A STUDY OF RESPIRATOR FIT AND FACE SIZES OF NATIONAL HEALTH LABORATORY SERVICE (NHLS) RESPIRATOR USERS DURING 2013-2014

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DECLARATION

I, Mafanato Jeanneth Manganyi, declare that this research report is my own 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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M.J. Manganyi

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ABSTRACT

Introduction

In the hierarchy of controls, the use of respirators is listed as the least preferable means of exposure or infection control; however it is often the primary means of protection in many industries including the health care industry. The National Health Laboratory Service (NHLS) provides diagnostic pathology laboratory services to the national and provincial health departments in nine South African Provinces. NHLS staff includes N95 respirator users working with infectious diseases such as tuberculosis (TB). It has been shown that an individual's facial structure influences their chances of achieving respirator fit.

Study aim

This study aims to describe the proportion of NHLS respirator users with adequate quantitative respirator fit while wearing their currently supplied respirators.

Study objectives

1. To determine the proportion of NHLS respirator users achieving an adequate fit
2. To describe facial characteristics of NHLS respirator users and to group these faces into three face sizes (small, medium and large) based on the NIOSH fit test panel and two facial dimensions (face width and face length)
3. To explore the relationship between face size and demographic variables (sex, age, and race) of tested NHLS respirator users
4. To explore the influence of face size on respirator fit obtained by NHLS respirator users wearing their current respirator

Materials and methods

This was a cross sectional study with descriptive and analytical components. NHLS employees from selected laboratories in Gauteng, Cape Town and Durban were invited to participate. Study participants were respirator users and the majority were exposed to hazardous biological agents (HBA) including tuberculosis (TB).

The NHLS employees included the four common South African race groups (as per Statistics South Africa) namely African, White, Coloured and Asian. A minimum sample size of 240 study participants was calculated for the study based on 30 participants per race group and sex. At the close of data collection 610 employees participated in this study.

Quantitative respirator fit testing was conducted using a Portacount fit testing machine. Four facial dimensions were taken using callipers and a tape measure. STATA 12 was used to perform descriptive and interferential statistics. The associations between pass and fail and key predictors were investigated by chi-square tests. Student's t-tests and Kruskal-Wallis one way analysis of variance were used to investigate the overall fit factor in groups by face size, sex, race, age group and nose bridge width. The effect of the independent variables was explored using multiple linear regressions stratified by sex.

Results and discussion

Of the 610 employees who participated, a large percentage (78%) of NHLS respirator users failed fit testing and was not protected by their currently supplied medium size respirator. Ninety one percent of the respirators supplied were medium. The race group which achieved a highest proportion of fit factor passes was White (27%) followed by Africans (26%), a drop of pass rate was seen in Coloureds (21%) while the Asians achieved the lowest proportion at 7%. These poor pass rates indicate that a respiratory protection programme is needed in the NHLS, with focus on supplying the correct size and style of respirators.

When the measured face length and face width of participants were plotted against the new bivariate NIOSH fit test panel, it was found that 35%, 58% and 7% of the participants had small, medium and large faces respectively. Our study population did fall within the panel but the distributions were different between cells compared to the American population. In the South African population Asians were more likely to be associated with a small face than Africans (p=0.00), Whites (p=0.00) and Coloureds (p= 0.00). While the Coloureds were not significantly different from the Whites or Africans (p= 0.397 p=0.713).

The study showed that in addition to face length and face width, nose bridge width play a role in respirator fit. Multiple linear regression analysis showed that face size and nose bridge width were both significant predictors of overall fit. Although both sex and race predicted respirator fit in unadjusted analysis, these fell away when facial characteristic measurements were placed in the model. This suggests that sex and race maybe proxies for facial characteristics in predicting respirator fit.

Conclusion and recommendation

The high percentage of employees in this study sample achieving poor fit with their current respirator indicates a need for immediate testing of all NHLS respirator users and for a range of sizes and styles of respirators to be provided to all staff requiring respirators.

The use of poorly fitting respirators could create a false impression of protection in the laboratories where employees are possibly exposed to HBA's including all types of TB. This also leads to in a large amount of funds being spent on purchasing ineffective respirators at the NHLS. A respiratory protection programme including respirator fit testing needs to be compiled, implemented and reviewed regularly to ensure sustainability. Future studies may include the investigation of the relevance of panels used in designing respirators to be worn by South Africans.

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ABBREVIATIONS

NHLS	National Health Laboratory Service
NIOH	National Institute for Occupational Health
USA	United States of America
NIOSH	National Institute for Occupational Safety and Health, USA
OSHA	Occupational Safety and Health Administration, USA
NPPTL	National Personal Protective Technology Laboratory, USA
PPE	Personal protective equipment
QNFT	Quantitative fit testing
FFRs	Filtering face-piece respirators
RFTPs	Respirator Fit Test Panels
FF	Fit Factor
HBA	Hazardous biological agents
TB	Tuberculosis
HCWs	Health care workers
PCA	Principal component analysis
WHO	World Health Organization
MRC	Medical Research Council

CHAPTER 1: INTRODUCTION AND LITERATURE REVIEW

1.1 Introduction

1.1.1 Laboratory workers inhalable hazards

Medical laboratory workers are exposed to a range of chemical and biological substances while performing their daily tasks. Some of the chemicals have been found to be mutagenic, genotoxic or teratogenic in experimental animal studies (1). Occupational exposure of laboratory workers to chemicals has also been associated with cancer and adverse reproductive outcomes (1). Laboratory work during pregnancy may reduce foetal growth and also increase the risk of post term delivery (1). Laboratory workers are at risk of work acquired infections from exposure to pathogenic organisms (2). A study conducted among employees working in biomedical research laboratories showed a slight effect on preterm and post term birth from exposure to solvents and bacteria as well as slight increase in the estimates for low and high birth weight (3).

1.1.2 Risk of health care workers contracting TB

Health care workers (HCWs) in primary health care facilities are at risk of contracting occupational TB (4). The standardised incidence ratio for smear positive TB in primary health care workers indicated an incidence rate more than that of the general population (4). An association was found between work location and job categories with a high risk of contracting TB compared with the general population (5). This association was also found in workers in TB laboratories (5). An increased incidence of TB was also found in HCWs living with HIV (6).

The risk of contracting TB in the laboratory has been reported to be from twice as high to more than eight times higher than that of non-laboratory workers or the general population (7). Technicians handling pathological specimens had a significantly higher risk than other medical workers (7), (8). There is evidence that laboratory procedures dealing with live cultured M. tuberculosis pose a very high risk, requiring attention to be paid not only providing controls in the facility and safe equipment but also to good laboratory practices by the laboratory employees (9).

A focal spread was found to occur in microbiology laboratories where a high volume of infective TB specimens were handled (10). A study showed that working in a mycobacteriology laboratory versus working in a bacteriology, virology, serology, or parasitology laboratory was a risk factor for latent TB infection (11). In this study, 57% of the laboratory HCWs surveyed had latent TB infection which was higher in mycobacteriology workers than in non-mycobacteriology workers (11).

1.1.3 Global burden of TB

The World Health Organization (WHO) reported in the 2014 Global Tuberculosis Report that tuberculosis (TB) remains one of the world's deadliest communicable diseases (12). It was reported that in 2013, an estimated 9.0 million people developed TB and 1.5 million died from the disease, 360 000 of whom were HIV-positive (12). The South African population is heavily burdened with tuberculosis (TB) infection with the second highest rate in the world and the highest drug resistant type (13) more than double those observed in other developing countries and up to 60 times higher than those currently seen in USA and Western Europe (14).

The chemical hazards present in laboratories and the increased risk of contracting infectious diseases notably TB, especially in a high TB setting mean that effective controls need to be in place to protect these workers.

1.1.4 Occupational hygiene control measures

In occupational hygiene, the traditional hierarchy of controls incorporates primary approaches to control or reduce exposure involving elimination or substitution, then engineering controls, administrative controls, and last the use of personal protective equipment (14). Elimination of hazards is best while personal protective equipment is the least preferable. In practice, however, personal protective equipment such as respirators are often the first to be used either while others controls are being implemented or long term due to the cost of the other controls (15).

1.1.5 The WHO TB infection controls in a health care setting

The WHO has specific strategies for TB infection control for health-care facilities. They consist of facility–level measures, administrative controls, ventilation and the use of personal protective equipment including particulate respirators (16). In modern countries the transmission of TB has been reduced through a combination of infection control strategies (3).

These strategies include comprehensive treatment protocols, administrative measures (staff training programmes), environmental controls (ventilation, isolation, air filtration, and ultraviolet germicidal irradiation) and the use of respiratory protective equipment (RPE) (3).

1.1.6 Respirators use in health care and laboratories

N95 filtering-face pieces are the respiratory protective equipment most frequently used in health care settings to prevent inhalation of droplet nuclei carrying mycobacterium tuberculosis (M.tb) bacilli (17). It was shown that because M.tb droplets are in the range of 1µm to 5µm aerodynamic diameter, N95 respirators don't only filter 95% of these droplets, they permit little penetration and filter as much as 99.5 % of the bacilli (17).

NIOSH approved N99 and N100 are also used in the medical laboratory. N99 and N100 filter at least 99 % and 99, 7 % of airborne particles respectively (18). European approved FFP2 and FFP3 are different classes of respirators used in the medical laboratory filtering at least 90 % and 99 % of the particles respectively (19). The use of an exhalation valve reduces exhalation resistance, which makes it easier to breathe (exhale) (18). Respirators with exhalation valves should not be used in situations where a sterile field is required (e.g. during an invasive procedure in an operating or procedure room) because the exhalation valve allows unfiltered exhaled air to escape into the sterile field (18). There are two respirator shapes cup and duck bill, the cup-shaped respirators were the most commonly used but the duck bill design accommodates different facial movement (19).

Depending on the chemicals in the laboratories and their concentrations, a variety of suitable cartridge respirators should be used to protect against inhalation of chemicals. In specialised viral laboratories suitable respirators should be identified.

The use of respirators is listed as the last means of exposure or infection control, however it is often the primary or only means of protection available in many industries including health care. There is a knowledge gap where many respirator users are unsure of the differences between a respirator and a surgical mask and the role that respirator size and type plays. The current perception in many workplaces in South Africa is that one size respirator size fits all employees. There are few organisations in South Africa which implement a respiratory protective programme which includes education for employees on the correct type, size and limitation of respirators supplied to them. Most organisations are not aware of the benefit of conducting respirator fit testing.

Leakage of contaminants through face seals has long been recognised as a major limitation of the degree of protection achieved from respirators (20). To reduce a leakage respirator must be selected which is appropriate for the specific individual taking into account factors affecting fit such as face size and shape as well as facial hair (21). A quantitative fit test (QNFT) is the most accurate way to assess if a specific type, style and size of respirator adequately fits a particular individual.

To ensure that the respirator is effective at reducing risk, it is important to match the people according to their facial characteristics with the correct size and style of the respirator. The fit factor achieved during fit testing has shown to be a meaningful indicator of respirator performance in actual workplace environments (22). Respirator fit testing also ensures an individual knows how to don and wear the respirator properly (23, 24). Fit-testing is an important element of a respiratory protection programme (25).

1.1.7 The National Health Laboratory Service

The National Health Laboratory Service (NHLS) is a public, medical laboratory service with laboratories across South Africa. Its activities comprise diagnostic laboratory services, research, teaching and training, and production of sera for anti-snake venom, reagents and media. The NHLS is the largest diagnostic pathology laboratory service in South Africa. It employs approximately 6,700 staff. There are 349 laboratories across the nine provinces. The NHLS serves approximately 80% of the South African population (26)

NHLS employs a large number of employees who work with biological agents. These employees are at risk of hazardous exposures to these agents. Currently NHLS uses respirators as an extra protection particularly against inhalation of *M.tb* bacilli. Respirator fit testing was not conducted in the NHLS. Additionally, only medium respirators were provided and it is well known that they do not fit all faces as there is a variability in physical dimensions of both people and respirators. This study aimed to describe the level of protection currently afforded to NHLS respirator users by their currently supplied respirators.

1.2 Literature review

Sufficient evidence exists to warrant sufficient protection of laboratory employees for possible health effects of exposure to specific groups of chemicals, and biological agents (27). Respirators provide protection against inhalation of harmful substances and are relied upon in many laboratory settings. Protection is however only achieved if respirators function and fit adequately.

1.2.1 Respirator fit

The pilot study by Spies, 2011 (15) showed that in order to improve fit, a respiratory protection programme is essential before issuing respirators and more than one respirator type or shape and size should be available as “ one size does not fit all” (15). A study on factors affecting the location and shape of face seal leak sites limited to Caucasian respirator wearers was conducted (20). The analysis indicated that an individual‘s facial structure, possibly influenced by sex and race may be a factor (20). The study outcomes suggested that manufacturers should consider facial shapes and size when designing respirators (20).

1.2.2 Design of respirators and respirator fit test panels

Respirators are designed to fit as many people as possible, the designs are based on facial anthropometric (human facial size and shape) data obtained from large groups of people who participated in projects to design respirator fit test panels (RFTPs) (28, 29). Respirator fit test panels provide an objective tool for selecting representative human test subjects based on their facial characteristics for use in research, product development and certification of respirators (30).

1.2.3 Los Alamos - the commonly used panel

The 1973 Los Alamos National Laboratory (LANL) recommended bivariate fit test panels for full face-piece and half –mask respirators are based on facial measurements taken from 1967 and 1968 U.S. Air Force Anthropometric surveys (31), (29). The full face-piece panel is based on the bivariate distribution of face length and face width. The half face-piece panel is based on the bivariate distribution of the face length and lip length (31), (29). Concerns were raised with these fit test panels as they were not representative of the facial dimensions of current U.S. civilian respirator wearers (31), (29).

1.2.4 The revised American respirator fit test panel

In 2003, a NIOSH study responded to the concerns around the Los Alamos panel, creating a large anthropometric database by measuring civilian heads and faces of 3997 respirator users. Dimensions for the panel were chosen to maximise their utility in the design and testing of new respiratory protection equipment (32).

Multivariate analyses of the data from this study and the previous military data revealed that using historical military data would be inadequate for describing the anthropometric variability of the current U.S. work force (32).

Using the newly collected anthropometric database two new respirator fit test panels were developed (33). One fit test panel (bivariate) was developed using the traditional bivariate approach with cells defined on face length and face width (33). This panel covers 96.7% of the male and 98.7 % of the female civilian workforce. It has limits of 98.5mm to 138.5 mm for face length and 120.5 mm to 158.5 mm for face width which are significantly different from the limits of the LANL (33).

More than 95% of the NIOSH study subjects are within the boundary of the panel. Another panel based on PCA (Principal Component Analysis) was developed using the scores from the first two principal components obtained from a set of 10 facial dimensions (33). This panel covers 95.2% of the men and 97.6% of the female civilian workforce. Both panels more accurately represent the population than the LANL panel and may be more appropriate for testing both half and full face respirators (33).

Another study (34) concluded that with the use of the new NIOSH fit test panels by manufacturers to develop new sizes, the correlation between respirator fit and respirator fit test panel by respirator size may be better than with the Los Alamos panel and the protection afforded to users could improve for users whose physiognomy did not match the previous sizes. (34)

1.2.5 Race group and sex

The results from a USA study published in 2005 on the effect of subject characteristics on respirator fit recommended face length and width measurements for defining the RFTPs for half-face respirators rather than face length and lip length as used previously (35). The study findings also showed that facial dimensions are likely to be different for various ethnic groups so the applicability of the RFTPs for ethnic groups needs to be confirmed as past studies on respirator fit have mostly been carried out on American Caucasian and/or male subjects with little attention paid to race or sex (35).

A study by Zhuang, 2010 (36) on facial anthropometric differences found significant differences between males and females, and between racial / ethnic groups (36). The study also revealed that race is second to sex for impacting on face size and shape characteristics (36).

A Chinese study (28) investigated whether American RFTPs are applicable to their workforce. The results revealed that 12-35% of subjects fell outside the ranges derived from American RFTPs as Chinese subjects generally had shorter and wider facial characteristics than the American group. It was concluded that Chinese groups need an optimal RFTP based on their facial anthropometry (28), (37). A similar study by Benson in 2012 showed that Chinese head forms had a wider face, shorter face length and smaller nose protrusion as proven previously (38). A Korean study showed that Korean males and females also have different facial dimensions compared with those of white American males and females (39).

1.2.6 South Africa and respirator fit

During World War I, a rapid improvement occurred in respiratory protection. The Mark IV dust respirator was developed at the time by the UK Chemical Defence Research Department at Porton and was tested in South Africa for use in mining and while suitable for Europeans the face-piece did not fit the black miners (40). An improved face-piece was then developed by Professor R Dart at the University of the Witwatersrand and a satisfactory fit was obtained on about 80 % of the natives (40).

A South African pilot study by Spies et al. in 2011 found a large percentage of failed fit tests using a common medium respirator and concluded that reliance on medium size respirators in South Africa is likely to be a problem, resulting in a false sense of protection for many South African employees (15).

The use of personal protective equipment (PPE) such as respirators to protect workers from exposure to airborne hazardous substances is often the only "control" method used in many South African workplaces, although it should be viewed as a last resort after other control methods have been implemented (15). Also, fit testing is not done even though many studies have suggested the importance of fit test prior to issuing respirators to employees as well as the availability of different sizes as it was evident that “one size does not fit all” (15)

Variability in genetic structure observed among the African populations is likely due to ethnicity, language and geography. This is based on the study of the Genetic Structure and History of Africans and African Americans (41). The study observed significant associations between genetic and linguistic diversity reflecting the concomitant spread of languages, genes and often culture (41).

1.3 Study aim

This study aims to describe the proportion of NHLS respirator users with adequate quantitative respirator fit while wearing their current respirators.

1.4 Study objectives

1. To determine the proportion of NHLS respirator users achieving an adequate fit
2. To describe facial characteristics of NHLS respirator users and to group these faces into three face sizes (small, medium and large) based on the NIOSH fit test panel and two facial dimensions (face width and face length)
3. To explore the relationship between face size and demographic variables (sex, age, and race) of tested NHLS respirator users
4. To explore the influence of face size on respirator fit obtained by NHLS respirator users wearing their current respirator

CHAPTER 2: MATERIAL AND METHODS

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

2.1 Study design

This study was a cross sectional study with descriptive and analytical components.

2.2 Study population

The NHLS has approximately 349 laboratories across the nine provinces of South Africa. These laboratories include those responsible for diagnostic analysis of specimens including sputum containing TB received from government hospitals. In order to obtain a sample of the main race groups found in South Africa, study participants were drawn from all respirator users in the Gauteng region along with selected Durban and Cape Town facilities who were approached to participate.

2.3 Sampling

A minimum sample size of 240 study participants was calculated for this study based on 30 participants per race group and sex to allow for meaningful analysis. The sampling was stratified by race and sex.

The participants recruited included the four South African race groups recognised by Statistics South Africa namely African, White, Coloured, and Asian. Non-South Africans who met all the inclusion criteria were included. Inclusion criteria were NHLS laboratory employees that used a respirator and worked with hazardous biological specimens or chemicals and signed a consent form to participate.

It was anticipated that some male participants would not be clean shaven during the time of the test. Participants with a few days of facial hair growth (stubble) were allowed to participate and they were included but facial hair was noted. Only employees with beards were excluded.

All respirator users employed in the main laboratories handling TB samples in Gauteng were included and all respirator users working in the NICD and NIOH laboratories were invited. Respirator users from other Gauteng laboratories, who requested testing, were included. There was no sampling of participants; all consenting respirator users in the relevant laboratories were included.

The Gauteng Province sample consisted predominantly of African and White participants. Six large TB laboratories from Cape Town and Durban were included in the study to specifically increase the sample of the less numerous race groups, namely Coloureds and Asians. All respirator users from these laboratories were included so again there was no sampling used.

2.4 Measurement and data collection

Data collection was conducted by the principal investigator assisted by three National Institute for Occupational Health (NIOH), Occupational Hygiene employees. The NIOH employees who assisted in conducting fit testing were monitored for competence by the trained occupational hygienist before participating in the study. To reduce interpersonal variations in collecting facial anthropometric data, the principal investigator who was competent by training and experience in reproducibly measuring facial characteristic collected all the facial measurements.

2.4.1 Respirator fit testing

Participants were trained in the correct wearing of a respirator before they were fit tested. Employees were fit tested with their currently supplied N95 disposable respirator. TSI Portacount Model 8038 was used in the study. The Portacount is an ambient aerosol monitor which allows quantitative fit testing by measuring aerosol (present in the ambient air) concentrations outside and inside the respirator and, from the difference, computing the fit factor.

OSHA–Accepted Fit Test Protocol was followed (42, 43). To ensure validity and reliability of the instrumentation, the Portacount was calibrated annually. Pre–checks on the instrumentation were done before fit testing was conducted.

Before each test, the subject donned their usual respirator per the respirator's manufacturer's instruction (42, 43). During a fit test, each subject performed six exercises, namely (1) normal breathing (2) deep breathing (3) moving the head up and down (4) moving the head side to side (6) normal breathing. For the talking exercise, the "Rainbow passage" was used (see appendix 3).

Employees who were not comfortable to read, were requested to count numbers or say their names repeatedly. A participant passed the fit test if the overall fit factor of the six exercises was $\geq$ 100 (42, 43). Employees were fit tested once with their current supplied respirator.

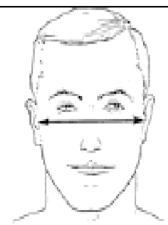
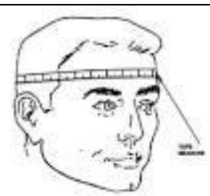
The results of the fit test were expressed as a continuous fit factor, this was then categorised into 2 groups; pass or fail with a minimum fit factor of 100 required to pass. A fit factor of 100 means that the air inside the respirator is 100 times cleaner than the air outside and this is a minimum required fit factor for a disposable respirator including N95 (42, 43).

2.4.2 Facial characteristics

Facial dimensions were measured in accordance with Garments construction and anthropometric survey – body dimensions (ISO 8559:1989) and basic human body measurements for technical design (ISO 7250:1996). Measurements took 13 minutes per person.

Four face measurements were performed on all participants and facial variables measured included face length, face width, nose bridge width and head circumference as highlighted below (Table 1).

Table 1: Four selected facial characteristics relevant to respirator fit (33)

Face Measurement	Diagram	Description
Face Length		Distance as measured with a sliding calliper in the midsagittal plane between the menton landmark and sellion landmark
Face Width		Maximum horizontal breadth of the face as measured with a spreading calliper between the zygomatic arches
Nose bridge width		Horizontal breadth of nose as measured with a sliding calliper at the sellion landmark and a depth equal to one –half the distance from the bridge of the nose to the eyes
Head circumference		The maximum circumference of the head measured with a tape measure just above the ridges of the eyebrows and the attachment of the ears is measured with a tape. The subject sits looking straight ahead. The plane of the tape will be higher in the front than in the back and the sides should be parallel. Enough tension is exerted to compress the hair

Measurements taken from employees with an increased head circumference due to head coverings and hairstyles were excluded. All measurements were made in millimetres to one decimal point using a sliding calliper, a spreading calliper and a measuring tape.

The principal investigator was trained to conduct facial dimension measurements by Ziqing Zhuang, an anthropology expert from the NPPTL laboratory, NIOSH, USA. The training was done until the measurement errors were less than, or equal to, allowable errors.

The allowable error means allowable difference between two measurements of facial dimension by the same measurer or between different data collectors. This allowable error in measurement is based on the work done by a number of researchers (44), (45)

2.4.3 Demographic variables

A survey questionnaire was used to collect basic demographic variables such as sex, race and age. Possible impediments to respirator fit such as head coverings, hairstyles including braids and weaves, and beards were noted.

2.4.4 Data Processing methods and data analysis

Respirator fit test data were exported to an Excel spreadsheet directly from the Portacount. All other data were then entered onto the same Excel sheet. Data were exported to STATA version 12 for analysis. Descriptive statistics on respirator fit testing described the following:

- Count – Total number of study population
- Proportions – Percentage (% of employees who passed or failed fit testing)
- Mean fit factor pass / fail of study population
- Range – minimum and maximum fit factor achieved
- Percentage pass, mean fit, range of groups by study group, sex, race, and age group.
- Face sizes according to sex and race were described
- Proportions of participants falling into each face size group was described and compared with other international populations

The following inferential statistics were conducted on the data

- Chi-square test was used to determine the association between proportions of participants passing or failing the fit test and predictive factors such as sex, race, face size and nose bridge width. Chi square test for trend was used where there were more than two categories
- Face length and face width data were plotted on the NIOSH fit test panel to transform dimensions into categorical variables (small, medium and large faces) as well as retaining the original continuous variables (see figure 1)
- Kruskal-Wallis one way analysis of variance by ranks was conducted on the original overall fit factor data to determine the influence of face size on the overall fit factor, as well as other variables such as race and age group

- Pearson's correlation was used to investigate the correlation between facial characteristic measurements
- Students' t-test was conducted to investigate whether there were significant differences in overall fit factor by sex and race
- Nose bridge width and head circumference were included in a multiple linear regression with overall fit factor as the outcome variable and face size as the main independent variable

2.5 Ethics

Ethics clearance was obtained from the University of Witwatersrand before the study was conducted (see appendix 2, Ethics clearance certificate). All participants received an information sheet and a consent form. Participants signed a consent form to participate. Participants completed the necessary information on the survey questionnaire. Employees were allocated a unique identifying study number when the results were collected.

Results were available immediately to the participant after the fit test and made available only to their Laboratory Manager in a form of a report to ensure procurement of proper sizes. No published results are traceable to any individual participant. Summary data were made available to the management of NHLS.

CHAPTER 3: RESULTS

Six hundred and ten employees participated in this study and all of them were respirator users in the NHLS. The majority of participants were from the Gauteng Province. Some laboratories were using cartridge type respirators for chemical exposure but they were not fit tested as there was no adaptor to carry the fit testing. One laboratory did not have stock of respirators at the time of the assessment and so the staff could not be fit tested. However, facial dimensions were measured and respirator sizes and styles were predicted for recommendations. In total five hundred and sixty two employees were fit tested.

3.1 Description of study population

The sample population included a selection of NHLS laboratories from hospitals and institutes in the Gauteng Province, and the cities of Durban and Cape Town. Table 2 describes the laboratories and provinces that participants were recruited from.

Table 2: Description of geographical location and specific laboratories of employment of the NHLS study population

Region	Lab	n	Percent
Central Region (Gauteng) Total = 62	CLS TB LAB	5	0.8
	Chris Hani Baragwanath	11	1.8
	Helen Joseph	11	1.8
	NHLS TB central	35	5.8
NIOH (Gauteng) Total = 53	Immunology	16	2.6
	Health and safety	1	0.2
	Occupational medicine	1	0.2
	Occupational hygiene	10	1.6
	Toxicology	6	1.0
	Pathology	19	3.1
NICD (Gauteng) Total = 169	CEZD	33	5.4
	CTB	28	4.6
	DMP	12	2.0
	Immunology	2	0.3
	NTBRL	12	2.0
	RVU	7	1.2
	SBPRU	12	2.0
	SAVP	17	2.8

Region	Lab	n	Percent
	Stables	12	2.0
	SPU	21	3.5
	VDU	5	0.8
	Virology	8	1.3
Northern Region (Gauteng) Total = 119	DGM	43	7.1
	TAD	76	12.5
	Tygerburg	17	2.8
Cape Town City Total =112	Grooteschuur	63	10.3
	Green Point	22	3.6
	Red cross hospital	10	1.6
Durban City Total = 95	IALCH	67	11.0
	King Edward VIII	28	4.6
Total		**610**	**100**

Table 3 shows the different occupations of the sample population. Employees that participated generally had a tertiary degree and occupied: technologist, medical scientist and laboratory manager positions. Employees with matric certificates were mostly laboratory assistants and administrative services but only account for approximately 13% of participants.

Table 3: Occupations of NHLS study population

Occupation	n	Percent
Animal caretaker	27	4.4
Cleaner	6	1.0
Intern	82	13.5
Lab manager	15	2.5
Lab admin	35	5.8
Lab assistant	24	3.9
Lab general worker	14	2.3
Lab technician	118	19.4
Lab technologist	152	25.0
Medical scientist	56	9.2
Medical staff	58	9.5
Other	23	3.6
Total	**610**	**100**

Laboratory technologists and technicians, who made up a large proportion of the participants, were mostly involved in specimen preparation and analysis. The “other” category consisted of people who did not give their job titles.

The sex of the participants is described in Table 4 and was investigated in this study for its role in respirator fit through its effect on face size.

Table 4: Sex proportion of study population

Sex	n	Percent
Women	409	67.1
Men	201	33.0
Total	**610**	**100.0**

Of the 610 participants, 67% were women and 33% men. This is consistent with NHLS overall as the organisation employs mostly female personnel with a high percentage of them based in the laboratories.

The four South African race groups as designated by Statistics South Africa were invited to participate from the selected laboratories. Table 5 summarises the sample population by race and sex. This race based analysis was necessary as facial characteristics were expected to vary by race.

Table 5: Race groups and sex of NHLS study population

Race	Women (%)	Men (%)	Total (%)
African	242 (63)	145 (37)	387 (63)
Asian	59 (85)	10 (15)	69 (11)
Coloured	38 (67)	19 (33)	57 (9)
White	70 (72)	27 (28)	97 (16)
Total	**409 (67)**	**201 (32)**	**610 (100)**

The majority of the participants were Africans, reflecting the distribution of race in South Africa, followed by the White race group. Cape Town and Durban main laboratories were included to increase the number of Coloureds and Asians respectively for analysis.

The mean age of the sample population was 37 years with a median of 33 and a range of 19 to 84. The distributions of the participants by age group are shown below in Table 6.

Table 6: Distribution of NHLS study population in 10 year age groups

Age group	n	Percent
19-30	229	37.5
31-40	175	29.0
41-50	96	15.7
51+	110	18.0
Total	**610**	**100**

The highest proportion of participants was in the age group of 19-30 years.

Employees were fit tested with the respirators which were currently supplied in their laboratories. The reason was to evaluate if employees were currently protected by their respirators and if not an alternative respirator size or brand was recommended. Table 7 shows that 91% of the participants had been supplied with a medium size respirator during the period of the study.

Table 7: Respirator size used currently by the NHLS study population

Respirator size	n	Percent
Medium	532	90.8
Small	54	9.2
Total	**586**	**100**

A small percentage (9%) of participants had been supplied with a small respirator size and they were fit tested using those respirators. Participants were also requested to provide the respirator models/types which were currently supplied at the laboratory during the study (shown in Table 8). This variability was anticipated as each business unit manages its own procurement and there was little standardisation in supply of respirators.

Table 8: Description of respirator manufacturer and styles supplied to NHLS study population during the study period

Respirator type	n	Percent
3M 1883	1	0.2
3M 8810	4	0.7
3M FFP2	34	5.8

Respirator type	n	Percent
3M N95 1860	395	67.6
3M N95 1860 S	11	1.9
3M V-Flex 9105	3	0.5
3M N95 / P2	1	0.2
Kimberley-Clark N95	135	23.1
Total	**584**	**100**

The two respirator brands commonly used within NHLS laboratories were 3M and Kimberley-Clark. Seven different respirator styles were supplied by 3M; 67 % of the 3M respirators were the style 1860 which was the medium N95. 23 % of the respirators were supplied by Kimberley-Clark. Despite this there was a wide range of styles available, all of which are acceptable for medical laboratory staff.

Table 9 describes the different inhalation exposure hazards that the laboratory staff were potentially exposed to when conducting their daily tasks.

Table 9: Description of inhalation exposure hazard that the NHLS study population were potentially exposed to

Hazard	n	Percent
Chemicals only	39	6
HBA	119	20
Other	4	1
TB	448	73
Total	**610**	**100**

HBA =Hazardous Biological Agents TB=Tuberculosis

A large percentage (73%) of participants was potentially exposed to mycobacteria. Some employees (20%) were exposed to a number of hazardous biological agents (HBAs). 6% were exposed to chemicals which are used in the laboratories.

Some employees were still to be placed in laboratories and they were not aware of the hazards they would be exposed to, hence they indicated “other”.

Male employees with a few days growth of facial hair were allowed to participate. The table below indicates that 99 of the 194 male participants had facial hair on the day of the fit testing (Table 10).

Table 10: Proportion of male participants with facial hair present on the day of the test

Facial hair present	n	Percent
No	95	49
Yes	99	51
Total	**194***	**100**

*7 men did not answer the question

Employees with facial hair were those who had short (stubble) facial hair growth. Those with beards were not fit tested as it was anticipated that a fit would not be achieved by any disposable respirator size or style. However, facial dimension were taken and based on these measurements participants were advised on respirator size and style which was likely to fit.

3.2 Description of overall fit testing results for all NHLS study population

The results of the fit test were expressed as a fit factor, this was then categorised into 2 groups pass or fail with a minimum fit factor of 100 required to pass (Table11).

Table 11: Proportion of participants passing the respirator fit testing using a required minimum fit factor of 100

Fit factor pass/fail	n	Percent
Fail	437	78
Pass	125	22
Total	**562**	**100**

Seventy eight percent of the participants failed fit testing while 22 % passed fit testing (Table 11). The fit factor achieved ranged from 1.8 to 419. The mean fit factor was 64 which was far less than the required minimum fit factor of 100 (Table12)

Table 12: Overall fit factor of study population

Overall Fit Factor	Sample Population	Mean fit	SD	Range
Fit factor Fail	437	38	28	1.8 - 99
Fit factor Pass	125	156	46	100 - 419
Total	**562**	**64.33**	**59**	**1.8 - 419**

The mean fit factor for those who failed was 38 ranging from 1.8 to 99. Those who passed fit testing achieved a mean fit factor of 156 well above the required fit factor of 100.

3.3 Facial characteristics of the NHLS study population

Face length and face width were measured on the individuals who were fit tested. There were 16 participants who were not measured as the expert in facial dimensions was not available. Measurements of 594 NHLS face widths and face lengths were obtained (Figure 1) and plotted against the NIOSH fit test panels (Figure 2) to assess the distribution of NHLS collected data compared to the panel.

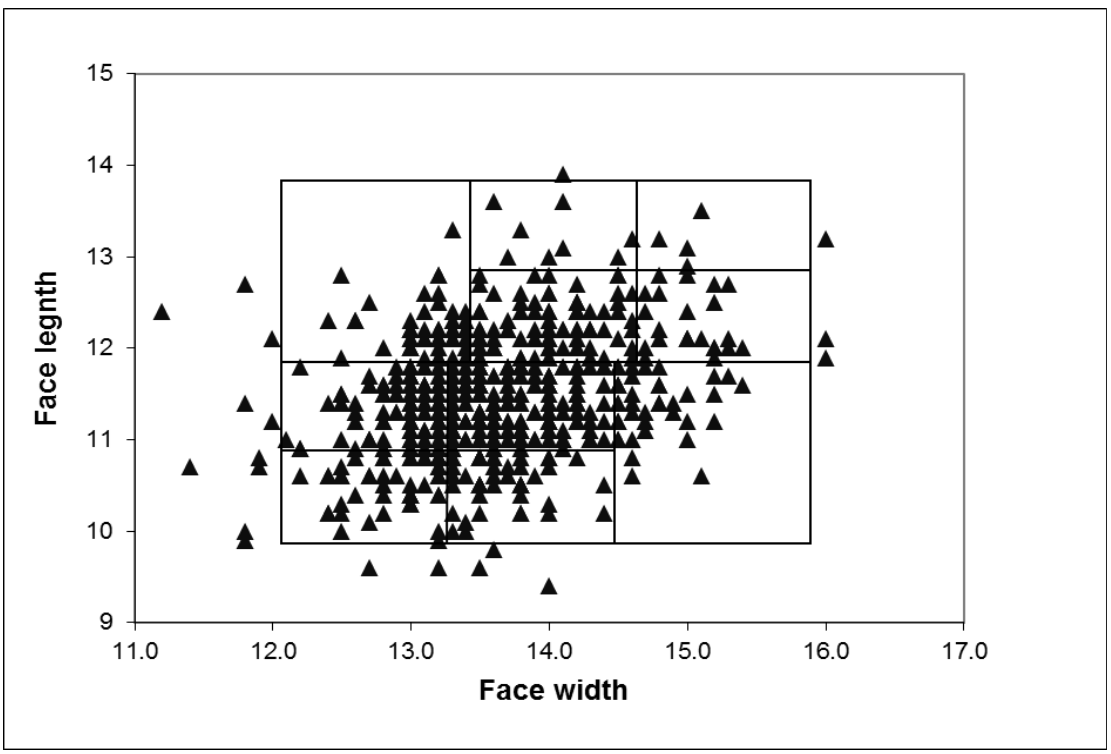


Figure 1: Plot of South African face width (cm) and face length (cm) on the NIOSH Fit Test Panel (bivariate panel)

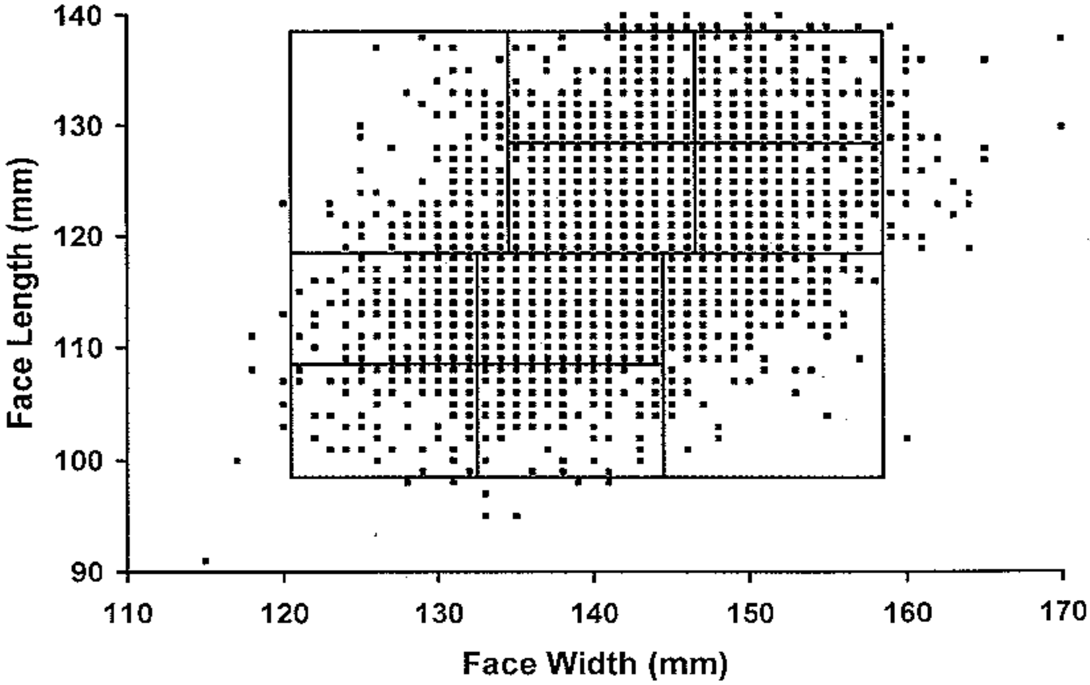


Figure 2: NIOSH Fit Test Panel (bivariate panel)

Figure 1 is a scatter plot of a bivariate (face length and face width) distribution of NHLS subjects against the boundaries of the new fit panel based on the 2003 NIOSH,USA survey data. The NIOSH fit test panel shown in figure 2 covers 96.7% of the male and 98.7% of the female civilian work force. The panel has a limit of 98.5 to 138.5 mm for face length and 120.5 to 158.5 mm for face width.

More than 95% of the NIOSH subjects are within the boundary of the panel. Our NHLS data distribution shows that 97% of the NHLS employees are within the panel but distribution within the panel is not even, the NHLS faces are more likely to be medium faces.

The participants who fell outside the NHLS panel on the small side were considered very small and those who fell outside on the large side were considered very large faces. The NHLS South African outliers are more likely to be small than large. The distribution of NHLS participants in the face sizes are provided in Table 13 below.

Table 13: Seven face size groups of NHLS study population categorised as per NIOSH fit test panel

Face size	n	Percent
very small	16	3
small	192	32
medium	307	52
medium small border	28	5
large	37	6
large medium border	10	2
very large	4	1
Total	**594**	**100**

The majority of the employees had medium faces (52%) close behind this was the small face group with 32%. While three percent of the participants had very small faces, one percent had very large faces. Both these latter group were outliers when plotted on the NIOSH fit test panel for American faces. The border groups may not achieve a fit factor pass using a medium respirator and should then be tested with the respirators for the groups they border on. Table 14 below summarises the distribution of three recognised face size groups of NHLS study population.

Table 14: Three recognised face size groups of NHLS study population categorised as per NIOSH fit test panel

Face size	n	Percent
Small	208	35
Medium	345	58
Large	41	7
Total	**594**	**100**

The NHLS study population when collapsed in three sizes had 58 % of the participants with medium face sizes, 35 % small and about seven percent large. Respirator procurement should reflect these proportions.

3.4 Relationship between demographic variables and face size for the NHLS study population

Table 15 below describes the proportion of the NHLS study population in the three face size group.

Table 15: Description of the proportion of the NHLS study population in the three face size groups by sex

Face size group	Women	Men	Total
Small (n)	182 (45%)	26 (14%)	208 (35%)
Medium (n)	214 (53%)	131(68%)	345 (58%)
Large (n)	5 (1%)	36 (19%)	41(7%)
Total	**401**	**193**	**594**

There was a significant difference in face sizes between the two sexes. Pearson chi-square test showed a significant difference (p=0.00) between proportion of women with small faces compared to men with small faces. Forty five percent of women participants had small faces while only 14% of men had small faces. More of the male participants had medium and large face sizes. Table 16 summarises the distribution of the NHLS study population in the three face size groups by race groups.

Table 16: Description of the proportion of the NHLS study population in the three face size groups and Statistics SA race groups

Face size	African	Asian	Coloured	White	Total
Small	116 (31%)	48 (72%)	18 (33%)	26 (27%)	208 (35%)
Medium	236 (63%)	17 (25%)	30 (56%)	62 (64%)	345 (58%)
Large	24 (6%)	2 (3%)	6 (11%)	9 (9%)	41(7%)
Total	**376**	**67**	**54**	**97**	**594**

A significant difference in face sizes amongst the race groups was found: 72 % of Asians had small faces compared to 27 % for White race group. Only 3% of large faces were observed in the Asian race group. The highest percentage of medium faces was observed in the White (64%), followed by the African group (63 %) and coloureds (56 %).

Chi-square tests showed that Asians were more likely to be associated with a small face than Africans (p=0.00), and the Whites (p=0.00) while the Coloureds were not significantly different from either the Whites (p= 0.397) or the Africans (p= 0.713) but they were significantly different from the Asians (p= 0.00).

Face size is based on face length and face width but two other characteristics are suspected to play a role in South African respirator fit (Table 17). The first is nose bridge width where the respirator needs to be moulded to fit and, secondly, head circumference which affects how tightly the respirator straps pull the respirator to the face.

Table 17: A description of four key facial characteristics for the NHLS study population

Variable	Mean	SD	IQR	Range
Face width	136.2	7	132 - 140	112-160
Face length	114.9	7	110 - 120	85 - 139
Nose bridge width	18.0	3	16 - 20	11-27
Head circumference	571.8	22	557 - 587	520-640

The average face size corresponds to a small face with a small nose bridge width. Tables 18 and 19 show a comparison of face width and face length of NHLS study population to international groups.

Table 18: A comparison of NHLS study population face width and face length to international studies of Koreans and Americans (39), (46)

Comparison group	Face width	Face length	Ratio FW/FL	n
South African female	134	113	**1.19**	399
South African male	141	119	**1.18**	196
Korean female *	136	110	**1.24**	40
Korean male	147	121	**1.21**	70
American female **	129	118	**1.09**	30
American male	139	126	**1.10**	38

The South African faces were shorter and wider than the Americans but not as wide as the Koreans. The ratio of NHLS face length and face width was calculated and then compared to those calculated for the other international groups. South Africans (NHLS respirator users) ratios were in-between the Koreans and Americans but there was a larger difference compared to the Americans. This may suggest the need to evaluate the USA bivariate (face length and face width) RFTP to determine if it is applicable to South Africans.

Table 19 shows that the ratio of face length and face width for the NHLS race groups was similar. The South African African males and females had the same ratio as each other. While the ratio of face length to width for South African Coloured males was the same as the Korean males. However all the South African race groups were different from the Americans. The South African Asian group is different from the Korean group as the majority of South African Asians originate from India.

Table 19: A comparison of NHLS study population to international groups using face width and face length by sex (39), (46)

Comparison group	**Face width**	**Face length**	**Ratio FW/FL**	**n**
South African African female	135	113	**1.19**	235
Asian	130	110	**1.18**	57
Coloured	133	113	**1.18**	37
White	135	115	**1.17**	70
South African African male	140	118	**1.19**	141
Asian	139	119	**1.17**	10
Coloured	142	117	**1.21**	18
White	142	123	**1.15**	27
Korean female *	136	110	**1.24**	40
Korean male	147	121	**1.21**	70
American female **	129	118	**1.09**	30
American male	139	126	**1.10**	38

Nose bridge width was evaluated in all participants as it plays a role in fit testing. Figure 3 shows the distribution of nose bridge width by sample population.

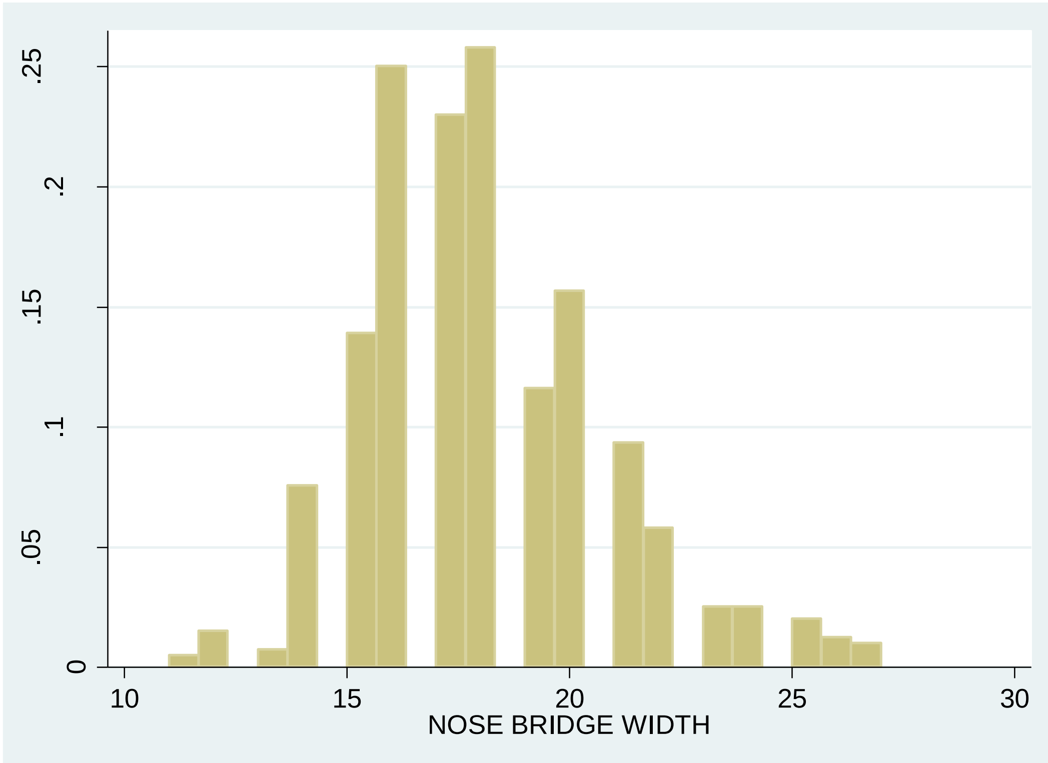


Figure 3: Distribution of nose bridge width (mm) of NHLS study population

Based on the distribution being close to consistent with a normal distribution, Pearson's correlation was used to investigate the correlation between facial characteristics. Slight significant correlation was seen between nose bridge and face width r =0.27 p = 0.000. A mild significant correlation was found between nose bridge and face length r= 0.22 p = 0.000. This suggests that nose bridge width is related but not strongly so to face size. Thus face size may be a predictor of nose bridge width but not enough to act as a proxy.

73 % of the participants had a narrow nose bridge width based on a cut off of 20mm chosen based on expert experience. Table 20 shows the nose bridge group by face sizes.

Table 20: Proportion of NHLS study population in the two nose bridge width groups

Nose bridge group	n	Percent
Narrow	434	73.2
Wide	159	26.8
Total	**593**	**100**

A large proportion of NHLS respirator users fell into the narrow nose bridge width group: 73%. This has implications for selecting respirator types. Table 21 shows the distribution of three face sizes by nose bridge group.

Table 21: Face size and nose bridge groups of NHLS study population

Face size	Narrow	Wide	Total
Small	179 (86%)	29 (14%)	208 (100%)
Medium	230 (67%)	113 (33%)	343 (100%)
Large	24 (59%)	17 (42%)	41 (100%)
Total	**433 (73%)**	**159 (27%)**	**592 (100%)**

The smaller your face the more likely you are to have a narrow nose bridge width (chi square p=0.00). The mean nose bridge width was 17 for small faces, 18 for medium faces and 19 for large faces. The range was similar for all face sizes being 11 to 27.

Table 22: Description of nose bridge width by face sizes of NHLS study population

		Nose bridge width		
Face size	**n**	**Mean**	**Min**	**Max**
Small	208	17	12	27
Medium	343	18	13	27
Large	41	19	11	26

On average small, medium and large faces had a significantly different mean nose bridge widths (Kruskal-Wallis p = 0.0001).

3.5 Influence of demographic variables and face size on respirator fit

There was a significant difference between proportions passing the respirator fit test in the different race groups (figure 4). Table 23 shows the proportion of NHLS study population who passed and failed respirator fit testing by sex and race group.

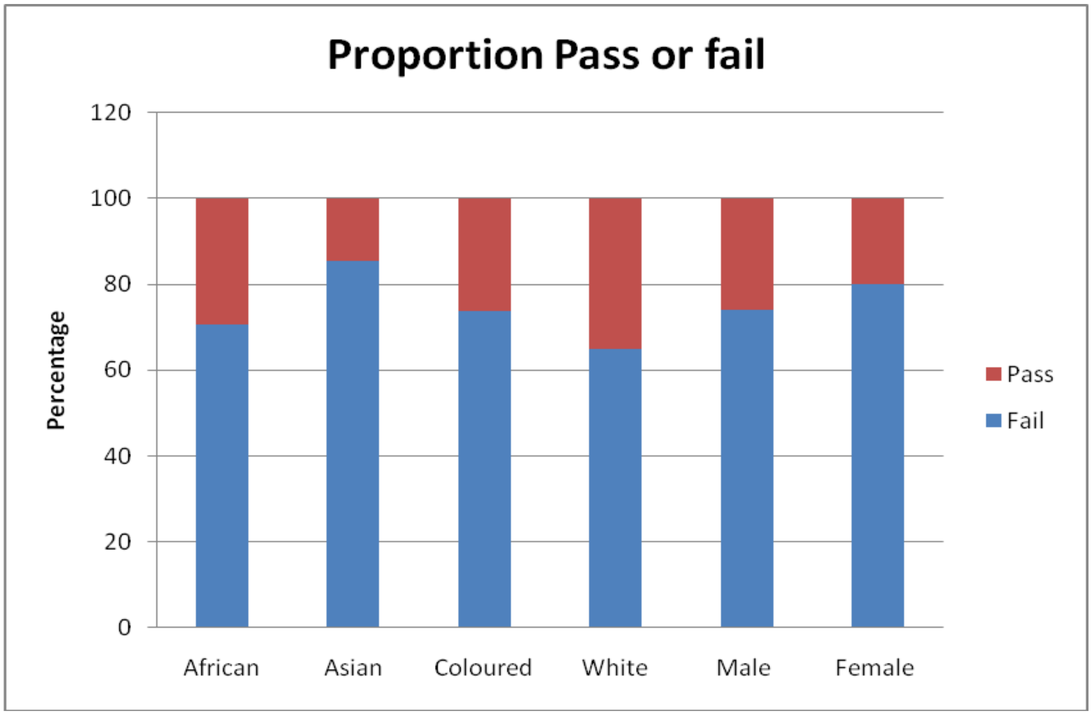


Figure 4: Proportion passing or failing fit test by race group

Table 23: Proportion of NHLS study group that passed or failed by sex and race group

Pass/ Fail	African (%)	Asian (%)	Coloured (%)	White (%)	Total
Fail women	172 (75)	50 (96)	28 (80)	50 (82)	300 (80)
Fail men	101 (74)	9 (90)	14 (78)	13 (65)	137 (74)
Pass women	57 (25)	2 (4)	7 (20)	11 (18)	77 (20)
Pass men	36 (26)	1(10)	4(22)	7(35)	48(26)
Total	**366**	**62**	**53**	**81**	**562**

A significant difference was found between the numbers of Asians failing compared to the other race groups (Kruskal-Wallis p = 0.0001). A significant decrease in the numbers of females passing was seen compared to males (Wilcoxon rank sum p= 0.0044). Table 24 below shows a mean fit factor of those who failed and passed by race group.

Table 24: Mean fit factor for those who failed and passed by race groups

Race	n		Median fit factor		Min		Max	
	fail	pass	fail	pass	fail	pass	fail	pass
African	273	93	33	156	2	100	99	419
Asian	59	3	19	177	2	109	98	222
Coloured	42	11	33	145	5	101	84	239
White	63	18	34	158	3	104	98	221

The mean fit factor for those who failed was significantly (Kruskal-Wallis p= 0.0139) lower amongst Asians, suggesting even less protection among Asians who failed than other race groups. All race groups achieved a mean fit factor pass which was well above 100 required for passing fit testing. The highest fit factor achieved in the African group was 419 which was more than four times the required fit factor. The study participants included men and women as presented in Tables 25 and 26 below.

Table 25: Mean fit factor for those who failed or passed by sex

Fit factor	Women	Men	p-value
Mean Fit factor fail	36 (SD = 28)	43 (SD = 29)	0.01
Mean Fit factor pass	154 (SD =42)	160 (SD =53)	0.59

Significantly worse protection was seen in women who failed compared to men who failed. Table 26 shows the mean overall fit factor by sex with men with facial hair removed.

Table 26: Overall fit factor by sex, men with facial hair removed from the sample

Sex	Women mean (SD)	Men mean (SD)	p-value
Mean Fit factor fail	35.6 (28)	48.7 (33)	0.3056
Mean fit factor pass	154.0 (49)	165.3 (66)	0.0009
Total	**59.7 (57)**	**84.1 (69)**	

The overall fit factor on failing is significantly lower in women when men with facial hair were removed. There was no significant difference seen in pass rates between age groups (Table 27).

Table 27: Proportions passing and failing by age group

Overall fit factor	19 - 30	31- 40	41- 50	51+	Total	p-value
Fail	171 (75%)	122 (70%)	72 (75%)	69 (65%)	434 (72%)	0.452
Pass	58 (25%)	53 (30%)	24 (25%)	38 (36%)	173 (29%)	0.702
Total	**229**	**175**	**96**	**107**	**607**	

There was no significant difference seen in pass rates between age groups. Any age group was as likely as each other to achieve a fail or pass fit factor. The proportion of those who passed and failed fit testing by face size is shown in Table 28 below.

Table 28: Proportion passing and failing by face size

Face size	Small	Medium	Large
Pass	43 (20%)	116 (34%)	11 (27%)
Fail	165 (80%)	229 (66%)	30 (73%)
Total	**424**	**170**	**594**

Chi2 p = 0.000 between small and medium Chi2 p=0.395 between medium and large
Chi2 p = 0.273 between small and large

There was a significant difference in the proportion of those who failed according to face size between small and medium faces but not between medium and large and small and large (Table 29).

Table 29: Face size and proportion of those achieving a good or poor fit for medium size respirators only

Face size	Small	Medium	Large
Pass	40 (22%)	108 (34%)	30 (73%)
Fail	140 (78%)	214 (66%)	11 (27%)

Chi2 for trend p = 0.000

Employees who were wearing a medium size respirator were significantly more likely to fail if they had a small or medium face.

The nose bridge width could have influenced the fit of the respirator. Table 30 describes the overall average fit factor and range of the NHLS study population.

Table 30: A description of overall average fit factor and range of study population by face size

Face size	n	Mean (SD)	Median	range
Small	192	49 (50)	29	1.8 – 260
Medium	316	72 (60)	58	2 – 265
Large	38	70 (62)	53	6 - 274

A significant difference (Kruskal-Wallis p = 0.0001) was seen in overall fit factor between face sizes. There was a difference between small and medium and large face sizes but no difference was seen in the fit factor between medium and large (Table 31).

Table 31: Nose bridge width and mean respirator fit for medium size respirators

Group	n	Mean fit factor	Std. Dev	95 % Conf. Interval	
Narrow	397	57.1	52.9	51.8	62.3
Wide	148	82.3	66.3	71.5	93.1

t-test p = 0.0000

There was a significant difference in mean fit factor between nose bridge width groups (Table 32).

Table 32: Nose bridge group and proportion of those who passed and failed

Proportion	Wide nose bridge	Narrow nose bridge	Total
Pass (n)	53 (36%)	68(17%)	121 (22%)
Fail (n)	95 (64%)	329 (83%)	424 (73%)
Total (n)	148 (100%)	397 (100%)	545 (100%)

Odds ratio = 2.69 p = 0.0000

The odds of passing a respirator fit test are 2.7 times more in those people with wide nose bridges compared to those with narrow nose bridge.

Multiple linear regression analysis was then conducted to identify significant predictors of successful fit as measured by quantitative fit testing; a significant model was generated stratified by sex for women (Table 33).

The same model in men was not significant and therefore is not presented. This model was not good possibly due to the small numbers (n=179) and large variation in men.

Sex is an effect modifier so two multiple linear regression regressions were conducted, one for each sex.

Table 33: Multiple linear regression analysis of fit factor and facial characteristics, race group and age for women

	Unadjusted p-value	**Adjusted p-value**
Face size	0.0001	0.046
Nose bridge width	0.0000	0.000
Head circumference	0.453	0.222
Race group	0.0001	0.618
Age	0.7727	0.493

The model was significant and provided an adjusted R squared of 0.93. Face size and nose bridge width were both significant predictors of overall fit. The model generated explained 9% of the variation in fit factor.

CHAPTER 4: DISCUSSION

Respirators are widely used within the NHLS diagnostic laboratories to provide protection against inhalable hazardous biological agents. At the time of the study, there was no respiratory protection programme implemented at NHLS laboratories to ensure employees are protected by the supplied respirators. A good respiratory protection programme includes medical evaluation of the user, selection of correct type and size, training and information on the correct use and respirator fit testing.

This study investigated the quantitative respirator fit of NHLS respirator users while wearing their currently supplied respirators. Each laboratory has dedicated personnel for requesting respirators from the purchasing department. However employees were not aware of the different respirator sizes which were available on the market. This may explain the predominance of medium size respirators in the NHLS.

Quantitative respirator fit has been shown to give a meaningful approximation of actual protection in the actual workplace environment (22, 47). N95 respirators are supplied within the NHLS laboratories which are suitable for hazardous biological agents (17). However 91% of the supplied respirators are medium and the brand most commonly used is 3M 1860 accounting for 68% of respirators. Since faces come in different sizes and a medium size respirator of one style such as 3M 1860 would not be expected to fit all employees.

Of the 610 employees who participated, the majority had tertiary qualifications and occupied technologist, medical scientist and laboratory manager positions. Approximately 13 % of participants were laboratory assistants and administration. This suggests that understanding donning and doffing requirements should not be a problem.

4.1 To determine the proportion of NHLS respirator users achieving an adequate fit

Of the 562 employees who were fit tested with the disposable respirators currently supplied to them, only 22% passed and were protected by their current supplied respirators. Since such a high proportion of participants failed the fit testing a widespread false sense of protection is likely within the NHLS. This result is in agreement with the findings of the pilot study by Spies, which investigated respirator fit among 30 South African NHLS employees: 86 % failed the fit testing using a medium size respirator (15).

A large Australian study (4472 health care workers) found a high proportion of good fit 82.9% with the first respirator tested (48). This study cannot be compared to ours in terms of proportion of participants passing as they selected respirators with the aim of achieving good fit (48). Another study in Australia which supports our findings found 84%, 72% and 66% health care workers failed their fit tests on 3 respirators types (49).

Thus limited literature was available to compare to our findings of proportions passing fit testing on one respirator as most countries which use fit testing regularly do not conduct prevalence of achieving fit studies, as they are well aware of the need for the right size respirator to match facial characteristics.

The race group which achieved the highest proportion of fit factor passes was White (27%) followed by Africans (26%) a drop of pass rate was seen in the Coloureds (21%) while the Asian group achieved the lowest proportion at 7%. Race has been found to be a significant predictor of fit in other studies (48), (36) which supports our finding. However, in multiple linear regression analysis of fit factor, race was not found to be an independent risk factor in women suggesting that race is merely a proxy for more proximal factors such as face size and nose bridge width.

Male participants achieved a significantly higher proportion of passes than women. Although a higher proportion of females (80%) failed fit testing as compared to male participants, there was initially no significant difference (p=0.139) among the two sexes. However some male participants were not clean shaven at the time of the fit testing and the association of sex with passing was significant (p=0.043) when all men with facial hair were removed from the group.

This is confirmed by the findings of the study (50) that investigated the effect of facial hair on the face seal of negative-pressure respirators. The significant effect of both race and sex can be used to predict fit of a supplied respirator for an individual in the absence of facial dimensions. This can be used to issue the respirator most likely to fit while waiting for fit testing.

The ages of participants ranged from 19 to 84 years with 66% of participants younger than 40 years. In age group 19-30 years, 78% failed the fit test while participants from 50 years and above achieved a similar fail rate of 75%, with no significant difference between age groups. This is in agreement with Oestenstad et al.,2007 study finding which showed no significant difference in respirator fit between males and females (51).

However, this is contrary to the findings of Zhuang and colleagues (35) where they found a significant difference in 19 facial characteristics for subjects 18 – 29 compared with those at least 45 years. The high proportion of participants 19-30 years of age in our study may have influenced our finding of no significant difference in age.

The mean fit factor for those who failed fit testing was 38 and this is far below the minimum required fit factor for a pass of 100. The fit factor achieved for all the participants ranged from 1.8 - 419. The lowest mean fit factor fail was 27 and was observed in the Asian group and the highest fit factor was 41 for Whites. The lower the fit factor the less protection provided by wearing the respirator.

4.2 To measure and describe four facial dimensions of selected NHLS respirator users

Four facial dimensions which are found to be relevant to respirator fit based on studies (30, 33-35) were measured during this study. Measurements included face length, face width, nose bridge width and head circumference. These measurements are useful in predicting the best respirator size or style for each individual.

The face lengths and widths measured in this study were plotted on the NIOSH fit test panel to investigate the distribution of the NHLS data and to assign face sizes. The NHLS data distribution showed that collected data consisted mainly of small and medium faces and most of outliers were very small faces.

Thirty-five percent, 58% and 7% of the participants had small, medium and large faces respectively as described by the NIOSH fit test panel. The NHLS participants did fall within the NIOSH fit test panel but the distributions were different between the cells. This implies that respirators designed using the NIOSH panel may not be ideal for South Africans. Respirators are needed for the very small faces which may not achieve a fit even with a small size respirator currently distributed by suppliers.

These findings suggest a need for a study to investigate the applicability of the NIOSH fit test panel to the South African population. Face size is based on face length and face width but two other characteristics are suspected to play a role in South African fit. The first is nose bridge width where the respirator needs to be moulded to fit and secondly head circumference which affects how tightly the respirator straps pull the respirator to the face.

Our study showed that the smaller your face the more likely you are to have a narrow nose bridge width (p=0.00). The significant influence of nose bridge width on respirator fit was also a finding in the study done by Wilkinson in 2010 (48).

Sex was a key determinant of face size: this study showed a significant difference between proportions of women with small faces compared to men with small faces. There was also a significant difference in proportions of face sizes amongst the race groups: 72 % of Asians had small faces compared to 27 % for white.

Only 3% of large faces were observed in the Asian race group. While the highest percentage of medium faces were observed in Whites (64%), followed by Africans (63 %) and Coloureds (56 %). The Zhuang et al., 2010 study revealed that race or ethnicity is second to sex for impacting on face size and shape characteristics and suggested that sex is a critical variable in determining respirator sizing.

4.3 To describe respirator fit factor and its association with facial characteristics, race and sex

A significant difference in respirator fit was found between Asians compared to the other race groups. A study by Wilkinson in 2010 (48) showed similar results, Asians had the highest failure rate as compared to other race groups that participated. Significantly less protection was seen for women of all races compared to men. This is consistent with the study by Han in 2000 (52) which found that medium respirators were more suitable for males than females in fitting performance.

Our study showed a significant difference in the proportions of those who failed according to face size (small, medium and large), similar to the findings of the study by Zhuang (30). The NHLS sample population consisted mainly of medium size faces yet despite this the majority of the sample failed fit testing on a medium respirator. The reason for poor fit with medium size respirator for medium faces could be due to the influence of other factors not always associated with face size, one of which is nose bridge width. The odds of passing a respirator fit test were found to be 2.7 times more likely in those people with wide nose bridges compared to those with narrow nose bridges. Thus respirator design needs to take possible narrow nose bridge width into account.

Multiple linear regression analysis showed that face size and nose bridge width were both significant predictors of overall fit. The results of the multivariate analysis of the study by Wilkinson et al. (48) supported our findings which also showed nose bridge width to be one of the best predictors of a successful fit.

4.4. LESSONS LEARNED

A number of lessons were learned during this study:

1. NHLS respirator users were not aware of information relating to the use of respirators.
2. Not all participants were given formal training on proper fitting, wearing and limitations of respirators.
3. The majority of employees were not aware of different respirator sizes and styles available.
4. The perception of “one size fit all” respirator size was mentioned by most participants.
5. Different respirator sizes were available in a few laboratories but employees could not differentiate between the two sizes.
6. Male employees had no idea of the effect of facial hair on achieving a good seal.
7. Procurement in these laboratories was not aware of the possibilities of receiving respirators which may not be adequately tested and certified for use (homologated), therefore stock is not checked for such upon receiving.

Respirator fit testing in South Africa is not regulated therefore it is perceived as an optional responsibility by many organisations including the NHLS. None of the laboratories was aware of the need or had compiled and implemented a respiratory protective programme.

4.5 LIMITATIONS

The limitations of this study include that it is of cross sectional design and participants were drawn from selected laboratories in three big cities and not randomly selected which may have resulted in some selection bias. The representation of race group and sex was not equal and this may also introduce some selection bias. Two respirator styles, cup and duck bill shapes were used and since face size play a role in the difference in fit between the two brands, this was not noted.

Head circumference was difficult to measure and thus determine its true effect on fit due to some religious groups wearing head coverings and other groups with braids. The numbers collected in this study were insufficient for a powerful analysis of determinants of fit. Smoking is a confounder to accurate measurement of fit so participants were requested not to smoke for 30 minutes prior to the testing but this instruction may not have been followed.

5: CONCLUSION AND RECOMMENDATIONS

5.1 Conclusion

This study shows that reliance on medium respirators is likely to be a major problem as it provides a false sense of protection to employees leaving them unprotected. The large percentage (78%) of employees in this study sample achieving poor fit with their current respirator indicates a need for urgent testing of all NHLS respirator users and an increased range of respirators to be provided to all staff requiring respirators.

The use of poorly fitting respirators could create an impression of false protection in the laboratories where employees were possibly exposed to HBAs including TB. Female employees accounted for a higher proportion of participants with small face sizes and were more at risk as the majority of currently supplied respirators were medium sizes and not likely to fit them. This also leads to a large amount of money being spent on purchasing ineffective respirators at the NHLS.

Asians achieved the lowest proportion at 7% when compared to other race groups and were less protected by the current supplied respirators. Since face size and nose bridge width were found to both be significant predictors of overall fit, this study finding may be useful during the selection the respirator size and style likely to fit the individual prior to respirator fit testing.

5.2 Recommendations

All participants who failed fit testing were recommended a style and size of respirator most likely to fit them adequately. These newly recommended respirators need to be fit tested on the participants to ensure that they are providing sufficient protection. Employees who passed fit testing were recommended to undergo fit testing at regular intervals such as once every two years or when required to do so i.e. when a new respirator is to be used, during and after pregnancy and when one has gained or lost significant amount of weight. Another recommendation made to NHLS was to procure their own equipment and training to allow regular fit testing across the country.

It was also recommended to the NHLS that laboratories should designate Safety Health and Environment Officers (SHE) to compile and implement a respiratory protection program (RPP).

An effective RPP should include the following constituents (21):

- Risk assessment
- Medical evaluations
- Selection of respirators
- Training and information
- Respirator fit testing
- Respirator maintenance and care
- Program evaluation
- Record keeping

The NHLS also needs a clean shaven policy for all male respirator users and going forward job advertisements for new posts where respirators are required need to include specifications on shaving.

Future research on respirator fit in South Africa should investigate the applicability of currently used Americans RFTPs to South Africans. Also the reliance on respirators by South African workforce including NHLS respirator users may create a false sense of protection; research is needed to identify exposure controls at source that can reduce reliance on respirators.

Appendix 1: Senate plagiarism policy

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SENATE PLAGIARISM POLICY: APPENDIX ONE

I, Mafanato Jeanneth Manganyi (Student number: 330342) am a student registered for the degree of Master of Occupational Hygiene (Occupational Hygiene) in the academic year 2015.

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.
- I have included as an appendix a report from "Turnitin" (or other approved plagiarism detection) software indicating the level of plagiarism in my research document.

Signature: ____________________ Date: 25 May 2015

Appendix 2: Ethics clearance certificate

R14/49 Ms Jeanneth Manganyi et al

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M131147

NAME: (Principal Investigator)	Ms Jeanneth Manganyi et al
DEPARTMENT:	Occupation Health National Health Laboratory Service
PROJECT TITLE:	A Study of Respirator Fit and Face Sizes of National Health Laboratory Service (NHLS) Respirator Users during 2013-2014
DATE CONSIDERED:	29/11/2013
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Prof David Rees/Ms Kerry Wilson
APPROVED BY:	Professor A Woodiwiss, Co-Chairperson, HREC (Medical)
DATE OF APPROVAL:	18/12/2013

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 Secretary in Room 10004, 10th floor, Senate House, University.
I/we fully understand the conditions under which I am/we are authorized 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 the application to the Committee. **I agree to submit a yearly progress report**.

Principal Investigator Signature   Date 08/01/2014

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Appendix 3: 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 beyond his reach, his friends say he is looking for the pot of gold at the end of the rainbow.

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