit Testing
QNFT:	Quantitative Fit Testing
SAVP:	South African Vaccine Producers
USA:	United States of America
UVGI:	Ultraviolet Germicidal Irradiation

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GLOSSARY

Alpha error: the error of failing a respirator that should pass

Beta error: the error of passing a respirator that should fail

Filtering face-piece respirator: a device designed to protect or reduce the wearer's exposure to airborne particles

Multiple donning: putting on the same respirator more than twice

N95: a tight fitting respirator that protects the wearer from small particles by filtering at least 95% of airborne particles

N99: a tight fitting respirator that protects the wearer from small particles by filtering at least 99% of airborne particles

N100: a tight fitting respirator that protects the wearer from small particles by filtering at least 99.9% of airborne particles

Non-respirator users: personnel are not exposed to hazardous biological agents and their occupation not requires the use of a respirator,, i.e. admin, librarian

Respirator users: personnel are expose to hazardous biological agents and their occupation requires the use of a respirator, i.e. scientist, technologist

Respirator donning: putting on the respirator

Respirator doffing: taking off the respirator

Respirator fit testing: observation of whether a respirator properly fits the face of the wearer, done either qualitative or quantitative fit test method

Qualitative fit testing: this method uses the sense of taste or smell to detect leakage into the respirator face-piece

Quantitative fit testing: this method uses a machine to measure the leakage into the respirator face-piece

CHAPTER 1: INTRODUCTION AND LITERATURE REVIEW

1.1 Introduction

1.1.1 Occupational hygiene control measures

Recommended control measures to reduce occupational health hazards in the workplace incorporate primary approaches based on the traditional industrial hygiene hierarchy of controls (1). These include elimination of the health hazard which is regarded as the best control option, followed by substitution, engineering, administrative and the recommended last resort is the use of personal protective equipment (PPE) (1). Despite PPE being the last resort, workers in healthcare settings and various industries are required to wear respiratory protective equipment to protect themselves from hazardous inhalable exposures such as mycobacteria, asbestos and silica (2, 3).

The Centers for Disease Control and Prevention (CDC), recommends that healthcare facilities should use a hierarchy of controls approach to prevent exposure of healthcare workers despite the fact that elimination and substitution are not possible (4). Other controls measures in healthcare setting include training of healthcare workers, educating patients on how to protect others from exposure, isolation of infectious cases in a small room that has a room air cleaner with high efficiency particulate air and the use of Ultraviolet Germicidal Irradiation to kill mycobacteria tuberculosis (5). It is essential for healthcare workers to understand the importance of infection control policies and their role in implementing them (5).

Unfortunately many South African industries use personal protective equipment such as respirators as their first means of control due to the high cost of other controls or while waiting for other controls to be implemented (6). Personal protective equipment is the least effective method of controlling occupational health hazards and should be used only when other methods cannot control hazards sufficiently, or to prevent residual risks. Personal protective equipment can be uncomfortable, may decrease work performance and create new health and safety hazards. For example, respirators can make it harder for a person to breathe and increase the discomfort in humid environments.

1.1.2 The use of respirators in healthcare settings and laboratories

The Centers for Disease Control and Prevention (CDC), including the National Institute for Occupational Safety and Health (NIOSH) (7), the Occupational Safety and Health Administrative (OSHA) (8) and the Food and Drug Administration (FDA) (9), have developed regulations and recommendations on the use of respiratory protection in healthcare settings.

There are a number of types of respirators available, including particulate or air-filtering face-pieces, which filter out airborne particles; air purifying respirators, which filter out chemicals and gases; airline respirators, which use compressed air from a remote source; and self-contained breathing apparatus, which have their own air supply (10). Particulate or air-purifying respirators can be further categorised into two: disposable; and reusable respirators with different models (3). Manufacturers recommend single use only for disposable face-piece respirators (3); but typically they are used until they become soiled or unsuitable for further use due to excessive resistance. Reusable respirators allow for the face-piece to be cleaned and reused but the filter cartridges are discarded and replaced when they become unsuitable for further use (3). Respirators also come in different designs, namely full-face and half-face. Full-face respirators protect the wearers face (mouth, nose and eyes), whereas half-face respirators protects only the mouth and nose of the wearer (10).

Healthcare workers are at risk of exposure to airborne and aerosolized biological hazards such as mycobacteria and pandemic influenza (11). Various types of masks and respirators are used in healthcare facilities, ranging from surgical or medical face masks, to N95, N99 and N100 medical respirators (12). N95, N99 and N100 filters at least 95%, 99% & 99.9% of airborne particles respectively (13). The difference amongst the products arises from their design and intended use (14). Disposable medical face masks also known as surgical masks, are not designed to protect the wearer against airborne hazards, but are designed to prevent the spread of infection from the wearer and do not provide a seal around the face (15); they are typically donned for a specific procedure and disposed off afterwards (16). A medical respirator is a fitted device designed to protect the wearer from respiratory infections. They provide a seal around the face and are categorised by their filtration capacity (15).

Most healthcare settings and laboratories use N95 filtering face-piece respirators (FFRs) to protect staff against exposure to airborne infectious diseases such as tuberculosis (4, 17). N95 respirators are disposable particulate respirators that have a filtration efficiency of at least 95% (10).

Leakage of contaminants through face seals where there is poor respirator fit has long been recognized as a concern and it limits the degree of protection provided by these half-face respirators (18).

Manufacturers of N95 filtering face-piece respirators recommend that the respirators (those that are both approved by the NIOSH as respirators and by the FDA for medical uses) should be discarded after each use (19, 20). Meaning they are regarded as single use only and are to be discarded once doffed. Single use implies when the user don a respirator and discard it after doffing and not that it is used for a single work shift (19).

It is a concern that many respirator users may not be aware that multiple donning of a respirator can result in poor fit. It is the experience of the researcher that the current practice in many industries in South Africa is that one respirator is issued to an individual employee each day or for even longer periods.

1.1.3 Respirator fit testing

Respirators come in different makes, types and sizes, as do faces, so the correct respirator has to be selected and the adequacy of the fit needs to be tested to ensure that the respirator is providing the protection it should. There are two methods for determining respirator fit, meaning the seal of the respirator when worn by an individual, which are: qualitative fit testing (QLFT); and quantitative fit testing (QNFT) (21). The QLFT method uses a hood that completely covers the wearer's head, and a challenging agent, such as saccharin is sprayed outside the respirator but inside the hood; the wearer has to respond if they can taste the agent (21). The limitation of QLFT is that it is a subjective method as it relies on the person to yield pass or fail (21). The benefit hamper is that it is cost effective. QNFT methods are objective and do not rely on the participants response and they provide numerical results. The standard instrument for

conducting QNFT is called a PortaCount and it measures the concentration of ambient particles inside and outside the respirator, and then calculates the overall fit factor as the ratio between the two (21). A fit factor of above 100 is regarded as a pass criterion for a good fit, indicating that the particle concentration inside the respirator is 100 times cleaner than the air outside the respirator (8, 21).

Respirator fit testing plays an essential role in a respiratory protection programme (22), as it ensures that employees know how to don and doff the respirator properly.

It is important in confirming that personnel have an adequately fitting respirator and also useful for training the wearer in proper donning procedures (23). To ensure that the respirator is effective at reducing the risk, it is important for individuals to know how many times donning can occur before discarding or changing the respirator to ensure continued protection.

1.2 Literature review

A recent study on NHLS employees indicated that majority of respirator users were not protected by their currently supplied respirator (24). During data collection, some employees reported being issued with one respirator per shift, which they repeatedly re-don for the entire shift. This raises a concern on the effect of multiple donning and doffing of the same respirator that could stress components such as head straps, strap adjustment and adjustable nose-pieces (25). Little information is available on the effect of multiple donning of the same respirator and storage thereof.

Multiple respirator fit tests have the potential to reduce both the alpha and beta error to less than half of that single respirator fit test (26). The alpha error is the error of failing a respirator that should pass, the beta error is the error of passing a respirator that should fail (26).

Johnson *et al*, 1998, showed that the N95 FFR can be re-used in the context of mycobacterium tuberculosis, as long as it is handled and stored properly, as the bacteria is not transmitted by surface contact but through inhalation (27). Special precautions must be taken when extending the use or re-using disposable respiratory protection to

prevent personal exposure from contact hazards (12). Extended use of a disposable respirator is when the respirator is worn for the whole shift without removing and re-donning, whilst re-using of disposable respirators consists of removing and re-donning the same respirator (12). Due to potential respirator contamination, both of these actions pose a transmission risk to healthcare workers (12).

The Centers for Disease Control and Prevention and Institute of Medicine (IOM) advised that the N95 respirators can be re-used by the same employees as long as it is still in good condition considering straps stretched, nosepiece broken, contamination, handling and safe storage, but for infection control purposes they recommend that the respirator should be discarded after single use (28, 29).

A recent study by Bergman *et al*, 2012, indicated that re-using a respirator increases the risk of self-inoculation as the respirator may begin to lose its effectiveness after multiple donning (25). In this study, they investigated the impact of multiple donning on the six different N95 FFR models using a group of 10 experienced test subjects per model. Subjects performed up to 20 consecutive tests using a modified respirator fit test protocol and their data suggested that five consecutive donning could be performed before fit factor consistently dropped below 100 (25). It was also recommended that re-using of respirators should be limited to not more than five times for a continued good seal (25).

In a similar study by Viscusi *et al*, 2011, six different N95 FFRs models were used for repeatedly fit testing (five consecutive fit tests) using a modified protocol to determine if ultraviolet germicidal irradiation (UVGI), moist heat incubation (MHI) or microwave-generated steam (MGS) decontamination affects the fitting characteristics. Each model had ten knowledgeable participants (30). They found that the N95 FFRs that had been through a cycle of various decontamination processes retained a proper fit over five consecutive donnings (30).

1.2.1 National Health Laboratory Service Employees

The National Health Laboratory Service (NHLS) is a public health entity with laboratories in all nine provinces, employing approximately 7000 employees. The NHLS has specialised institutes, namely: the National Institute for Communicable Diseases (NICD), the National Institute for Occupational Health (NIOH), and the South African Vaccine Producers (SAVP). Their activities comprise diagnostic laboratory services, research, teaching and training, advisory services and production of sera for anti-snake venom, reagents and media (31).

The NIOH is South Africa's major centre for occupational health development, training, service support and research, employing about 120 employees. It consists of six key divisions: Occupational Medicine and Epidemiology; Occupational Hygiene; Pathology; Toxicology and Analytical Services; National Cancer Registry and Cytology (32).

The National Health Laboratory Service employees work with hazardous biological agents and hazardous chemical substances; they are at potential risk of hazardous exposure to these agents. Some employees are laboratory personnel who rely on respiratory protective equipment to protect themselves from exposure to airborne infectious agents such as mycobacterium tuberculosis while some use a respirator as an extra protection. Some employees are provided with one disposable filtering face-piece respirator each day, which is worn throughout their working shift. This means, that when they break for lunch and tea they doff and keep for re-donning the same respirator upon return to the work area. This practice results in the multiple donnings which may reduce the material integrity of a respirator resulting in poor fit (26).

1.3 Justification of the study

The study was motivated by the fact that no other studies were found in the literature on the nature and extent of multiple donning of a respirator in South African healthcare settings. Particularly where the practice of multiple donning is widely practised.

Respirator fit testing was conducted on selected NHLS employees during 2013/2014 (24). A small percentage (22%) achieved a good initial fit on certain types/sizes of

respirators during their initial fit test (24). Currently there are no data available on the effects of the routine multiple donning of respirators used by NHLS employees. The actions of donning and doffing may potentially reduce their protective capabilities. This study aimed to examine how respirator fit is affected over multiple donning and doffing. The information will allow evaluation of current respirator practices by NHLS employees and will provide information for a South African policy.

1.4 Research question

Do N95 filtering face-piece respirators maintain acceptable levels of respirator fit following multiple donning and doffing of the same respirator in healthcare settings?

1.5 Study aim and objective

1.5.1 Study aim

The aim of this study was to determine if multiple donnings of the same respirator could influence the face seal resulting in poor fit of respirators worn by NIOH employees.

1.5.2 Study objectives

- ❖ To measure and describe the effect on quantitative respirator fit of multiple donning and doffing of the same N95 respirator worn by NIOH employees.
- ❖ To compare differences between men and women, different types of respirators and frequency of respirator usage.

The second objective that was written in the protocol “To investigate the effect of wearing a respirator during a normal 8 hour shift” was dropped because only one participant volunteer to perform the fit testing.

CHAPTER 2: MATERIALS AND METHODS

This section will describe the study design and sampling methods along with the data collection methods and analysis

2.1 Study design

The study design was a cross-sectional quantitative experimental study with descriptive components using information sheet and fit test to gather data

2.2 Study population and Setting

Study participants were drawn from staff volunteers at the NIOH at Braamfontein in the Gauteng region, all had been instructed in respirator donning. The study took place inside occupational hygiene laboratory at NIOH.

2.3 Study sampling

A minimum size of 10 study participants was determined for this study, as a similar successful experimental study by Bergman *et al*, which was conducted on a group of 10 subjects per model (25).

Study participants were invited based on previous data on NHLS respirator fit testing done in 2013/2014. Part of study population invited were NIOH staff who passed the previous fit testing.

The participants recruited included five sections within the NIOH, namely: Occupational Hygiene, Epidemiology, Immunology & Microbiology, Pathology and Library. The inclusion criteria were NIOH employees that used a respirator for protection against hazardous biological agents i.e. specimens or hazardous chemical substances; and non-respirator users; who signed consent form to participate and who passed the first fit test.

Some male participants were not clean-shaven during fit testing; however, they were allowed to participate in the study provided they passed the first fit test. The study excluded employees who previously failed fit tests and those with beards.

2.4 Measurement and data collection

The principal investigator, who had training in fit testing and extensive experience in conducting fit testing, conducted data collection. The principal investigator was involved in a previous respirator fit testing study that tested 562 NHLS employees during 2013/2014.

2.4.1 Quantitative respirator fit testing

The TSI PortaCount Model 8038+ was used in the study. This is an ambient aerosol monitor, which allows quantitative fit testing by measuring the differences in aerosol (present in the ambient air) concentrations outside and inside the respirator. A fit factor, which is a ratio of particles, was then computed. A fit factor of 100 and above means that the air inside the respirator is 100 times cleaner than the air outside and this is the minimum required fit factor for N95 disposable respirators to protect the wearer (33).

The study was conducted following the OSHA-Accepted Fit Test Protocol (33, 34); illustrated in Appendix A as a respirator fit test flow diagram. Pre-checks on the PortaCount were conducted daily before fit testing to ensure the validity and reliability of the instrument.

Participants particularly non-respirator users were trained in the correct wearing of a respirator before they were fit tested. Non-respirator users were fit tested with the 3M 1860 N95 disposable respirator, while respirator users were fit tested with their currently supplied N95 disposable respirators; namely: 3M 1860, 3M VFlex and Kimberly Clark.

The respirator was probed first using adaptors to connect with a tube (sample tube) which connects the respirator to the PortaCount machine.

Participant – respirator details such as name, brand, type and size of respirator were entered in the computer before the fit test started.

Before the fit test started, participants donned their respirators, performed a seal check and made necessary adjustments until a good fit was felt. The tester then waited for 3 minutes as an acclimatization period.

The respirator fit testing measurements were conducted while the participants wore their respirators and performed dynamic movements. These movements involved eight exercises, namely: (i) normal breathing – participant stood and breathed normally; (ii) deep breathing – participant took a deep breath at a leisurely pace; (iii) turning head side to side – participant holds their shoulder steady and turns their head slowly from full left to full right and pausing momentarily at each extreme; (iv) turning head up and down – participant slowly lifted their head to look up at the ceiling and then down to look at the floor; (v) talking – participant spoke out loud for the entire exercise, the rainbow passage shown in Appendix B was used for this exercise; (vi) grimace – participant made an exaggerated smile or frown in an effort to intentional break the face seal; (vii) bending over – participant bent at the waist and touched their toes; and the last exercise was (viii) normal breathing. Each exercise last about 60 seconds apart from grimace which was only 15 seconds long.

Those who were not comfortable reading the rainbow passage were requested to say their names or read news on their smart phone repeatedly. The fit test was performed with the person standing as it is required by OSHA-Accepted Fit Test Protocol. A fit factor was measured for each exercise apart from grimace; and at the end of the test an overall fit factor (final result) was calculated using the logarithmic mean of the fit factors from six exercises (grimace excluded). Participants passed the fit test when the overall mean fit factor of the six exercises was ≥ 100 . Grimace exercise was excluded because it is not deemed as an “exercise” like others; it is done intentionally to break the face seal of the respirator to see if the respirator will reset itself afterward.

Each participant was subjected to six consecutive fit tests, with two minutes break in between. In other words, the subject donned the respirator, tested while doing the

exercises, doffed it and rested for two minutes, then donned it again, tested and so on until six tests had been conducted.

The fit test results were calculated as a continuous fit factor, which was then categorised into pass or fail with a cut-off of the minimum fit factor of 100 required to pass.

2.4.2 Demographic variables

An information sheet form was used to collect basic demographic variables such as sex and occupation, and facial hair was noted. The information sheet was written in English, as participants were NIOH employees with post-matric education.

2.4.3 Data management and analysis

Respirator fit test data were exported to an excel spreadsheet from the PortaCount and all other data were entered onto the same excel sheet. Data were exported to STATA version 14 for analysis. Descriptive statistics on respirator fit testing described the following: proportions of employees who passed/failed fit testing; mean fit factor of study participants; and minimum and maximum fit factor achieved.

The inferential statistics investigated the relationship between the number of donning and the proportion of participants passing fit testing. Due to the inclusion criteria of a minimum pass of 100 and a machine cut off of 200 the data were not normally distributed and thus non-parametric statistics were used throughout. Differences between men and women and different types of respirators were compared using Wilcoxon rank sum tests. The proportion of participants passing the fifth and sixth donning were tested to determine if the proportion is significantly different from 95% which is the cut off for the acceptable number of donning to fail. The average decrease in fit factor was calculated for each individual to determine which ones are significantly different from the mean decrease of the group. A graph of decrease in fit factor was plotted over the number of measurements.

2.5 Ethics

Ethics clearance was obtained from the Human Research Ethics Committee (Medical) University of Witwatersrand before the study was conducted, Ethics Clearance Certificate shown in Appendix C.

Permission to conduct the study was acquired from the NHLS management, Permission Letter shown in Appendix D. The NIOH employees were approached to participate in the study and participation in the study was voluntary.

All participants received an information sheet, which gave brief information about the study and a consent form. Participants signed a consent form to participate in the study. Participants were allocated a unique identifying study number when collecting information and conducting fit test measurements.

Results were immediately available to all participants after fit testing and made available to their laboratory managers in the form of a report.

CHAPTER 3: RESULTS

About 29 volunteers were recruited for the study, four of the 29 failed the first fit test of the current study and were excluded. The participant was required to pass the first fit test in order to be subjected to six consecutive fit tests to determine the possibility of continued fit, thus that the four participants who failed the first fit test were not included in the result. The remaining 25 participants underwent six consecutive fit tests using the same respirator each time. No smoking 30 minutes prior to the test was reported.

3.1 Description of the study variables

The sample population came from one selected institute in the National Health Laboratory Service, namely the National Institute for Occupational Health (NIOH) in the Gauteng Province at Braamfontein area. Of the 25 study subjects nine (36%) were men and 16 (64%) women this is similar to the demographics of the institute.

Table 3.1: NIOH sections by number of participants and percentage

Laboratory / Section	n	% of participants
Epidemiology	2	8
Immunology & Microbiology	8	32
Library	4	16
Occupational hygiene	6	24
Pathology	4	16
Safety, Health and Environment	1	4
Total	25	100

Table 3.1 describes the NIOH sections that participants were recruited from. A large percentage of the study participants were from the Immunology and Microbiology section (32%) probably due to the nature of their work which required regular respirator use, followed by Occupational Hygiene (24%).

Table 3.2: Occupations of NIOH study participants

Occupation	n	% of participants
Medical scientist	10	40
Medical technologist	3	12
Medical technician	4	16
Lab manager	1	4
Lab assistant	3	12
Librarian	4	16
Total	25	100

Table 3.2 shows the different occupations of the sample population. NIOH employees who participated generally had a formal education and occupied positions such as laboratory assistant, medical technician, medical technologist, medical scientist and laboratory manager.

The medical scientists, medical technologists, medical technicians and the laboratory assistant used respirators and were mostly involved in specimen preparation and analysis. Medical scientists made up a large percentage of the study participants.

Table 3.3: Frequency of the respirator usage

Respirator use	n	%
Non-respirator users	4	16
Infrequently	8	32
2-3 times per week	4	16
Once a week	3	12
Daily	6	24
Total	25	100

Table 3.3 shows frequency of respirator use by the study population: 24% used respirators on a daily basis, while 16% used respirators two to three times in a week. The “infrequently” category entailed personnel who used respirator once in a month or once in two months.

Of the 10 subjects (those that used respirators daily and 2-3 times a week) in Table 3.3, two subjects change respirator after three donning, four subjects change respirator once a day and the other four change respirator after two days. Meaning they repeatedly don the same respirator more than five times.

Table 3.4: N95 respirator makes & sizes used by the study participants

Respirator make	Sizes	%
Kimberly Clark	2 small & 1 medium	12
3M 1860	15 small & 1 medium	64
3M VFlex	4 small & 2 medium	24
Total	25	100

Table 3.4 describes the respirator manufacturer, style and sizes used by the study population; 88% of the study participants were fit tested with respirators that were manufactured and supplied by 3M; 64% used a respirator style with an oval shape, while 36% used the style of the respirator of a “V” shape. 84% of the study participants used a small size respirator; the remaining 16% used a medium size respirator.

Of the 25 study participants, eight percent of the subjects were smokers. Of the nine men, only three (33%) had facial hair present on the day of the test and they had very short facial hair growth.

Instructions on respirator fit testing were given to all study participants. A large proportion (76%) of the study participants had previous knowledge on respirator donning.

3.2 Description of overall fit testing results

The overall fit test results for all six donning, were analysed further for changes in fit.

Table 3.5: Percentages of pass/fail for fit tests 1-6

	Test 1	Test 2	Test 3	Test 4	Test 5	Test 6
Pass	25	23	19	17	17	18
Fail	0	2 (8%)	6 (24%)	8 (32%)	8 (32%)	7 (28%)
Total	25	25	25	25	25	25

Table 3.5 shows percentages of pass/fail fit tests for the six testing sessions, showing an overall reduction in the percentages of who passed test. The percentage of passed tests deteriorated until after the 4th donning but then stabilised, as indicated in the table.

Table 3.6: Frequency of participants with ≥ 2 consecutive fit factors of ≤ 100 by respirator type

Respirator type	Participants
Kimberly Clark	1/3
3M 1860	5/16
3M VFlex	2/6
Total	8/25

Table 3.6 summarizes the occurrence of two or more consecutive fit tests with a fit factor less than 100 (i.e. failed test). Of the 25 study participants, eight experienced consecutive fit factors ≤ 100 . Three of this eight experienced two consecutive fit factors ≤ 100 ; two experienced three consecutive fit factors ≤ 100 , two experienced four consecutive fit factors ≤ 100 and one experienced five consecutive fit factors ≤ 100 .

During the study period, no test subjects experienced a head strap or nosepiece break.

Table 3.7: Description of overall fit factor of the study population

	Total	Respirator size		Sex	
	25	Small 21	Medium 4	Men 9	Women 16
Median (IQR) fit score 1st donning	195 (139-200)	174 (126-200)	200 (173-200)	145 (126-200)	197 (153-200)
Median (IQR) fit factor 6th donning	150 (72-92)	150 (61-188)	150 (86-200)	133 (72-188)	158 (78-197)
Median change over all six tests	21 (0-87)	21 (0-87)	38 (0-86)	13 (0- 87)	23 (0-92)
Pvalue for 1st, and 6th, donning, small and medium, and men and women	0.0271	0.8819		0.7750	

Table 3.7 describes the overall fit factor for the initial and last measurements along with change in fit factor.

The Wilcoxon rank sum test showed a significant difference ($p=0.0271$) between the first and sixth measurements but, there was no significant difference ($p=0.3584$) between the second and sixth measurements, signifying that the first donning of a respirator does not significantly alter the fit factor. Change in overall respirator fit from measurement 1st to 6th was not significantly different in men and compared to women as was the case for respirator size. Although no significant differences were seen, small size respirators tended towards a lower fit initially, while men appeared to have a lower fit factor initially. In summary sex and respirator size played no role in change in fit factor over time.

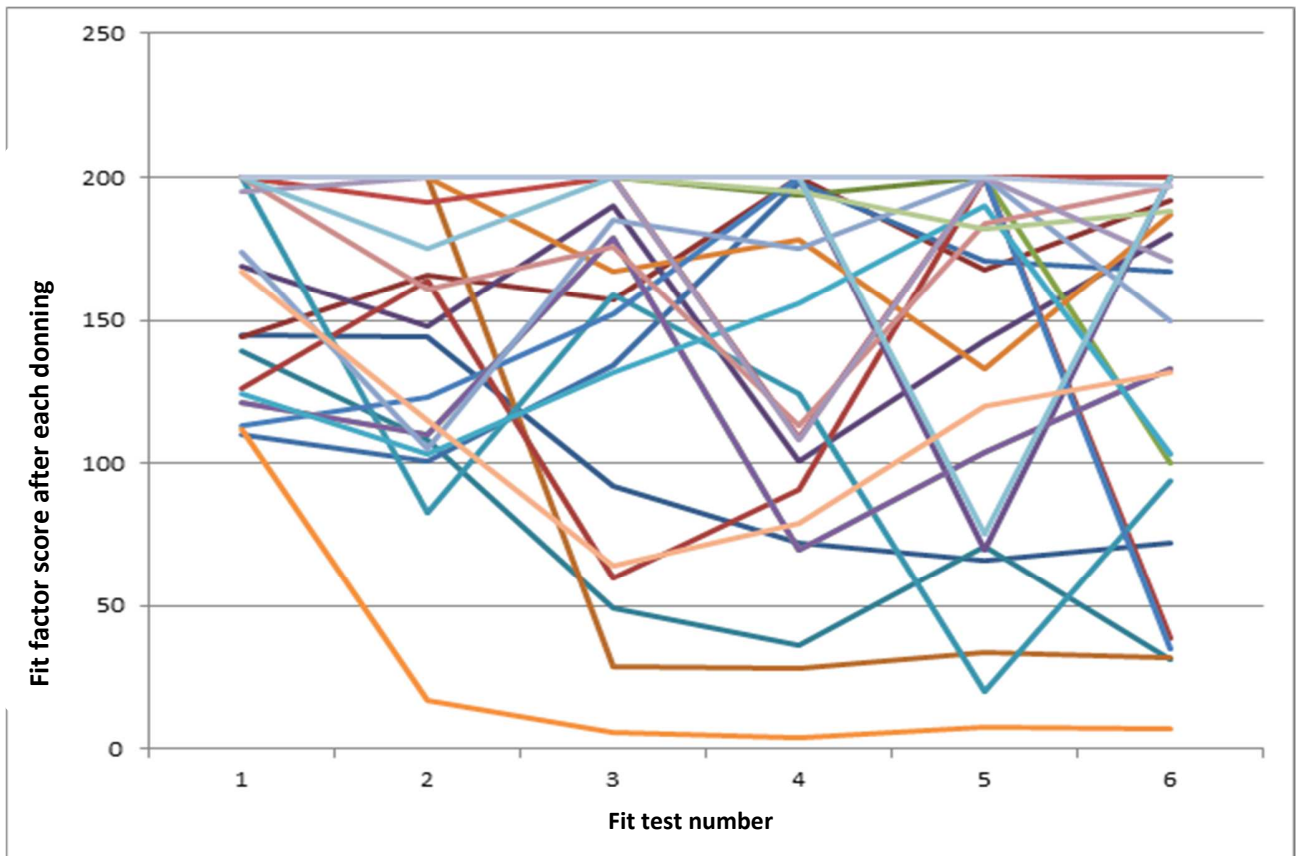


Figure 3.1: Trend in overall fit factor for all study participants (25) across six fit tests

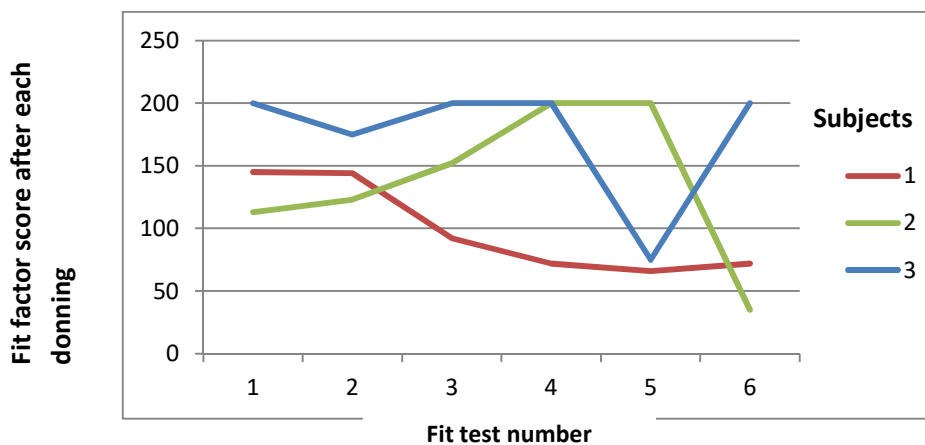


Figure 3.2: Trend in overall fit factor for Kimberley Clark N95 for three study participants

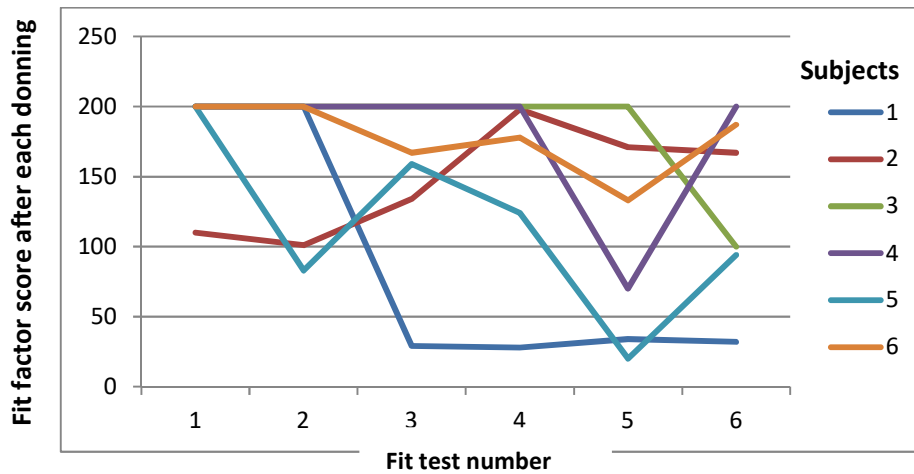


Figure 3.3: Trend in overall fit factor for 3M VFlex N95 for six study participants

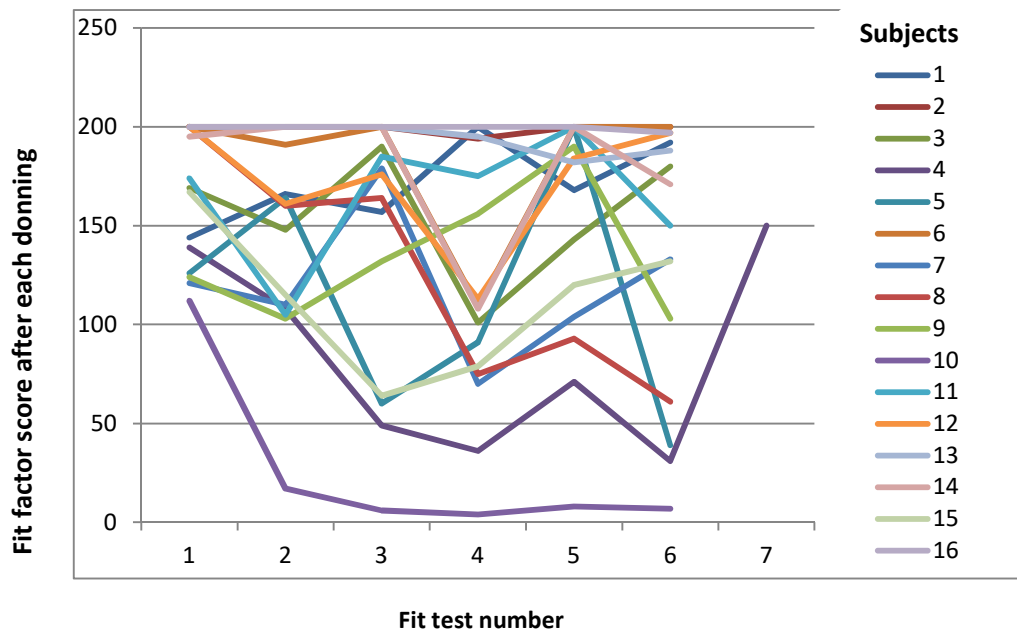


Figure 3.4: Trend in overall fit factor for 3M 1860 N95 for 16 study participants

The above figures (fig. 3.1 – 3.4), show each participants fit factor at each of the six fit testing and then by respirator type. Of the 25 study participants, only 13 achieved the overall fit factor of above 100 throughout the fit testing. The study participants were more likely to fail the fourth and fifth fit testing but a clear pattern of declining fit scores after each donning was not apparent.

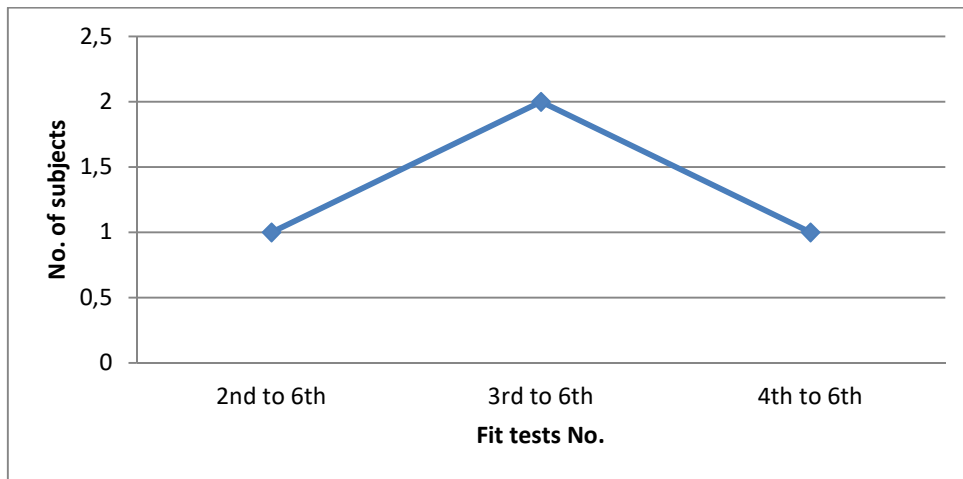


Figure 3.5: Participants with persistent fit test failures

Figure 3.5 shows four participants with persistent fit test failures following the first failure. One subject experience 2nd to 6th fit tests failures, two subjects experience 3rd to 6th fit test failures and one subject experience 4th to 6th fit tests failures.

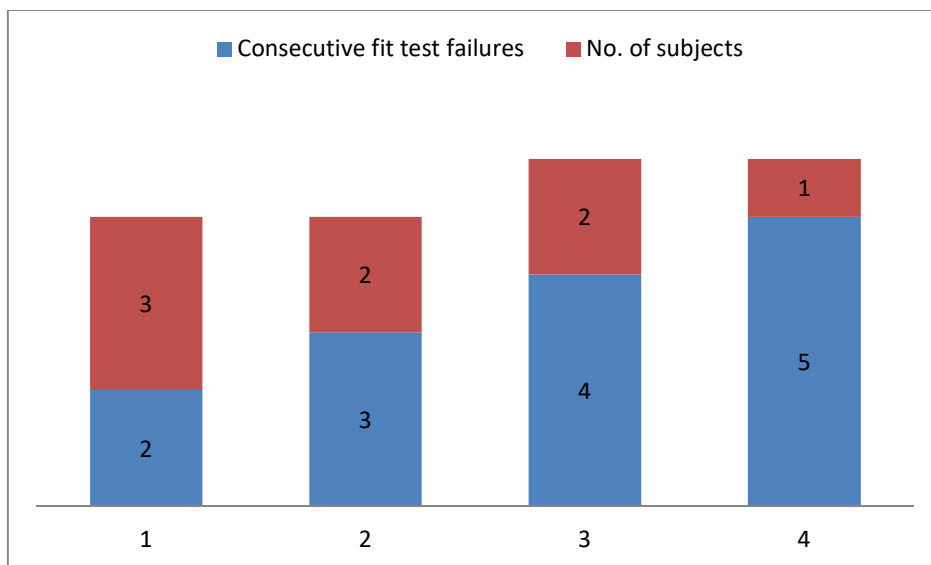


Figure 3.6: Participants with consecutive fit test failures

Figure 3.6 shows eight participants with consecutive fit factor less than 100. One subject failed five donning (2nd to 6th); two subjects failed four donning (3rd to 6th); two subjects failed three different donning (3rd to 5th and 4th to 6th); and three subjects failed two donning (two subjects failed donning 3rd & 4th while one subject failed donning 5th & 6th).

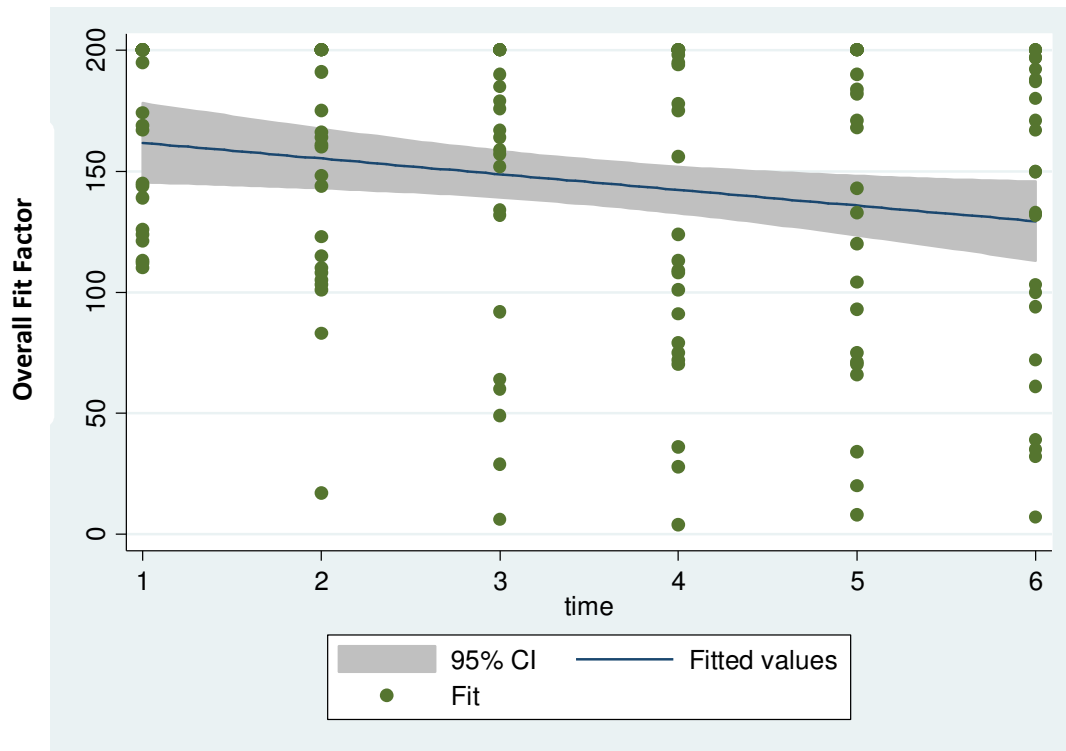


Figure 3.7: Overall fit factor for confidence interval

Figure 3.7 indicates that there was a significant negative trend in respirator fit with each donning, in the data collected. Using a linear regression with time series data, the tests showed that fit test does decrease with sequential donning ($p=0.019$), but the regression analysis shows that six donning are unlikely to result in a decrease to below 100 in respirator fit. The lower 95% confidence interval (CI) also does not include the cut off 100.

CHAPTER 4: DISCUSSION

The aim of this project was to investigate the effect of multiple donning and doffing of respirator fit on National Institute for Occupational Health employees while wearing their currently supplied respirators. Our study focused on disposable N95 filtering face-piece respirators used for protection against HBAs.

The study included 25 participants, and 72% (18) achieved an overall fit factor above 100 for the 6th fit test, although only 13 (52%) achieved the overall fit factor of above 100 for all six consecutive tests, indicating that 20% (5/25) failed a test and then achieved a pass in the 6th fit test. The best overall fit factors were observed for donning one, two and three with 100%, 92% and 76% passing respectively, possibly because of the relatively little wear of the respirator components or because donning was still done conscientiously or both.

Respirator fit failures increased until after the fourth donning but they stabilised at around 30%. Only four participants had persistent fit test failure after the first failure, one subject donning were below 100 after the fourth donning and stayed below for remaining two tests. Two explanations suggest themselves: a relatively small proportion of respirators may not be able to tolerate repetitive donning; and/or donning fatigue occurred in a proportion of participants which resulted in failure to follow adequate donning practices.

Four participants achieved a good overall fit factor above 200 after six donnings.

The relatively high proportions of overall fit test passes up to the sixth donnings were not anticipated, given that the N95 respirators are considered limited-use devices. But this result is in agreement with the findings of the NIOSH study, which investigated the impact of multiple donning. Their study found a high percentage (81-93%) of donning group 1-5 with an fit factor ≥ 100 ; but dropped to 53-75% for donning group 16-20 (25).

Women participants achieved a significantly higher proportion of passes than men, being 81% and 75% respectively. However, no significant difference between men and women in mean fit test score between the first and sixth donning was found.

Occurrences of two or more consecutive fit test scores of less than 100 were observed from eight participants; however, the fit testing was sustained until the sixth fit test. The head strap and nose-piece breaks were not witnessed in this project and thus unlikely to be the cause of poor fit.

The overall fit test results for this study gradually deteriorated after multiple consecutive donning but the overall fit factor was never below the 100 cut off. Although the literature on respirator multiple donning is insufficient, this experimental study results are in agreement with the findings of the NIOSH study, which investigated the impact of multiple consecutive donning on filtering face-piece respirator fit (25). The NIOSH study established that the fit of the filtering face-piece respirator gradually decreased after multiple donning and the data suggested that five consecutive donnings could be performed before filtering face-piece respirator consistently dropped below 100 (25).

A large number (80%) of participants fit test scores increased in a subsequent donning after a decrease. This suggests that donning itself plays a role in fit factor and repeat donning; and not only the respirator. The change in scores may be due to donning practises which illustrates why PPE should be the last resort as it may be affected by human behaviour while mechanical or administrative controls are less likely to be affected.

In considering the findings of this study, it is important to bear in mind that the population groups were not well represented; there were 8% white and 92% black, although a previous study by Manganyi *et al*, 2017, showed race did not play a role in respirator fit (24). The response rate was good, as the study resulted in a total number of 29 volunteers compared to the estimated minimum size of 10.

Lesson Learned

From this study, it was learned that the concern of multiple donning and doffing appears to be acceptably small for a small number of repeat donning. The NIOH employees (respirator users) were not cognisant about the consequences surrounding multiple donning and doffing of the same respirator, as some employees were repeatedly using

the same respirator for more than two times and some were given one respirator for the whole shift or week. The storage and contamination of respirators was not examined in this study but also plays a role in the safe re-use of respirators.

Limitations

The limitation of this study include that it is of experimental components and participation was volunteer. The study participants were reluctant to participate for the second objective that it is to wear the same respirator for the 8hour while fit test is done at two hour interval.

CHAPTER 5: CONCLUSION AND RECOMMENDATIONS

5.1 Conclusion

This study answered the research question “Does N95 filtering face-piece respirators maintain acceptable levels of respirator fit following multiple donning and doffing of the same respirator in healthcare settings?” The consecutive six donnings of respirator fit testing carried out in this study demonstrated that not all respirator users will maintain acceptable levels of respirator fit following multiple donnings and doffings of the same respirator in healthcare settings; but 52% of the study participants retains the ability to form an acceptable seal after six donnings.

It is anticipated that this study will contribute to information, raise awareness and improve the respirator protection procedures aimed at reducing exposure and health risks associated with airborne particles in healthcare setting and in laboratory environment.

This study indicates that on average a respirator may be reused five times without affecting the ability of the respirator to form a seal. The ability of respirator users to always don a respirator correctly is less certain and regular training may be required. Thus, implementation of the hierarchy of controls is recommended.

5.2 Recommendations

It is recommended that all NHLS respirator users who are re-using respirator should undergo training in donning. Since multiple respirator fit tests have the potential to reduce both the alpha and beta error to less than half of that single respirator fit test (26). Therefore multiple respirator fit tests can eliminate both alpha and beta error (26) and also used as training method for proper donning (35).

Risk of contamination for re-use of the respirator needs to be investigated, as well as the best storage for re-used respirators.

The Effect of Multiple Donning on Respirator Fit in NHLS Employees

It is also recommended that NHLS should implement clean-shaven policy for all men respirator users and management should adhere to all element of respiratory protection program during procuring; they must select the correct N95 FFRs.

The lack of research in multiple donnings of respirators is reflected in varied and sometimes it is conflicting the respirator protection program, respirator policies and guidelines. Thus, further research should be conducted to identify the causes of the change in fit across donnings to ensure the safety of staff using respirators.

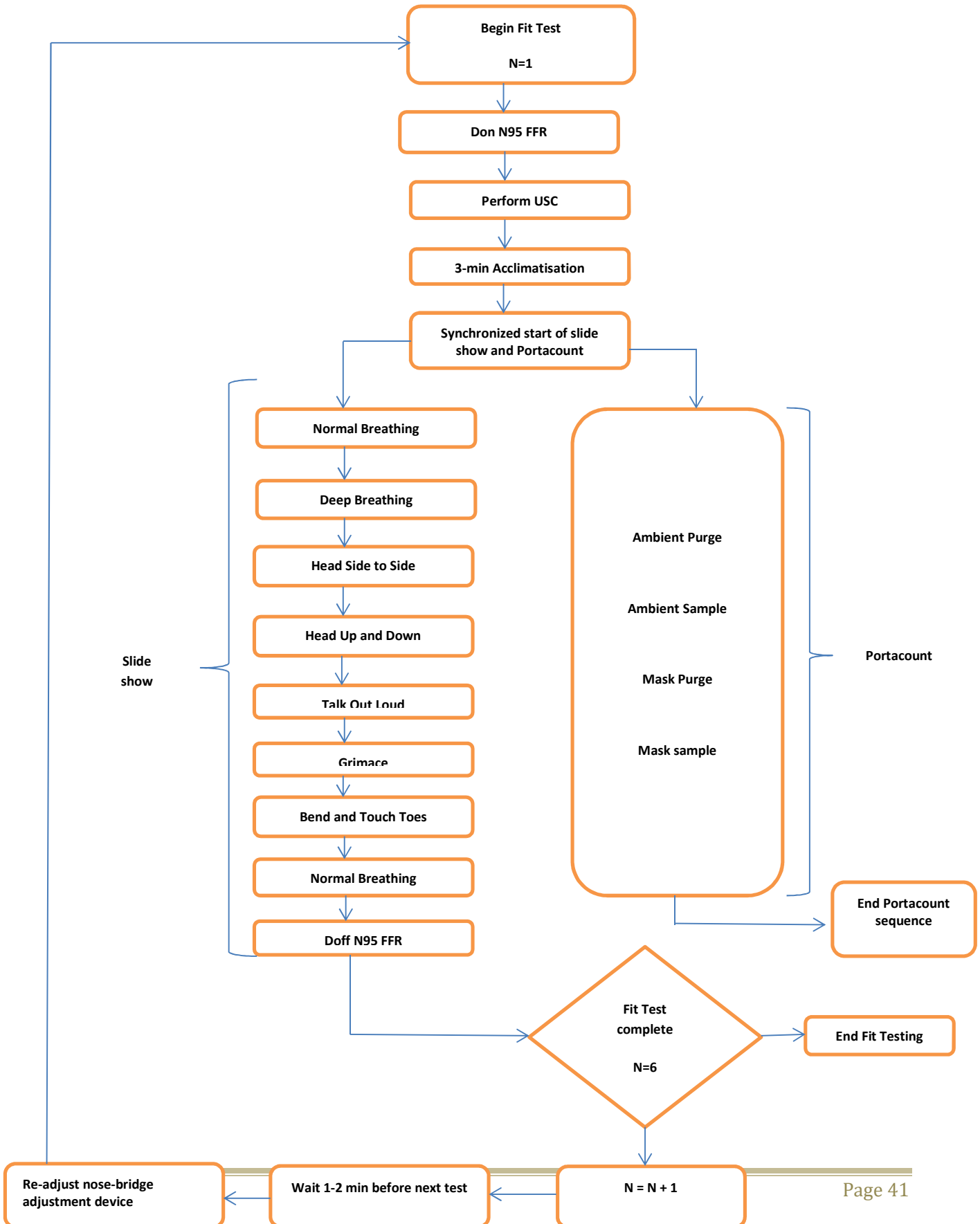
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7.1 Appendix A: Respirator Fit Test Flow Diagram



7.2 Appendix B: The Rainbow Passage

THE RAINBOW PASSAGE

When the sunlight strikes raindrops in the air, they act like a prism and form a rainbow. The rainbow is a division of white light into many beautiful colors. These take the shape of a long round arch, with its path high above, and its two ends apparently beyond the horizon. There is, according to legend, a boiling pot of gold at one end. People look, but no one ever finds it. When a man looks for something's beyond his reach, his friends say he is looking for the pot of gold at the end of the rainbow.

Fairbanks, G. 1960 "Voice and Articulation Drill Book". Harper & Row, New York.

7.3 Appendix C: Ethics Clearance Certificate



R14/49 Cynthia Dansile Vuma

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M160339

NAME: Cynthia Dansile Vuma
(Principal Investigator)

DEPARTMENT: Public Health
National Health Laboratory Service

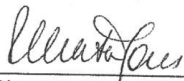
PROJECT TITLE: The Effect of Multiple Donning on Respirator Fit in
National Health Laboratory Service Employees
During 2016

DATE CONSIDERED: 01/04/2016

DECISION: Approved unconditionally

CONDITIONS:

SUPERVISOR: Dr K. Wilson and Prof D. Rees

APPROVED BY: 

Professor P. Cleaton-Jones, Chairperson, HREC (Medical)

DATE OF APPROVAL: 04/05/2016

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary in Room 10004, 10th floor, Senate House/2nd floor, Phillip Tobias Building, Parktown, University of the Witwatersrand. I/We fully understand the conditions under which I am/we are authorised to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit to the Committee. **I agree to submit a yearly progress report.** The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. In this case, the study was initially reviewed in March and will therefore be due in the month of March each year.

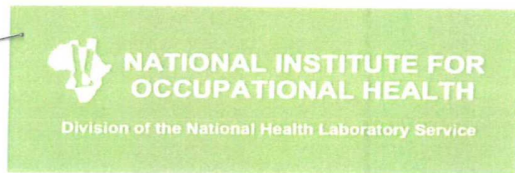


Principal Investigator Signature

Date 10 May 2016

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

7.4 Appendix D: Permission Letter



MEMO. ■

Office of the Executive Director
25 Hospital Street, Constitution Hill, Johannesburg

To: Ethics Committee
University of the Witwatersrand

From: Dr Sophia Kisting
NIOH Executive Director

Date: 18 January 2016

RE: Permission to conduct research

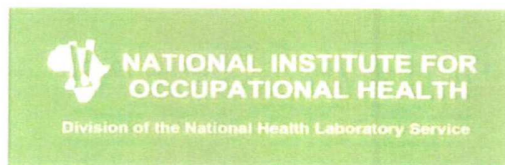
Dear Colleagues

The study "The effect of multiple donning on respirator fit in National Health Laboratory Service employees during 2016", Principal Investigator: Danisile Vuma and Project Supervisors: Dr Kerry Wilson, Prof David Rees and Mrs Jeanneth Manganyi has reference.

This letter serves to confirm that the Researcher has requested and been granted permission by the NIOH to conduct the above mentioned research amongst employees in the organisation. The results will be presented to the employees involved and a written report provided to the NHLS Occupational Safety, Health and Environment department along with recommendations.

Kind regards,


Dr Sophia Kisting
Executive Director
National Institute for Occupational Health (NIOH)
National Health Laboratory Service (NHLS)
Tel: +27(0)11 712 6522/6413 | Cell: +27 (0)82 609 5406 | Fax: +27 (0)11 712 6523
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Practice Number: 5200296

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Chairperson: Prof Barry Schoub | CEO: Ms Joyce Mogale
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Practice number: 5200296

7.5 Appendix E: Senate Plagiarism Policy



I **Cynthia Dansile Vuma** (Student number: **608623**) am a student

Registered for the degree of **MPH: Occupational Hygiene** in the academic year **2018**.

I hereby declare the following:

- ❖ I am aware that plagiarism (the use of someone else's work without their permission and/or without acknowledging the original source) is wrong.
- ❖ I confirm that the work submitted for assessment for the above degree is my own unaided work except where I have explicitly indicated otherwise.
- ❖ I have followed the required conventions in referencing the thoughts and ideas of others.
- ❖ I understand that the University of the Witwatersrand may take disciplinary action against me if there is a belief that this is not my own unaided work or that I have failed to acknowledge the source of the ideas or words in my writing.

Signature:

A handwritten signature in black ink, appearing to read 'Cynthia Dansile Vuma', written over a horizontal line.

Date: 2 November 2018