

**Use and fit of filtering facepiece respirators in a department of
anaesthesiology**

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A research report submitted to the Faculty of Health Sciences, University of the
Witwatersrand, in partial fulfilment of the requirements for the

degree of

Master of Medicine in the branch of Anaesthesiology

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Declaration

I, Marthinet Niemandt declare that this research report is my own work.

It is being submitted for the degree of Master of Medicine in the branch of Anaesthesiology at the University of the Witwatersrand, Johannesburg. It has never been submitted before for any degree or examination at this or any other University.

.....

..... day of November, 2016

Dedicated to those friends and colleagues who contracted tuberculosis while serving patients.

Abstract

Background: Reliable protection against nosocomial tuberculosis transmission in theatre depends on the appropriate use of filtering facepiece respirators (FFRs) with an N95 filter, as recommended by the Centers for Disease Control and Prevention.

Aim: To describe anaesthetist compliance and comfort with the use of FFRs, followed by donning technique and fit tests outcomes.

Design: Prospective, contextual, descriptive, two part study.

Setting: Part 1 was done in a university affiliated department of anaesthesiology. Part 2 was a pilot study in the theatre complex of a 1200-bed tertiary-level academic hospital.

Participants: Part 1 – anaesthetists in the department selected by convenience sampling (n=140). Part 2 – anaesthetists selected by stratified random sampling (10 male and 10 female).

Methods: In Part 1 a self-administered questionnaire was distributed. In Part 2 the donning technique was directly observed, corrected, then followed by qualitative fit testing with the single model and size FFR available.

Results: Part 1 -Compliance with the use of the FFR was inadequate with a compliance score of 14.5 (SD 5.0) out of 25. FFRs are deemed to be uncomfortable (discomfort score of 9.9 (SD 4.0) out of 21.) Part 2 - Of the 20 anaesthetists, six (30%), five males and one female, passed the fit test.

Conclusions: Compliance with FFR use was poor and anaesthetists at the research institution found the FFRs uncomfortable. FFR donning technique was observed to be lacking. Research with a larger study group is required. Poor fit test results were most likely due to the availability of only one size and model of FFR.

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List of Abbreviations

BCG:	Bacillus Calmette–Guérin
CDC:	Centers for Disease Control and Prevention
CI:	Confidence interval
CMJAH:	Charlotte Maxeke Johannesburg Academic Hospital
CSIR:	Council for Scientific and Industrial Research
FFP:	Filtering facepiece
FFR:	Filtering facepiece respirator
HCW:	Healthcare workers
HIV:	Human immunodeficiency virus
IQR:	Interquartile ranges
KZN:	KwaZulu-Natal
MDR-TB:	Multi-drug resistant tuberculosis
NIOSH:	National Institute for Occupational Safety and Health
OSHA:	The Occupational Safety & Health Administration
SANS:	South African National Standard
SD:	Standard deviation
TB:	Tuberculosis
TST:	Tuberculin skin test
UVGI:	Ultraviolet germicidal irradiation
USA:	United States of America
Wits:	University of the Witwatersrand
WHO:	World Health Organisation
XDR-TB:	Extensively drug-resistant tuberculosis

Section 1: Review of the Literature

1.1 Introduction

The tuberculosis (TB) epidemic remains a global challenge. The purpose of this literature review is to portray the background of anaesthetists' vulnerability and the protection required against occupational TB transmission.

An initial description of TB in South Africa is followed by the pathophysiology and transmission of TB. The context of drug resistant TB and the high prevalence of co-infection with HIV in South Africa are illuminated.

The phenomenon of nosocomial transmission of TB is depicted, with emphasis on the risk of transmission to healthcare workers (HCWs). Guidelines for TB infection control in hospitals are described with an in depth exploration of personal respiratory protection devices, their history and classification, with specific focus on the filtering facepiece respirator (FFR). The importance of an impenetrable face seal is clarified together with methods to check the face seal such as the self-fit check and the fit test. Different fit tests and their procedures are described.

Literature regarding the use of FFRs is organised into FFR performance, face fitting characteristics and HCW compliance with the use of the FFR. A summary of where the FFR fits into the recommended international and South African infection control guidelines as well as local guidelines for infection control at Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) follows.

Anaesthetists are a vulnerable group of HCWs due to their proximity to patients with potentially undiagnosed TB. Anaesthetic manipulation may cause coughing, which results in aerosolisation of infectious droplets. The guidelines on the perioperative management of the patient with active TB are discussed.

1.2 TB in South Africa

1.2.1 Incidence

The World Health Organisation (WHO) estimated in 2014 there were 9.6 million new diagnoses of TB worldwide and that TB killed 1.5 million people globally. South Africa suffers severely with an estimated prevalence rate of 696 cases per 100 000 people weighed against the worldwide average of 133 cases per 100 000 people. (1) According to the WHO statistics an estimated 450 000 new cases of active TB were diagnosed in South Africa in 2013. (2) The implication is that almost 1% of the 50 586 757 South African population (3) will develop active TB disease every year. (4) The consequences of TB are more far reaching than the morbidity and mortality numbers imply, because most TB patients are in the economically active population group of 15 - 64 years of age. (5)

1.2.2 Pathophysiology and transmission

The unique way that TB spreads from human to human is different to that of many other infectious pathogens, such as adenovirus or rhinovirus, where droplet spread happens by surface contact. (6) Transmission is by airborne particles called droplet nuclei. When a person with active TB coughs, talks, sings or sneezes, these particles are expelled. One cough potentially produces 3000 droplet nuclei of 1 - 5 micrometres in diameter. This explains why pulmonary as well as laryngeal TB is highly contagious. When these droplet nuclei, containing 1 - 5 bacilli each, are inhaled the mycobacteria will begin to replicate in the recipient's alveoli. Between 1 and 10 bacilli are infectious and can cause either latent or active disease. Of those with normal immunity who get infected, 10% will develop active disease (half of these in the first two years and half later on in life) and 90% will develop latent TB. It is more probable that immune compromised individuals will develop active TB than those with normal immunity. (7)

Direct sun- and ultraviolet light kill the tubercle bacillus. For that reason most transmission happens in dark and poorly ventilated areas. Droplet nuclei remain airborne for up to four hours. Close contact and prolonged exposure to contaminated air increase the risk of transmission. The higher the concentration of bacilli in the air, the higher the likelihood of TB transmission is. (7)

1.2.3 Relationship with HIV

TB and HIV have been described as “synergistic pandemics”. (8) Advancing immunosuppression increases the host’s susceptibility to TB infection, which causes an escalation in the number of TB cases and complicates the natural course and pattern of disease. The diagnosis of TB becomes more challenging in cases of established HIV. (7)

The Annual Performance Plan of 2012/13 - 2014/15 of the South African Department of Health states that 73% of patients with TB are also HIV positive. (9) Globally the WHO estimates this number to be around 77%. (1) It is reckoned that 10% of newly diagnosed HIV positive patients have undiagnosed TB. A patient with HIV has an annual risk of 10% of contracting TB, compared to an HIV negative patient’s lifetime risk of 10%. (7)

Limited data is available regarding the incidence of HIV among patients presenting for surgery in South Africa. Approximately 20 – 25% of patients with HIV will need an operation during the course of their disease. (10)

1.2.4 Multi-drug resistant TB and extensively drug-resistant TB

Worldwide an estimated 3.3% of newly diagnosed cases and 20% of formerly treated cases are multi-drug resistant TB (MDR-TB). The WHO reports 4700 (3700 – 5900) notified cases of MDR-TB in South Africa in 2014. (1) Since 2006 extensively drug-resistant (XDR-TB) strains pose unparalleled public health challenges, especially when considered in the context of insufficient infection control practices. In 2010 there were 741 confirmed cases of XDR-TB, a disease that is exceptionally challenging and costly to treat and has a very high mortality. (7) It was previously thought that drug-resistant TB arises primarily from poor treatment adherence of drug-susceptible TB, but D’Souza et al (11) confirmed in Mumbai high levels of MDR-TB in treatment naïve individuals.

1.3 Nosocomial TB

1.3.1 TB and HCWs

Healthcare facilities harbour high density populations of potentially contagious patients. Hospital acquired TB is a threat to other patients, and an important occupational hazard for HCWs who are often inadvertently exposed to undiagnosed TB infected patients. It would

be unfeasible to calculate the absolute number of HCWs who get infected with TB in healthcare facilities, because by the time the diagnosis is made it may be a considerable time since the incident of exposure. MDR- and XDR-TB amplify the daily perils HCWs face. (12)

Menzies et al (13) conducted a systematic review to investigate the prevalence and incidence of TB among HCWs. Twelve studies from “low and middle income countries” from 1960 - 2005 were included and it found “the median prevalence of latent TB infection” among HCWs from these countries to be 63% (range 33 – 79%). The median prevalence from the eight studies from high income countries from 1992 - 2005 was 24% (range 4 – 46%). In these countries latent TB infection was reliably related to occupational exposure. HCWs had disproportionately higher rates of active TB than the overall population.

A meta-analysis by Baussano et al (14) used data extracted from 43 studies published from January 2005 to July 2010 to calculate the incidence rate ratio of TB infection among HCWs. Incidence rate ratio is explained as the difference in the risk of HCWs contracting TB compared to the risk of the overall population, indicating the fraction of TB infection in HCWs ascribed to healthcare setting exposure. The median estimated TB incidence rate ratio for countries with a high incidence of TB (>100 cases per 100 000 persons) was 5.4 (interquartile range 1.7 - 9.1.) The analysis is limited by substantial heterogeneity between studies. No studies from South Africa were included.

A study by the University Research Company (15) together with the Desmond Tutu Tuberculosis Centre investigated the magnitude and effect of occupational TB transmission on HCWs in 132 randomly selected South African healthcare facilities in 2008. They found South African HCWs have an average TB burden of 2%. This number may underreport the true incidence as only 40% of the facilities investigated had an employee TB screening program as well as an official occupational health policy in place.

Tudor et al (16) conducted a retrospective cohort study from 2006 to 2010 in KwaZulu-Natal (KZN). They analysed 1313 HCWs' files and found 112 (9%) diagnoses of TB during that time. The incidence rate of TB in HCWs in this sample was calculated as 1958 per 100 000 person-years for 2010. The incidence of TB in South Africa at the time was 981 per 100 000. In the same study it was found that among the 112 HCWs with TB, 15 (13%) had MDR-TB. These

cases all occurred in HCWs who had never even worked in a TB ward. Thirteen of these HCWs died from TB disease. The poor quality of occupational clinic employee records is a limitation, as those with missing data were excluded. Some HCWs probably received their TB treatment outside the hospital and healthy employees did not have charts at the occupational health clinic, resulting in exclusion and inclusion bias. Risk factors for TB transmission elucidated by this study are HIV co-infection and a history of working in certain areas, including TB wards, paediatric wards, outpatient departments, stores or workshops. The prevalence of HIV among HCWs in South Africa was 16% in 2002. (17) Diabetes and other chronic illnesses are also potential risk factors (18), but this was not investigated. The authors advocate routine TB screening of HCWs, and improved infection control procedures throughout the hospital.

O'Donnell et al (19) conducted a retrospective review of the charts of patients hospitalised for commencing MDR or XDR-TB treatment between 2003 and 2008 at a KZN referral hospital. A total of 231 HCWs (55% HIV positive) and 4151 non-HCWs (57% HIV positive) were included. The incidence of MDR-TB cases was estimated at 64.8 per 100 000 HCWs versus 11.9 per 100 000 "non-HCWs" (incidence rate ratio of 5.46). Occupational XDR-TB cases were estimated to have an incidence of 7.2 per 100 000 contrasted with 1.1 per 100 000 in "non-HCWs" (incidence rate ratio of 6.69). As the setting studied was a TB referral hospital, the findings are subject to referral bias.

Occupational TB has debilitating consequences for a HCW's personal and professional life. Padayatchi et al (20) conducted a case series of five HIV negative doctors diagnosed with MDR-TB between 2000 and 2003 in South Africa, to determine the long-term psychosocial sequelae they suffered. Four of the five doctors (80%) decided to change the course of their career to work in specialist areas with negligible exposure to infectious patients. The fifth doctor suffered significant physical disability and has not been able to work since falling ill. All but one are still suffering from long term complications many years after completing treatment, including hearing impairment, deafness, tinnitus, anxiety, panic attacks, short term memory impairment, weakness, pain, neuropathy, loss of bladder and bowel control.

Naidoo et al (21) explored individual "experiences, attitudes and perceptions" of 40 medical doctors who became infected with TB from 2007 to 2009 in KZN. Only two (5%) doctors

previously worked in a specialised TB clinic or ward. Enduring the treatment was difficult for 27 (67.5%) doctors and 13 (32.5%) considered defaulting. Feelings of regret for choosing a career in clinical medicine were reported, as well as feelings of anger and resentment towards the patients who infected them. TB causes the South African healthcare system to lose HCWs to absenteeism, disability, demoralisation, hospitalisation and death. A HCW with active TB endangers both patients and colleagues. (22)

1.3.2 TB infection control

In South Africa it is the responsibility of the employer to provide a “reasonably safe workplace without risk to the health of employees” according to the Occupational Health and Safety Act No. 85 of 1993. (23)

Methods to prevent TB transmission in healthcare environments were categorised by the Centers for Disease Control and Prevention (CDC) into three hierarchical components. (24) Firstly **administrative measures** aim to decrease the actual number of infectious droplets coughed into the air by prompt and accurate diagnosis, isolation and treatment of TB patients. Cough hygiene practices are an example of such respiratory source control. A coughing patient with active, untreated TB should use a surgical facemask in public spaces as a short-term measure.

Secondly, **environmental or architectural measures** are aimed at eliminating the number of droplets present in the air. These measures include natural or mechanical ventilation systems and extractor turbines, sunlight or ultraviolet irradiation (25, 26), high-efficiency particulate air filters on exhaust air outlets and negative air ionisation. (2)

The third component comprises personal protective equipment, specifically the correct and consistent use of personal **respiratory protection devices**. (27) As this is the focus of the study it will be discussed in more detail.

1.4 Respiratory protection devices

Classification of respiratory protective devices

Both masks and respirators have a facepiece that is tied to the user's head with straps or elastic bands. There is a clear distinction between masks and respirators. Masks are intended to protect the surroundings (such as the operating field) from particles and droplets produced by the user. Some surgical masks are specialised to protect the user from fluids splashes, but commonly masks do not reduce exposure of the wearer to bio aerosols and airborne particles. Masks cannot create a tight-fitting seal with one's face. (29)

A respirator is a device with the purpose of providing the wearer with a recognised level of respiratory protection from inhaling aerosolised contaminants. Two main categories of respirators exist: an **air-supplied respirator** delivers piped clean air from an unpolluted source, avoiding the harmful particles, fumes or gases completely. An **air-purifying respirator** allows polluted air to flow through a filter, thereby entrapping particulate matter and delivering the user with purified air distal to the filter. (30) Since the filters cannot be cleaned, respirators are either disposable, single-use models with a limited lifespan, or the more expensive reusable types with replaceable cartridges.

Respirators can also be classified according to the part of the face that is covered. A **full face respirator** covers the entire face. The facepiece of a **half face respirator** should cover the nose, mouth and chin. The type of respirator required depends on the type of hazard to be encountered. Half face respirators should be used when there is no risk of harm to the eyes or skin. A **quarter face mask** covers the mouth and nose, it is not considered a respirator. (30)

Respirators are used by the military, mining-, science- and health industry among others. A HCW needs an appropriate disposable air-purifying respirator that filters airborne particles, for personal respiratory protection against pathogens such as the infectious droplet nuclei carrying TB bacilli expelled by coughing patients. (28)

Respirators can be further classified according to the filter used. The National Institute for Occupational Safety and Health (NIOSH) is the USA Government agency that certifies and approves respiratory protective devices for use in the workplace. The N, R and P

designations depict how oil resistant the filter is. The efficiency rating refers to the percentage of airborne particles that are filtered. Table 1.1 depicts the CDC classification on NIOSH-Approved Particulate filters. (31)

Table 1.1 Classification according to the type of filter (31)

Filter	Oil resistance	Efficiency rating (percentage of airborne particles filtered)
N95	None	At least 95%
N99	None	At least 99%
N100	None	At least 99.97%
R95	Somewhat resistant	At least 95%
R99	Somewhat resistant	At least 99%
R100	Somewhat resistant	At least 99.97%
P95	Strongly resistant	At least 95%
P99	Strongly resistant	At least 99%
P100	Strongly resistant	At least 99.97%

1.5 Filtering facepiece respirator

The N95 FFR is the most affordable of the nine types of particulate FFRs that meet NIOSH requirements, and is thus the most popular in industrial and healthcare settings. (31, 32) In the literature this product is referred to as the FFR but colloquially it is often erroneously referred to as the “N95 mask”. The FFRs are available in variations of a firm cup shape as shown in figure 1.1, also called a tortoise-shell shape, and in a softer duck bill shape.

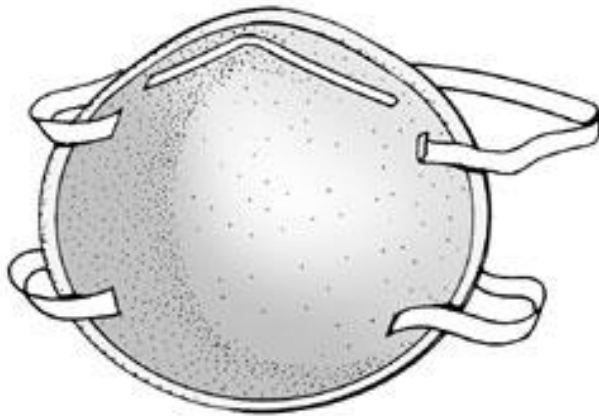


Figure 1.1 A filtering facepiece respirator (33)

A NIOSH approved N95 FFR may not allow more than 5% penetration of aerosolised sodium chloride particles (diameter 0.3 micrometre) at a flow rate of 85 litres per minute. (34)

To determine filtration efficiencies of N95 FFRs, Qian et al (35) calculated aerosol mass concentrations inside different companies' N95 FFRs by doing measurements with particle-size spectrometers, using bacteria with a similar size and shape to TB bacilli. They showed mean filtration efficiencies of more than 99.5%. Penetrated mass fraction is the term used to describe the aerosol mass that penetrated the filter as a fraction of the aerosol mass it was challenged with. When there is no leakage around the edges of the respirator, the penetrated mass fraction of the respirator is 0.02% for larger particles and 1.7% for particles smaller than a micrometre in diameter.

Leaking around a poor face seal is the limiting factor when it comes to the protection offered by a FFR. The European Committee for Standardization requires that respiratory protective devices are tested for total inward leakage, a measure of how much ambient air leaks into the breathing zone between the skin and the FFR. This can be determined in a laboratory by using either aerosolised sodium chloride or sulphur hexafluoride. (36)

The South African National Standard for FFRs (SANS 50149:2003) as set by the Council for Scientific and Industrial Research (CSIR) is an identical implementation of the European Standards of Disposable Respirators (EN149:2001 Ed2). (37-39) The EN 149 standard is deemed to be superior to the NIOSH standard, because it includes the criteria for total

inward leakage, fit and seal. FFRs are classified as filtering facepiece (FFP) 1, 2 or 3. FFP1 reduces the wearer’s exposure to airborne particles by a factor of four and allows for 25% total inward leakage rate (refer to Table 1.2). In medical respiratory protection FFP2 respirators are recommended. The NIOSH approved N95 FFR cannot be compared to EN149:2001 standards as the test requirements are very different.

Table 1.2 European Standards of Disposable Respirators of EN149: 2001 (38, 39)

Classification	Protection factor	Filter penetration limit (at 95L/min air flow)	Inward leakage
FFP1	4	Filters ≥ 80% of airborne particles	<22%
FFP2	10	Filters ≥ 94% of airborne particles	<8%
FFP3	20	Filters ≥ 99% if airborne particles	<2%

The face-seal, the self-fit check and the fit test procedures shall be discussed.

1.5.1 The face-seal

The FFR can only protect the user if it is properly selected, correctly donned, forms an impenetrable seal with the user’s face and worn all the time that the user is exposed to potential airborne hazards. Appropriate doffing technique and disposal or maintenance are essential. The idea behind fit testing is to identify that small percentage of individuals who will have an inadequate fit with the first respirator they try. (36)

1.5.2 The self-fit check

In the absence of the time consuming fit test, the self-fit check gives an indication of the quality of the seal, but it does not replace proper fit testing. Manganyi and Wilson (40) recommended that employees be trained to perform a daily self-fit check (or seal check). The following self-fit check is recommended by the manufacturer 3M™ in the technical datasheet of the 3M™ Aura™ N95 Respirators. (41)

- Cup both hands to cover the front of the FFR without disturbing the seal.
- Forcibly exhale.
- Readjust the nose clip to eliminate leakage around the nose.
- Readjust the straps to eliminate leakage at the edges of the FFR.

1.5.3 Fit testing procedures

Fit testing follows a standard procedure to determine if a given model and size of FFR will fit the specific wearer and should be done with the same FFR that he/she will have access to in the field. (42) Qualitative or quantitative fit test methods are available.

Qualitative fit testing relies on a subjective response from the user to the agent tested. If the user cannot detect or smell a standardised indicator odour or mist while breathing through the FFR it means two things: the specific FFR has the potential to provide a satisfactory face seal with his or her face and that the user can don the mask correctly. The qualitative respirator fit test is affordable, uses simple equipment and is easily available from local dealers of personal protective equipment. (40) Clayton et al (36) make an important statement: "Passing a fit test does not guarantee that every time a wearer dons a facepiece an adequate fit will be achieved."

Quantitative fit tests objectively generate a fit factor number. This is mainly done for research and quality control purposes and requires expensive equipment like a condensation particle counting instrument (Portacount®) and a customised FFR fitted with a sampling probe connected to the particle counter with a sampling line. (43) Quantitative fit tests are superior to qualitative testing.

How often a fit test should be done is a matter of great controversy in the literature at the moment. Canadian, American and Australian guidelines demand either annual or biannual fit testing. In the United Kingdom a second fit test is only required when the user changes to a different respirator model or if the user has undergone major changes to his or her facial characteristics. This may happen in cases of severe weight loss or gain and also in cases of dentition alterations or surgery. (36)

Fit testing is mandatory in the USA according to the American Standard ANSI Z88.2 of 1969. The mandatory fit testing protocols are set out in the subpart on personal protective equipment in the Occupational Safety & Health Administration (OSHA) Standard 1910.134 Appendix A as published by the USA Department of Labor (44). A summary of the protocols will be discussed.

Fit testing is not regulated in South Africa and the National Infection and Protection Control Policy and Strategy (45) does not specify a protocol for fit testing. However the CSIR does not perceive it to be merely an optional responsibility and recommends that fit testing should be done initially as the worker is allocated to a place with potential TB contact, and thereafter it should be repeated at least annually. (46)

Fit testing procedures – general OSHA requirements

Most, but not all, of the general requirements are described here. (44) Employees are asked not to eat, drink, smoke or chew gum for half an hour before testing, so as to not confuse the taste of the test solution. Drinking water is allowed.

Guidance as to the proper technique of donning the FFR is given. A mirror should be available for self-observation. The employee selects a FFR from an adequate assortment of respirator styles and sizes. The FFR should fit comfortably on the employee's face, with room for protective eyewear and room to talk. (44)

OSHA criteria for acceptability of the FFR fit are:

- Chin properly placed;
- Adequate strap tension, not overly tightened;
- Fit across nose bridge;
- Respirator of proper size to span distance from nose to chin;
- Tendency of respirator to slip;
- Self-observation in mirror to evaluate fit and respirator position. (44)

The test is abandoned if the employee has facial hair that would hinder the FFR from forming a seal with the skin. This also applies to any type of apparel that cannot be removed and interferes with an acceptable fit. (44)

Employees will be asked to do the following exercises for qualitative and quantitative fit tests.

- Without talking, the employee breathes normally.
- The employee breathes slowly and deeply, avoiding hyperventilation.
- The employee slowly turns his/her head all the way from side to side. Inhale at each side.
- The employee slowly moves his/her head up and down. Inhale when looking upwards.
- The employee talks out loud. The subject can read from a text, or recite a poem.
- The employee bends over at the waist as if touching his/her toes. This exercise can be substituted by jogging on the spot.
- Normal breathing. (44)

Dedicate 60 seconds per exercise. The fit test is abandoned if the employee adjusts the respirator fit during the test exercises.

OSHA Qualitative fit test protocols

Isoamyl acetate (banana oil) fit test protocol

After screening for the employee's ability to smell banana oil, a chosen FFR is donned. The exercises described above are performed in the test chamber filled with the vapour of the isoamyl acetate. The fit test is failed if the employee becomes aware of the banana odour. He/she should leave the room, remove the FFR and repeat the test with a different size or model FFR until the test is passed. (44)

Saccharin and Denatonium Benzoate (Bitrex®) fit test protocol

Firstly the employee's ability to taste the test agent, which could be saccharin or Bitrex®, is screened for. The employee dons the fit test enclosure (a hood that fits over the head and shoulders) without wearing the FFR. The test conductor introduces a fine mist of diluted saccharin or diluted Bitrex® solution into the enclosure with a nebulizer. The nozzle of the nebulizer fits through a 1.9 cm hole facing the employee's breathing zone. The employee is asked to breathe with the mouth slightly open and the tongue extended. After 10 rapid

sprays the employee should try to detect the taste. More sprays may be introduced if needed. As soon as the employee reports tasting something, the screening test is completed. The employee may don the chosen FFR and proceed to the fit test.

The fit test is done with the employee wearing the FFR correctly donned inside the enclosure. The undiluted test solution is aerosolized through the hole while the employee breathes as indicated. The employee is requested to perform the exercises mentioned under general requirements. If the employee reports detecting the test solution, the fit is deemed to be unacceptable. An alternative FFR should be fitted and the entire procedure repeated. The employee shall only remain unaware of any taste or smell, if the FFR fits perfectly with no face leak shall.

Saccharin is a freely available artificial non-caloric sweetener approved in more than 100 countries and also by regulatory agencies that include the USA Food and Drug Administration, the Joint Expert Committee on Food Additives of the WHO, Health Canada and the European Food Safety Authority. (47)

Bitrex® is officially recognised in more than 40 countries as a safe “taste aversion agent” in domestic liquids to deter children from ingesting them. (48) It was approved in the United Kingdom and the USA in the early 1960s. (49) The bitter taste causes an almost involuntary reaction from the test subject, making false results unlikely. (44)

Stannic chloride fit test protocol

Smoke that is irritating to eyes and airways is used. (44) It is not discussed as other humane and environment friendly fit testing options are available.

Quantitative fit test protocols

Two quantitative fit test methods are available to test the seal of FFRs: Ambient test agent aerosol with a condensation nuclei counter, for example the Portacount® (most common method), or alternatively the controlled negative pressure FitTester 3000TM capable of determining the volumetric leak rate of the FFR (44). The equipment for these tests are expensive to come by and won't be discussed further.

1.5.4 Design of FFRs

Manufacturers design FFRs based on anthropometric data on facial characteristics and sizes obtained from large numbers of people grouped into “respirator fit test panels”. These panels were originally developed by the NIOSH based on data from the USA. (50, 51) Face length and width appear to be the most important measurements, but lip length and nasal width may also be relevant. Previous studies on respirator fit underrepresent the facial dimensions of females and non-Caucasians. (52) Data on South African facial dimensions are limited and the FFRs manufactured for local use may not be applicable to the inhomogeneous characteristics of South African faces. (40)

1.5.5 Sizes of FFRs

The CSIR recommend that institutional bulk orders should reflect the normal distribution across small, medium and large sizes (20% small, 60% medium and 20% large) but it is more important to accommodate local demographics. (37)

Spies et al (53) conducted a preliminary study on 29 South African volunteers from both genders and different races. The sample group’s anthropometric measurements represented a range of facial dimensions. Repeated quantitative fit testing was done with the volunteers wearing a medium size FFR from a commonly available brand. Facial dimensions of the males in the group were found to be fairly similar to those measured in Korea and America. (53) A satisfactory fit was achieved by 4 (13.8%) participants. The large percentage that failed the fit test leads to the conclusion that more than one respirator model and/or shape should be available. “One size does not fit all.”

1.6 FFR use

1.6.1 FFR performance and face fitting characteristics

FFR performance has been studied extensively in laboratory settings, but it is not clear how the research translates to a precise level of HCW protection. (27, 54) This may be the reason why some HCWs elect not to use FFRs at all, despite working in potentially contaminated environments.

Coffey et al (43) evaluated on behalf of the NIOSH the performance of 18 N95 respirator models available in 1998 with five different fit tests including both qualitative and quantitative tests. The second component of the evaluation was to determine whether fit testing had an effect on the level of protection. Level of protection was evaluated and rank-ordered by four different measures of protection. Twenty-five people with different facial dimensions participated. It was found that passing the fit test positively correlates with an increased level of protection.

1.6.2 HCW knowledge, attitudes and use of FFR

Manganyi et al (40) state that there is poor understanding of the proper use of FFRs and fit testing in South Africa. HCWs are hardly ever trained on how FFRs are supposed to fit, how they should be donned and worn and what their shortcomings are. Most don't know that there are different sizes and styles of FFRs available, nor are they aware that facial hair renders the face seal ineffective. South African employers are still of the erroneous opinion that one size of FFR will fit all employees.

Adeleke (22) collected data from focus group discussions and semi-structured interviews with HCWs from two clinics in Khayelitsha. It was found that despite dreading nosocomial TB, HCWs sometimes neglected personal protective equipment, because of discomfort, feeling smothered and difficulty in breathing associated with wearing the FFR. Importantly it was found that HCWs use personal protective equipment in a reactive fashion, an FFR would only be donned once TB has been diagnosed. This shows that there is poor understanding of the potential risk posed by undiagnosed and untreated TB cases and indicates the importance for education on proactive FFR use. Other complaints that the staff highlighted are that it feels hot, it is a communication barrier, proper donning and doffing take a long time and it chokes them.

Bhebhe et al (55) performed a cross-sectional descriptive study at the Maluti Adventist Hospital in Lesotho in 2011. Seven HCW were diagnosed with healthcare-associated TB in 2009 in this hospital. Of the 129 respondents, 115 (89.2%) demonstrated adequate knowledge of transmission and prevention of TB. Despite the adequate knowledge only 38.8% of the respondents stated that they use the N-95 respirator. Forty seven of the

participants (36.4%) reported that they were aware that their personal TB infection control practices were incorrect. (55)

Biscotto et al (56) randomly observed 145 HCWs in a Brazilian hospital between December 2000 and March 2001. Of the HCWs who partook in the study 59.3% were nurses and 30.3% were doctors and 10.3% other. Only 25% of HCWs used respirators for intubation. For encounters with patients in TB isolation respirators were worn for only 39.5% of encounters. Facial leakage was observed in 39% of HCWs who actually did wear the FFR, even though all users received training and fit testing at the beginning of the trial period. The most common cause of leakage was improper placement or tension of the straps. The FFRs themselves were observed, 90.3% were dirty, 19.4% were crushed or torn and 1.1% were moist. (56) The limitations of this direct observation study are that HCWs were aware of the study and their behaviour may have been influenced by the presence of the study personal over the defined time period.

Bryce et al (54) analysed 137 questionnaires distributed among HCWs in Vancouver Canada in a facility that uses airborne precautions when confronted with “patients with a new onset respiratory illness”. TB ward staff were excluded. More than 95% of participants had a fit test at least once in their career and about 60% reported annual fit testing.

Compliance with FFR guidelines was examined by means of a six-point Likert scale from 0 - 5. The range of the “compliance score” was 0 - 25 and the mean score was 21.2 (SD: 2.9). (54)

The five statements concerning compliance were:

- I wear an N95 respirator when there is the possibility of an infectious airborne disease
- I perform a fit check after putting on my N95 respirator
- I clean my hands before removing my N95 respirator
- I discard my N95 respirator immediately after use
- I take my N95 respirator off after I leave the room. (54)

The results show that despite regular training and well established airborne precaution practices at the hospital, some employees still do not understand or have a negative attitude towards fit testing and compliance with infection control precautions. In poor resource environments in the developing world the problem is compounded by a higher incidence of TB, insufficient training and restricted access to FFRs.

The same questionnaire also generated a “comfort-score” by asking participants to compare the FFR with a surgical mask on a Likert scale from 1 - 5 on four statements concerning comfort: (54)

- The N95 respirator is comfortable
- The N95 respirator does not make me short of breath
- The N95 respirator does not make me claustrophobic
- The N95 respirator does not make me feel dizzy. (54)

No FFR was found to be more comfortable than the other. The “global comfort score” was 13.6/20. (54)

1.6.3 Guidance and recommendations on infection control

The recommended CDC guidelines, the National Institute for Health and Care Excellence guidelines and South African National Infection Prevention and Control Policy and Strategy, as well as protocol for infection control at CMJAH are briefly discussed.

Personal respiratory protection is recommended by the CDC, especially in settings where exposure controls are inadequate. A comprehensive respiratory protection program should be implemented featuring aspects such as the assigning of a responsible administrator,

training of HCWs on the hazards and prevention of TB transmission and FFR selection with periodical FFR fit testing. (27)

The updated National Institute for Health and Care Excellence guidelines from January 2016 recommend tuberculin skin test (TST) programmes for at-risk staff. A positive TST warrants treatment with isoniazid for 6 - 9 months to prevent progression to active disease. (57) Bacillus Calmette–Guérin (BCG) immunisation can lead to incorrect interpretation of the TST result.

The South African National Infection Prevention and Control Policy and Strategy from April 2007 declares that too few HCWs have formal training in infection control. (45) All HCWs need to be made aware of the significance of “prevention, surveillance and control of infections amongst HCWs.”

The Infection Prevention & Control Protocol Isolation Precautions at the Charlotte Maxeke Johannesburg Academic Hospital in Gauteng were due for revision in August 2015, however are still unavailable. Currently the guidelines state that in the case of pulmonary TB, chicken pox, shingles and measles the following airborne precautions should be followed:

The patient is placed in a private ward/ cubicle. The door must be kept closed. A mask and apron/gown are put on when entering the room. In the case of MDR/XDR TB N95 respirators must be collected from Infection Prevention and Control Area 421. If the patient has to be transported to other areas, the patient must wear a surgical mask. (58)

The suboptimal implementation of infection control guidelines requires an urgent transformation in workplace behaviour. Infection control practices will only be sustained when HCWs have insight into the risk of occupational TB and receive in-service training on TB infection control practices. (22) As emphasised by Whitelaw (59), the financial considerations of FFRs are but one of the difficulties of its use in South Africa, the others being discomfort, the lack of fit testing and the lack of adequate training.

1.7 TB and the anaesthetist

1.7.1 Undiagnosed patients

Anaesthetists have contact with infectious patients coming for surgery, especially when there is a delayed diagnosis and treatment initiation.

1.7.2 High risk procedures

Anaesthetists are closely involved in high risk procedures that induce coughing such as intubation, ventilation, bronchoscopy and suctioning of the airways. Catanzaro (60) alleged in 1982 that mainly bronchoscopy and intubation were predominant risk factors for occupational TB transmission. This was based on the finding that 10 out of 13 HCWs present at the bronchoscopy of an infectious patient, subsequently converted to TST positive. High exposure situations according to TB guidelines by Chughtai et al (61) include “Exposure to drug resistant organism; culture/DST [Drug Susceptibility Testing], and other high risk procedures in laboratory; high risk areas; specialised treatment centres and emergency surgery of infectious cases.”

1.7.3 Administrative and environmental control inadequate in operating theatre

Both administrative and environmental transmission control measures are almost impossible to achieve in operating theatres. Instead of open windows and doors to provide a natural ventilation system and sunlight, theatres are windowless and doors remain closed. To compound the problem operating rooms are positively pressurised with air vents close to the floor. (62) The positive pressure in theatre tends to disperse the infectious droplet nuclei. Prolonged exposure to the suspended tubercle bacilli in the closed environment of an operating room creates optimal circumstances for transmission. Isolation of the patient is administratively problematic during transport, in the pre-operative area, or recovery room. Infectious patients enter and leave through the same central areas as everyone else. Therefore the anaesthetist is at a significant risk of acquiring TB at work.

In 2005 the CDC recommended that ultraviolet germicidal irradiation (UVGI) supplement existing TB transmission control programs in hospitals. UVGI is an environmental control measure of air disinfection. (26) Nardell et al (63) makes a case for upper-room UVGI in

bronchoscopy procedure rooms. These UVGI lamps predominantly emit ultraviolet C light, with a wavelength around 253.7nm, as this wavelength is mostly absorbed by the superficial layers of the skin and cornea, thus theoretically causing less skin cancer and cataracts than ultraviolet A and B light. (64) The high position of the UVGI ensures that radiation exposure to the occupants in the room is minimized. Research done by Escombe et al (25) in Lima, Peru showed that upper-room UVGI are an effective intervention in reducing TB transmission. The safety of UVGI in the operating theatre where there are many reflective surfaces has not yet been established.

1.7.4 Guidance on the perioperative management of the patient with active TB

The CDC 2005 guidelines on the perioperative management of patients with active TB have not yet been updated and advise that elective surgery be avoided until the patient has been on treatment for two to three weeks, is clinically improving, and has laboratory evidence of three negative sputum samples on three different days. Elective cases should be scheduled as the last case on the list to maximise time for comprehensive decontamination after hours. (27)

The patient should be transferred to theatre wearing a surgical mask. (27) Dharmadhikari et al (65) published research done at the Airborne Infections Research Facility in eMalaheni, previously called Witbank. Guinea pigs were used because they are very susceptible to TB transmission. Exhaust air was piped from a specialised MDR-TB ward to the enclosure of the guinea pigs for three months. When the patients in the ward wore surgical masks for 80% of the time a 56% decrease in TB transmission to the guinea pigs was shown. Hui et al (66) used a human patient simulator to show that neither a surgical mask nor a FFR can prevent sideways leakage when challenged with the force and volume of a cough. Both reduced the expelled air dispersion significantly from an uncovered cough, thereby protecting the environment by keeping infectious droplets in the immediate vicinity of the patient. It was concluded that the extra discomfort and cost associated with the FFR do not add any benefit in protecting the environment from the cough of the wearer.

The patient should be transported straight to theatre and not to the common pre-operative waiting area. Only the necessary staff should be present in theatre to minimise the number

of HCWs exposed. Everyone present in theatre should wear an appropriate, well-fitting FFR. During intubation the anaesthetist should ensure sufficient hypnosis and muscle relaxation to prevent coughing. (67)

Air cleaning technology such as UVGI and high-efficiency particulate air filters may be implemented in theatre to reduce the quantity and concentration of airborne infectious droplets. Installation and maintenance of this technology is expensive. Bacterial filters should be used in the breathing circuit, both at the patient end and at the expiratory limb to protect the anaesthetic machine from contamination. Pleated hydrophobic filters do not allow *M bovis* (a test surrogate for *M tuberculosis*) to penetrate. (68) Jackson et al (67) advocate sterilisation of the used breathing circuit, but if resources allow it would be prudent to safely dispose of it. The patient should be recovered in either theatre, or an isolation room in the ward.

1.8 Summary

In South Africa the high incidence of TB poses a considerable occupational health risk to HCWs. A comprehensive respiratory protection program consists of administrative, environmental and personal protection measures. HCWs who have access to the recommended personal respiratory protection are still at risk of TB transmission when there is a face leak between the FFR and the skin. An inappropriately fitted or sized FFR may give the HCW a false sense of protection. Compliance with infection control guidelines is universally insufficient. Due to the nature and environment of their occupation, anaesthetists are a vulnerable group of HCWs due to their proximity to patients with potentially undiagnosed TB and high risk procedures.

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Journal article (examples)

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2. Camins BC, Richmond AM, Dyer KL, et al. A crossover intervention trial evaluating the efficacy of a chlorhexidine-impregnated sponge in reducing catheter-related bloodstream infections among patients undergoing hemodialysis. *Infect Control Hosp Epidemiol* 2010;31:1118-1123.

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3. Figueroa P, Johanssen KL, Price FG, et al. Outbreak of *Acinetobacter* infection in a neonatal intensive care unit. *Pediatr Infect Dis J* (in press).

Paper presented at a professional meeting (example)

4. Chen LF, Freeman JT, Sexton DJ, Choi YI, Anderson DJ. NHSN definition of laboratory detected BSI is overly sensitive for *Enterococcus*. In: Program and abstracts of the 19th Annual Scientific Meeting of the Society for Healthcare Epidemiology of America (SHEA); March 18– 22, 2009; San Diego, CA. Abstract 359.

Book (example)

5. Heoprich PD. *Infectious Diseases*. 2nd ed. New York, NY: Harper & Row; 1977.

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6. Schaffner W. Psittacosis: ornithosis, parrot fever. In: Beeson PB, McDermott W, Wyngaarden JB, eds. *Cecil Textbook of Medicine*. 15th ed. Philadelphia, PA: W. B. Saunders; 1979:336-338.

Web page (example)

7. Clinical laboratory fee schedule. Centers for Medicare and Medicaid Services website.http://www.cms.gov/ClinicalLabFeeSched/02_clinlab.asp#TopOfPage. Published 2010. Accessed April 2, 2010.

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Section 3: Draft Article

Use and fit of filtering facepiece respirators in a department of anaesthesiology

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Running title: Use and fit of respirators by anaesthetists

Word count: 3000

Cover letter

26-10-2016

To the editor

All authors have read and approved the manuscript titled **Use and fit of filtering facepiece respirators in a department of anaesthesiology**. It is being submitted for the degree of Master of Medicine in the branch of Anaesthesiology at the University of the Witwatersrand, Johannesburg. It has never been submitted before for publication elsewhere and it is not currently under consideration for publication by another journal.

Individuals who are especially qualified to review the manuscript:

1. Dr Warren Lowman, University of the Witwatersrand, Warren.Lowman@wits.ac.za
2. Prof Ivan Joubert, University of Cape Town, Ivan.Joubert@uct.ac.za

Thank you for your consideration of the manuscript.

Dr M Niemandt

Abstract

Background: Reliable protection against nosocomial tuberculosis transmission in theatre depends on the appropriate use of filtering facepiece respirators (FFRs) with an N95 filter, as recommended by the Centers for Disease Control and Prevention.

Aim: To describe anaesthetist compliance and comfort with the use of FFRs, followed by donning technique and fit tests outcomes.

Design: Prospective, contextual, descriptive, two part study.

Setting: Part 1 was done in a university affiliated department of anaesthesiology. Part 2 was a pilot study in the theatre complex of a 1200-bed tertiary-level academic hospital.

Participants: Part 1 – anaesthetists in the department selected by convenience sampling (n=140). Part 2 – anaesthetists selected by stratified random sampling (10 male and 10 female).

Methods: In Part 1 a self-administered questionnaire was distributed. In Part 2 the donning technique was directly observed, corrected, then followed by qualitative fit testing with the single model and size FFR available.

Results: Part 1 -Compliance with the use of the FFR was inadequate with a compliance score of 14.5 (SD 5.0) out of 25. FFRs are deemed to be uncomfortable (discomfort score of 9.9 (SD 4.0) out of 21.) Part 2 - Of the 20 anaesthetists, six (30%), five males and one female, passed the fit test.

Conclusions: Compliance with FFR use was poor and anaesthetists at the research institution found the FFRs uncomfortable. FFR donning technique was observed to be lacking. Research with a larger study group is required. Poor fit test results were most likely due to the availability of only one size and model of FFR.

Introduction

“Tuberculosis (TB) remains a global health problem”.¹ The estimated prevalence in South Africa is 696 cases per 100 000 compared to the global average of 133 cases per 100 000.¹ HIV and TB are symbiotic co-epidemics.^{2, 3} Approximately 10% of patients newly diagnosed with HIV have undiagnosed TB.⁴ The emergence of multi-drug resistant and extensively drug-resistant TB endangers the public and especially healthcare workers (HCWs).⁴⁻⁶ In 2009 the overall prevalence of TB among South African HCWs was about 5%.⁷

Prevention of transmission of nosocomial TB requires three measures of control.^{8, 9} Firstly administrative measures which include early diagnosis, isolation and treatment. Secondly environmental measures including provision of natural or mechanical ventilation systems, extractor turbines, sunlight or ultraviolet irradiation, high-efficiency particulate air filters on exhaust air outlets and negative air ionization.¹⁰ Both administrative and environmental controls are almost impossible to achieve in operating theatres. The third measure of control is personal respiratory protection devices.¹¹ The most reliable protection from TB transmission in theatre is the correct use of a filtering facepiece respirator (FFR) with an N95 filter which allows penetration of less than 5% of airborne particles, providing that it is properly selected, correctly donned forming an impenetrable seal on the user’s face and worn whenever exposed to potential airborne hazards.¹²

Guidelines from the World Health Organisation and the Centers for Disease Control and Prevention recommend that HCWs who work in a high risk environment for TB exposure, should use “fit tested” FFRs. Fit tests aim to assess and correct the user’s donning technique and to identify those who have an inadequate fit with a specific size or model of respirator.^{11,13,14}

Anaesthetists are especially vulnerable due to their proximity to the airways of patients with potentially undiagnosed TB and their involvement in procedures that cause aerosolisation of infectious droplets.¹⁵ Incorrect use of the FFR, such as poor compliance, improper donning technique or an inadequate seal causing inward leakage, may put the user, in this case the anaesthetist, at risk.¹⁶ Compliance is a multifactorial issue, of which comfort of the FFR is an important factor.^{17,18}

The practice with regard to compliance, comfort, donning technique and fit of FFRs by anaesthetists from the Department of Anaesthesiology at the University of the Witwatersrand was not known. A two part study was undertaken which aimed to describe the anaesthetists' compliance and comfort when using FFRs, the adequacy of their donning technique and the outcome of formal fit tests.

Methods

The study design was prospective, descriptive and contextual. Approval was obtained from the University of the Witwatersrand Human Research Ethics Committee and other relevant authorities prior to commencing the study.

Part 1: a three sectioned anonymous, self-administered questionnaire was completed in the department. After an extensive review of the literature the two published questionnaires developed by Bryce et al were deemed the most appropriate.¹⁹ The comfort questionnaire was modified as follows, two statements identified in the literature were included, the Likert scale was changed to a more suitable four points instead of six and a review panel recommended the original negative statements be changed to generate a *discomfort* score for clarity. Thus a higher score on the comfort scale indicates more discomfort. The questionnaire was then

reviewed by senior consultants in the department to ensure validity for the South African context as the original questionnaire was used in a developed country. The final three sections were demographics, five statements concerning compliance on a six point Likert scale and seven statements concerning comfort on a four point Likert scale. The compliance score was out of 25 and the comfort score out of 21.

At the time of the study it was known that there were 214 eligible anaesthetists in the department, however 64 (30%) were inaccessible due to leave or out of town rotations. The accessible anaesthetists (N=150) were approached at departmental academic meetings and a response of more than 80% was targeted using convenience sampling. Questionnaires were returned into a sealed box and the completed questionnaire implied consent. Consultants were termed “senior anaesthetists” and medical officers and registrars “junior anaesthetists”.

Part 2: a pilot study was conducted to determine the adequacy of 20 anaesthetists’ donning technique and the outcome of a fit test. A room in the theatre complex of Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) affiliated to University of the Witwatersrand was used. Currently this hospital has only one model of FFR for use in the operating theatre (Quali-Med Medical & Safety Equipment CC Edenvale, South Africa) and this model is only available in one size.

Stratified random sampling, using pregenerated random numbers between 1 and 1 000 000 from the website random.org, was utilised to compile a sampling frame for each gender of the anaesthetists in the department at CMJAH.²⁰ The first 10 males and 10 females on the list were invited to participate. The exclusion criteria included participants with facial hair which could prevent a seal, who were claustrophobic, had a medical condition that precluded them from wearing a FFR, had a problem with taste, a blocked nose or a known sensitivity to

denatonium benzoate (Bitrex[®] Edinburgh, UK). Bitrex[®] is an internationally approved safe “taste aversive agent” used in household liquids.²¹ If a selected participant refused or was excluded, the next participant of the same gender on the randomisation list was approached and invited to take part in the study. Part 2 of the study took place over three days.

Twenty participants gave written consent and refrained from eating, drinking or smoking for 30 minutes prior to their appointments. A hood with a hole in front of the breathing zone (called the fit test enclosure) was placed over the participant’s head and shoulders. Taste screening was performed with the participant’s eyes closed. A fine mist of the threshold check solution (pre-prepared 27 mg of Bitrex[®] diluted to 200 ml in 5% saline) was nebulised into the fit test enclosure. If the participants detected the bitter taste while breathing with their mouths slightly open and tongues extended, they could continue the test.

A single assessor (MN) scored the participants’ donning technique of a disposable respirator according to eight criteria (summarised in Table 3 of the results). Thereafter training was given to ensure that the FFR was donned according to the manufacturer’s instructions.

A fit test according to the Occupational Safety & Health Administration Standard 1910.134 instructions was performed by one author (MN), using a fit test kit from Sperian Protection[®] (Honeywell International Inc. New Jersey, United States) with Bitrex[®] solution (337.5 milligrams of Bitrex[®] diluted to 200 ml in 5% saline.)²²

Each participant was instructed to don the fit test enclosure while wearing the correctly donned FFR. The Bitrex[®] solution was introduced into the fit test enclosure with a nebuliser while the participant breathed normally. The participant was then instructed to breathe deeply, move the head from side to side, move the head up and down, count out loud, bend

over and then breathe normally again.²² If the participant did not detect the bitter taste, the test was passed. However if Bitrex[®] was tasted at any point during these exercises the test was stopped and the participant was deemed to have an unacceptable fit and therefore failed the fit test. The bitter taste caused an almost involuntary reaction from the participants, making false results unlikely.

Data analysis

The data was analysed using Stata version 13.1 (StataCorp) statistical programme.

Descriptive and inferential statistics were used.

Part 1: data on the Likert scale are reported on both the ordinal and interval level. The summated data on the compliance and comfort scores were normally distributed and reported as means with standard deviations (SD). However data from individual statements were skewed and reported as medians with interquartile ranges (IQR). The options on the Likert scales were amalgamated into categories (as shown in Figures 1 and 2). The compliance of senior anaesthetists versus junior anaesthetists as well as the comfort of males versus females were compared using independent T-tests.

Part 2: medians and ranges as well as frequencies and percentages were used to describe the donning technique. A frequency and percentage were used to describe the outcome of the fit test.

Results

Part 1: of the 152 questionnaires distributed 140 (92.1%) were returned, representing 65.4% of the 214 members of the department and a 92.1% response rate.

Ninety three (67.1%) participants were female, 53 (37.9%) were senior anaesthetists (consultants), and 87 (62.1%) were junior anaesthetists consisting of 61 (43.6%) registrars and 26 (18.6%) medical officers.

Fourteen (10%) participants indicated that they have never used a FFP before and were therefore excluded from further analysis. The mean compliance score for the remaining 126 (90%) participants was 14.5 (SD 5.02, 95% CI 13.60 - 15.35) out of 25 ranging from 3 - 25. Table 1 shows the compliance score results for individual statements. Figure 1 is a representation of the amalgamated Likert scale categories for each statement.

Of the 14 participants who indicated that they have never used a FFR, 11 were senior anaesthetists. The mean compliance score of the remaining senior anaesthetists (n=42) using FFRs was 15.7 (SD 5.16, 95% CI 14.18 - 17.30) and for the junior anaesthetists (n=84), 13.5 (SD 4.88, 95% CI 12.48 - 14.58), with ranges of 3 - 25 and 4 - 25 respectively. This difference was significant ($P = 0.046$).

The mean *discomfort* score was 9.9 (SD 3.98, 95% CI 9.19 - 10.58) out of 21 ranging from 1 - 18. Table 2 shows the *discomfort* scores for individual statements. The amalgamated Likert scale categories for each statement are represented in Figure 2. Not a single participant found the FFR 100% comfortable, although two participants scored a total of 1 out of 21 (thus scoring the FFR to be mostly comfortable).

Females scored a mean of 10.5 (SD 4.1, 95% CI 9.63 - 11.36) range 1 - 18, making them more uncomfortable ($P = 0.01$) than the males who scored a mean of 8.5 (SD 3.30 95% CI 7.50 - 9.57) range 3 - 15.

Part 2: in total 24 participants were randomised as 4 were excluded due to facial hair, a blocked nose, claustrophobia and failing the sensitivity test. The median score for the donning technique was 6 (range 4 - 8) out of 8. Table 3 shows the donning technique results. Six (30%) participants passed the fit test. Of the 10 males, 5 (50%) passed, however only 1 (10%) of the 10 females passed.

Discussion

This two part study explored how respiratory protection fails anaesthetists due to their own poor compliance, possibly as result of discomfort, with FFR use; as well as poor donning technique and ultimately poor fit with the FFR itself.

The summated compliance score of 14.5 (58%) out of 25 in our study is lower than the 21.5 (86%) found by Bryce et al in Canada.¹⁹ Our participants consistently scored lower than the participants in the Canadian study on every individual compliance statement. This is a concerning finding as TB is more prevalent in South Africa than in Canada. Biscotto et al randomly observed 145 HCWs in a Brazilian hospital between December 2000 and March 2001.¹⁶ They found that only 25% of HCWs used FFRs for intubation and that only 20% used an FFR when performing a potentially infectious aerosol producing procedure. Self-reported questionnaires, such as used in our study, likely overestimate compliance when compared to direct observational studies.

Eleven (78.6%) of the 14 participants in our study who indicated that they have never worn an FFR before were senior anaesthetists. Adeleke observed, in two clinics in Khayelitsha, that HCWs were influenced by their colleagues' personal protection practices.¹⁷ Harrington

mentions that HCWs feel marginalised and stigmatised when using personal protective equipment.²³

Bryce et al investigated four statements concerning comfort on a six point Likert scale.¹⁸ Unfortunately our summated discomfort score of 9.9 out of 21 cannot be directly compared to their “comfort score” of 13.6 out of 20, due to structuring of the statements and the way results were reported (they used means and SDs, whereas ours are reported as medians and IQRs). Their participants indicated a mean score of 3.2 (SD 1.3) out of 5 for the statement “The N95 respirator is comfortable.” In our study the median (IQR) score for the statement “The N95 respirator is uncomfortable” was 2 (2 - 3) out of 3, with only 15 (11.9%) participants never or seldom find the FFR uncomfortable (Figure 2). It appears that the participants in the study by Bryce et al found respirators more comfortable than participants in our study.¹⁸ This may be because there was a selection of FFRs available. In the study by Baig et al 24% of participants found the FFR to be comfortable most of the time or always (N=149).²⁴

In our study 58 (46%) participants stated that the FFR never or seldom makes them short of breath and 55 (43.7%) found that the FFR never or seldom makes them hot and sweaty, which is more than Baig et al found with 36% and 20% respectively not reporting shortness of breath and rarely or never experiencing an increase in facial temperature when wearing the FFR.²⁴ Thirty one (24.6%) of our participants reported that the FFR never or seldom makes it difficult to communicate, which is similar to 22% of those in Baig et al’s study.²⁴ Adeleke found that HCWs sometimes neglected personal protective equipment, despite dreading TB infection, because of discomfort, feeling smothered and difficulty in breathing when using the FFR.¹⁷ Other complaints reported by this author include the FFR makes one feel hot, it is a

communication barrier and proper donning and doffing take a long time. Discomfort of using FFRs appears to be prevalent and as such may pose a safety issue.

Gender was found to be significant in our study with males being more comfortable with wearing FFRs than females. This is similar to the findings by Baig et al²⁴. A FFR fit test trainer from a FFR manufacturing company claims that due to make-up, FFRs make females feel sweaty and sticky and may result in a rash. She advises females to remove their make-up before donning the FFR.²⁵

The median score for the donning technique was 6 out of 8. One (5%) participant achieved 8 out of 8 for adequacy of the donning technique. This participant, and another who achieved 7 out of 8 had received formal training on donning the FFR in preparation for an Ebola outbreak in 2015. No other participant received formal training.

Lee et al recommended that the National Institute for Occupational Safety and Health should specify that a minimum of 90% of randomly chosen users pass the fit test as a criteria for a certified FFR brand to be utilised in the implementation of an infection control program.²⁶ After donning the FFR adequately, 6 (30%) participants passed the fit test in our study. Biscotto et al observed facial leakage in 39% of participants, even though all of them received prior training and fit testing.²² Fit testing results are usually better in a controlled setting such as in our study than when working in the field. In the study by Bryce et al 217 participants were fit tested with three different models of FFRs, but only 150 (69.1%) passed.¹⁹ The discrepancy in pass rates between our study and these two studies can possibly be due to us having only one model and one size of FFR available.

In our study half the male participants, but only one (10%) female passed the fit test. The difference was statistically insignificant ($P=0.05$), possibly because of the small sample size. McMahon et al fit tested 1271 HCWs.²⁷ The fit test pass rate for their initial selection of FFR was 95.1% in males and 85.4% in females, a statistically significant difference. The study emphasises that women need a more extensive selection of FFRs options. Lee et al did however not find a difference in fit test pass rates between genders.²⁶

The large percentage that failed the fit test leads to the conclusion that more than one respirator model and size should be available. “One size does not fit all”.²⁸ FFRs are designed based on the anthropometric data of facial characteristics and sizes obtained from large numbers of people grouped into “respirator fit test panels”.²⁸ These panels were historically compiled by the National Institute for Occupational Safety and Health from American air force data.^{29, 30} Zhuang et al reported that previous fit test panels underrepresent the facial dimensions of females and non-Caucasians.³¹ Spies et al conducted a preliminary study on 29 South African volunteers from both genders and different races with a variety of facial characteristics.²⁸ Repeated quantitative fit testing achieved satisfactory fit in only 4 (13.8%) participants with a single size and model FFR.

The contextual design may limit the extent to which our results can be generalised to other contexts. Compliance is best tested by direct observation and not by self reporting. However for the scope of this study it was more appropriate to do self reporting due to cost, time and resource constraints. This methodology does not accurately reflect true compliance, although given the anonymous nature of the questionnaire participants are likely to answer truthfully about their own perception of how compliant they are.

The direct observation of the donning technique may influence findings as participants were aware of being observed. Some participants mentioned that there are no mirrors in theatre and thus it is a futile exercise to check FFR fit in a mirror. They requested that this statement be removed from the scoring of the donning technique or that mirrors be installed.

In conclusion, poor compliance should be addressed especially since there is such a high incidence of TB in South Africa. Formal training of anaesthetists on FFR donning and use is required. It is possible that more choice of FFR models and sizes may improve comfort and thereby improve compliance, both of which were poor in this study. The feasibility of regular fit testing of the anaesthetists in this department should be investigated. Research with a larger study group is required. The reliance on a single size and model of FFR in this department should be reconsidered.

Acknowledgements

The authors acknowledge the participants who were fit tested and the fit test trainer from 3M[®]. The fit test kit was borrowed from Quali-Med.

Declaration

This research was submitted to the Faculty of Health Sciences, University of the Witwatersrand, in partial fulfilment of the requirements for the degree of Master of Medicine in the branch of Anaesthesiology.

Conflict of interest

The authors report no competing interests relevant to this article.

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Tables

Table 1 Compliance score (Likert scale 0-5)

	Statement (n=129)	Median	IQR
1.	I wear an N95 respirator when there is the possibility of an infectious airborne disease.	3	2 - 4
2.	I perform a self-fit check after putting on my N95 respirator.	1	0 - 4
3.	I wash my hands before removing my N95 respirator.	1	0,25 - 5
4.	I discard my N95 respirator immediately after use.	5	3 - 5
5.	I take my N95 respirator off after I leave the room.	4	3 - 5

Table 2 Comfort score (Likert scale 0-3)

	Statement (n=126)	Median	IQR
1.	The N95 respirator is uncomfortable.	2	2 - 3
2.	The N95 respirator makes me short of breath.	2	1 - 2
3.	The N95 respirator makes me claustrophobic.	2	1 - 2
4.	The N95 respirator makes me feel dizzy.	0	0 - 1
5.	The N95 respirator makes it difficult to communicate.	2	2 - 2
6.	The N95 respirator gives me a rash.	0	0 - 0
7.	The N95 respirator makes me hot and sweaty.	2	1 - 2

Table 3 Donning technique results

	Criteria (n=20)	Correct n
1.	Chin placement	19
2.	Strap tension	18
3.	Upper strap placement	18
4.	Lower strap placement	11
5.	Nasal bridge fit	15
6.	Respirator fixed (does not slip)	20
7.	Evaluate respirator fit and position in mirror	14
8.	Perform a self-fit check	4

Figures

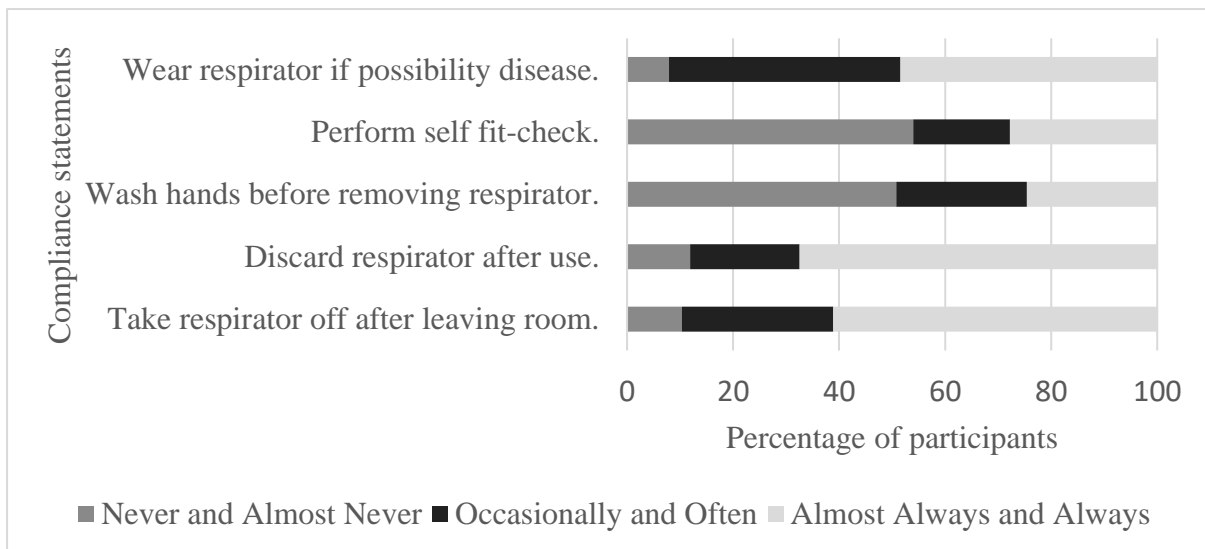


Figure 1 Compliance scores reported as ordinal data

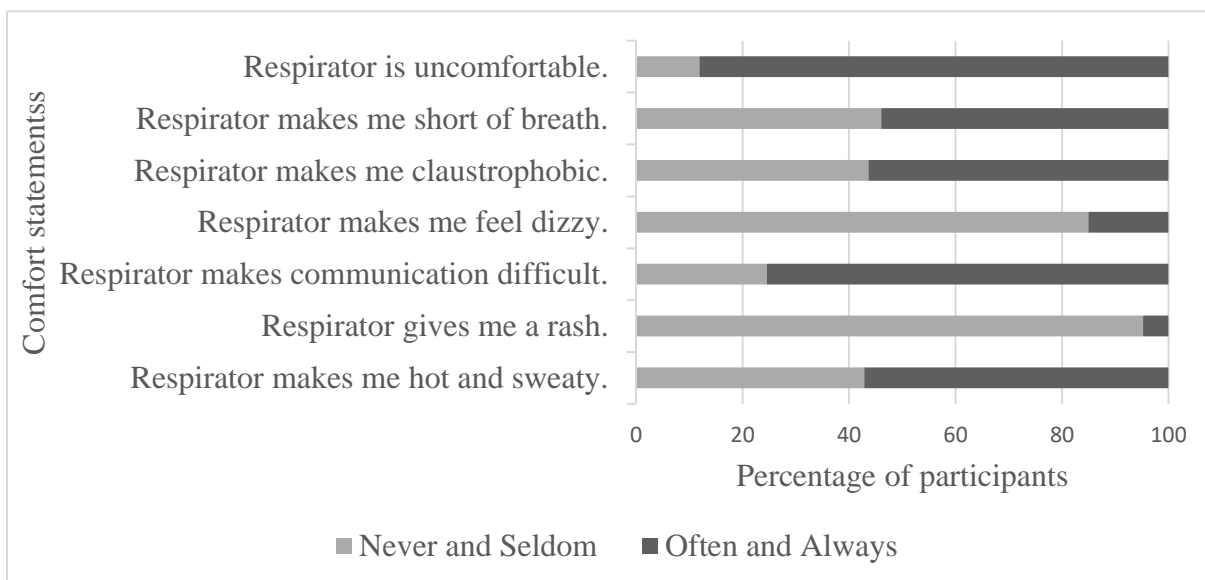


Figure 2 Comfort scores reported as ordinal data

Section 4: Appendices

4.1 Ethics clearance



R14/49 Dr Marthinet Niemandt et al

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M150711

NAME: Dr Marthinet Niemandt et al
(Principal Investigator)

DEPARTMENT: Anaesthesiology
Charlotte Maxeke Johannesburg Academic Hospital

PROJECT TITLE: Use and Fit of Filtering Facepiece Respirators in a
Department of Anaesthesiology

DATE CONSIDERED: 31/07/2015

DECISION: Approved unconditionally

CONDITIONS:

SUPERVISOR: Helen Perrie

APPROVED BY:

A handwritten signature in black ink, appearing to read 'P Cleaton-Jones', written over a horizontal line.

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

DATE OF APPROVAL: 23/09/2015

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 _____

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

4.2 Post graduate committee approval



Private Bag 3 Wits, 2050
Fax: 027117172119
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Reference: Ms Thokozile Nhlapo
E-mail: thokozile.nhlapo@wits.ac.za

Dr M Niemandt
501 Mentone Court
44 Riviera Road
Killarney
2193
South Africa

25 August 2015
Person No: 1256255
PAG

Dear Dr Niemandt

Master of Medicine: Approval of Title

We have pleasure in advising that your proposal entitled *Use and fit of filtering facepiece respirators in a Department of Anaesthesiology* has been approved. Please note that any amendments to this title have to be endorsed by the Faculty's higher degrees committee and formally approved.

Yours sincerely

A handwritten signature in cursive script, appearing to read "S. Benn", with a horizontal line underneath.

Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences

4.3 Approval from the Chief Executive Officer CMJAH



GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

CHARLOTTE MAXEKE JOHANNESBURG ACADEMIC HOSPITAL

Enquiries:
Mr. J. Maepa
Office of the Clinical Director
Tell: (011) 488-3365
Fax: (011) 488-3753
07 September 2015

Dear: Dr. Marthinet Niemandt

STUDY TITLE: Use and fit of filtering facepiece respirators in a Department of Anaesthesiology.


Permission is granted for you to conduct the above recruitment activities as described in your request provided:

1. Charlotte Maxeke Johannesburg Academic Hospital will not anyway incur or inherit costs as result of the said study.
2. Your study shall not disrupt services at the study sites.
3. Strict confidentiality shall be observed at all times.
4. Informed consent shall be solicited from patients participating in your study.

Please liaise with the HOD and Unit Manager or sister in charge to agree on the dates and time that would suit all parties.

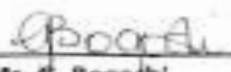
Kindly forward this office with the results of your study on completion of the research.

~~Supported/not supported~~



Dr. M.I. Mofokeng
Clinical Director
DATE: 7/9/2015

Approved/not approved



Ms. G. Bogoshi
Chief Executive Officer
DATE: 10.09.2015

Section 5: Annexure

Proposal

5.1 Introduction

Tuberculosis (TB) remains a far-reaching conundrum. Globally there were 8.6 million new cases of TB according to an estimation by the World Health Organisation (WHO) in 2012. (1) Seventy-five percent of these cases were in the African region and an estimated 450 000 new cases of active TB were diagnosed in South Africa in 2013.

HIV and TB are symbiotic co-epidemics. (2, 3) In 2012 73% of patients with TB were also HIV positive according to the South African Department of Health. (4) It is estimated that 10% of patients newly diagnosed with HIV have undiagnosed TB. (5)

The emergence of multi-drug resistant TB (MDR-TB) and extensively drug-resistant TB (XDR-TB) pose a danger to the public (5) and especially to healthcare workers (HCWs). (6, 7) Worldwide TB has been regarded as an occupational health risk to HCWs for almost a century. (8, 9) In South Africa the overall prevalence of TB among HCWs was found to be 5 % in 2009. (10)

The customary prevention of TB transmission in healthcare facilities is accomplished by three levels of control measures. (11, 12) The first level is termed **administrative controls**. This includes education about cough hygiene and early diagnosis, isolation and treatment of patients with active disease. Secondly **environmental** or architectural controls are directed at reducing the number of airborne, infectious droplets. These measures include natural or mechanical ventilation systems, extractor turbines, sunlight or ultraviolet irradiation, (13, 14) high-efficiency particulate air filters on exhaust air outlets and negative air ionization. The third level is the correct and consistent use of personal **respiratory protection devices**. (15)

Direct sunlight and ultraviolet light kill the tubercle bacilli. For that reason most transmission happens in dark and poorly ventilated areas where droplet nuclei can stay suspended for up to four hours. (16) Both administrative and environmental transmission

control measures are extremely difficult and expensive to achieve in the operating room. This author is of the opinion that the most reliable method of protection from TB transmission available to HCWs in the operating theatre is consistent and correct use of disposable personal respiratory protection devices.

The universally recommended respiratory protection device for protection against TB transmission is a filtering facepiece respirator (FFR) with an N95 filter. N95 filters are not oil resistant and will filter at least 95% of airborne particles (17). The filter is only effective if it forms an impenetrable seal on the user's face.

It is essential that the FFR is correctly selected, fitted and donned and worn the whole time that the user is exposed to potential airborne hazards. The idea behind fit testing is to test and correct the user's donning technique, and then to identify that small percentage of individuals who will have an inadequate fit with the first model respirator they try on (18).

Anaesthetists are a vulnerable group of HCWs due to their proximity to high risk procedures on patients with potentially undiagnosed TB. Procedures that cause coughing result in aerosolisation of droplets containing the infectious tubercle bacilli. (19)

Guidelines from the WHO (1) and Centers for Disease Control and Prevention (15) recommend the use of fit tested FFRs for those HCWs who work in high exposure risk areas.

The Infection Prevention & Control Protocol Isolation Precautions of Charlotte Maxeke Johannesburg Academic Hospital (CMJAH), endorsed by the Gauteng Province Department of Health mention that FFRs should be worn by HCWs caring for a patient with suspected or confirmed MDR- or XDR-TB. (19) The revised infection control guidelines were due for distribution in May and June 2016, but were not yet available at the time of printing.

Due to the nature and environment of their occupation, anaesthetists who have access to the recommended N95 FFR are still at risk of TB transmission, if there is a face leak between the FFR and the skin, or if compliance with the use of the FFR in applicable situations is poor. Comfort is a factor that also influences compliance. (21, 22)

5.2 Problem statement

In the case of anaesthetists the only reliable defence against occupational TB is the appropriate use of personal respiratory protection devices. At the CMJAH an N95 FFR is used, but this can only be effective if the right size and model is correctly donned, forms an impenetrable seal on the wearer's face and the wearer is compliant with use in relevant situations. The practice with regard to the compliance and comfort of the use of FFRs by anaesthetists from the Department of Anaesthesiology at the University of the Witwatersrand (Wits) and the fit of the FFRs that is available at hospitals affiliated to the department is not known.

5.3 Aims and objectives

This study will be done in two parts.

5.3.1 Part I

The aim of Part I of the study is to describe the compliance and the comfort of use of the FFR of the anaesthetists in the Department of Anaesthesiology at Wits.

The primary objectives of Part I of the study are to:

- describe the compliance of anaesthetists with use of the FFR
- describe the comfort of anaesthetists wearing the FFR.

The secondary objectives of Part I are to:

- compare the compliance with FFR use of consultants to that of junior anaesthetists
- compare the comfort of FFR use between males and females.

5.3.2 Part II

Part II will be a pilot study with the aim of describing the FFR donning technique and the outcome of the fit test of the anaesthetists in the Department of Anaesthesiology at CMJAH.

The primary objectives of Part II of the study are to:

- describe the adequacy of the FFR donning technique
- describe the outcome of the FFR fit test.

The secondary objective of Part II of this study is to compare FFR fit test outcome with gender.

5.4 Research assumptions

The following definitions will be used in the study.

Anaesthetist: is any qualified doctor working in the Department of Anaesthesiology including medical officers, registrars and consultants.

Medical officer: a qualified doctor practising in the Department of Anaesthesiology under specialist supervision. Medical officers with more than 10 years of anaesthetic experience are career medical officers and are considered as consultants.

Registrar: a qualified doctor who is registered with the Health Professionals Council of South Africa as a trainee anaesthetist.

Consultant: an anaesthetist who is registered with the Health Professionals Council of South Africa as a specialist anaesthesiologist.

Junior anaesthetists: include medical officers and registrars.

Compliance: determined according to the compliance questionnaire (Appendix A) adopted from the published questionnaire by Bryce et al. (23)

Adequate technique: to demonstrate adequate technique the participant needs to score 100% of the criteria on the technique score sheet (Appendix B).

Filtering facepiece respirator (FFR): the FFR used in this study is the specific model (FFP2 respirator by Quali-Med Medical & Safety Equipment CC) procured by CMJAH infection control department for protection against nosocomial TB at the time of the study. This FFR is only available in one size. It is colloquially known as an “N95 mask”.

Fit test kit: the kit used in the fit test is from Sperian Protection® (Honeywell International Inc. New Jersey, United States) qualitative fit test apparatus, as recommended by the representative for respiratory protection devices from the company Quali-Med.

5.5 Demarcation of study field

Part I of the study will be conducted in the Department of Anaesthesiology, affiliated to the Faculty of Health Sciences of the University of the Witwatersrand. The staff complement of the department is 75 consultants, 112 registrars and 27 medical officers.

Part II of the study will be conducted in the theatre complex of CMJAH affiliated to the Department of Anaesthesiology at the University of the Witwatersrand. CMJAH is a 1200 bed central hospital. The hospital has 23 theatres. On average 23 000 cases are done annually. The anaesthesia staff complement at this theatre complex is 25 consultants and 37 registrars and medical officers.

5.6 Ethical considerations

Approval to conduct the study will be sought from the Human Research Ethics Committee (Medical) and the Postgraduate Committee of the University of the Witwatersrand. Permission to conduct Part II of the study at CMJAH will be obtained from the Chief Executive Officer prior to commencement of the study (Appendix C).

For Part I participants will be approached at the departmental academic meetings. The study will be explained to them and they will be invited to take part. The researcher will distribute an information letter (Appendix D) and the questionnaires (Appendix A). The participant's consent is implied if the questionnaire is returned.

Anonymity will be ensured in Part I by collecting data on questionnaires without identifying information. Confidentiality will be ensured in Part I, because only the researcher and supervisors will have access to the raw data. If compliance with FFR use is found to be poor

based on the questionnaire, a training session will be organised to improve compliance with respiratory protection amongst members of the department.

For Part II of the study participants will be randomly selected. Those participants who have been selected will be approached in person, the study explained and they will be invited to take part. An information letter (Appendix E) will be given to them to read and if they agree, they will be asked to sign the consent form (Appendix F). If someone chooses to decline participation in the study the next person on the randomised list will be approached and invited to part take.

Anonymity will not be possible in Part II of the study as the researcher will conduct the test, however the data generated will be documented and reported anonymously. The participants will be assured that there will be no negative consequences for participation regardless of the outcome. Confidentiality will be ensured in Part II of the study, because only the researcher and supervisors will have access to the information and raw data. The Head of Department of Anaesthesiology will be notified if:

- The donning technique is inadequate to organise training.
- If it is found that a number of participants do not pass the fit test despite adequate training in the donning technique, the appropriateness of the brand procured should be investigated. Importantly only group, not individual data will be reported to the Head of Department of Anaesthesiology.

The fit test is performed with the use of aerosolised Bitrex® spray. Bitrex® has been routinely used as a taste aversion agent in household liquids to deter children from drinking them since its approval in the United Kingdom and the USA in the early 1960s. (24, 25) Participants will be asked to close their eyes whenever the solution is sprayed.

Data will be stored securely for six years after completion of study. The study will be conducted according to the principles of the Declaration of Helsinki (26) and the South African Guidelines for Good Clinical Practice. (27)

5.7 Research methodology

5.7.1 Research design

According to Creswell (28) a research design is the framework that guides the assumptions about variables established from the literature review, the approach to the appropriate investigation and decisions about data collection methods.

A prospective, contextual, descriptive research design will be followed in this study.

A prospective study according to Brink et al (29) is defined as: “data about a presumed cause are first collected and then the effect or outcome is measured.” The study is prospective as data will be collected at the outset and thereafter the outcome will be measured.

The study is contextual as it is concerned with understanding the true immediate circumstances, environment and context, with which the study problem is associated. (30) This study will be conducted contextually in the Department of Anaesthesiology affiliated to the University of the Witwatersrand.

A descriptive study gives an account of a singularity or occurrence in a study sample. The account is particular to that sample and may be unrelated to the larger population. Variables are depicted and explored as they exist naturally in order to provide a complete description of the study sample, and are not manipulated by the researcher. According to Brink et al (29) data for descriptive studies are classically collected by “structured observation, questionnaires and interviews or survey studies.”

Research methodology for Part I and Part II of the study will be discussed separately.

Part I

Study population

The study population consists of the anaesthetists working in the Department of Anaesthesiology.

Study sample

Sampling method

In this part of the study a convenience sampling method will be used. Convenience sampling is the same as “accidental” or “availability sampling”. (29) For Part I of the study readily accessible participants will be invited to partake at the departmental academic meetings.

Sample size

At the time of the study it was known that there were 214 eligible anaesthetists, but at the time of data collection it was calculated that approximately 30% of the anaesthetists would be inaccessible due to leave, out of town rotations etc. Of the 150 available anaesthetists a response rate of 120 (80%) will be targeted.

Inclusion and exclusion criteria

All anaesthetists working in the Department of Anaesthesiology meet the inclusion criteria of the study.

Exclusion criteria:

- anaesthetists who refuse to take part in the study
- anaesthetists who are on annual leave, special leave or sick leave
- blank questionnaires.

Collection of data

Research questionnaire

Following an extensive literature review, a data collection sheet with a three section questionnaire (Appendix A) was compiled for Part I of the study. Section 1 consists of the demographics of the participants, Section 2 is the compliance score and Section 3 is the comfort score.

Sections 2 and 3 are adaptations from published questionnaires on compliance and comfort developed by Bryce et al. (23) The comfort questionnaire was modified as follows, two statements identified in the literature were included, the Likert scale was changed to a more suitable four points instead of six and a review panel recommended the original negative statements be changed to generate a *discomfort* score for clarity. Thus a higher score on the comfort scale indicates more discomfort.

The adapted questionnaire was reviewed by three senior consultants in the Department of Anaesthesiology to ensure that it is valid in the South African context as the original questionnaire was used in a hospital in a developed country. Suggested changes were incorporated. The final three sections were demographics, five statements concerning compliance on a six point Likert scale and seven statements concerning comfort on a four point Likert scale. The compliance score was out of 25 and the comfort score out of 21. The method of using questionnaires in this study sample is appropriate as the participants are educated and cooperative with research. (29)

In Section 1 the following demographics will be collected:

- professional designation
- gender

Section 2 will comprise of five statements concerning compliance using a six point Likert scale. Section 3 will consist of seven statements concerning comfort using a four point Likert scale.

Data collection

Data will be collected on a Wednesday afternoon at the departmental academic meetings. The convenor of the academic meeting will be approached and asked for permission to address the meeting. The study will be introduced, followed by an explanation of the aims and objectives. The participants who decide they want to partake in the study will receive the information letter and a questionnaire. The questionnaires will be numbered to keep track of the response rate. The researcher will be present to distribute the questionnaires and to assist with any queries. Participants are granted 10 minutes to complete the questionnaire. A returned questionnaire will imply consent and the participants will place the completed questionnaires in a sealed collection box.

Data analysis

Data will be captured on Microsoft Office Excel® 2011 spread sheets for analysis. Anaesthetists will be scored according to a total score as well as on individual questions. The categorical variables will be described using frequencies and percentages. The Likert scales for compliance and comfort will be interpreted as interval data. The data will be analysed on Stata version 13.1 (StataCorp) statistical programme. Descriptive statistics will be used to describe the data. The compliance of senior anaesthetists will be compared to that of junior anaesthetists and the comfort scores of males and females will be compared using T-tests. A p-value of less than 0.05 will be considered as statistically significant.

Part II

Study population

The study population consists of the anaesthetists working in the Department of Anaesthesiology at CMJAH.

Study sample

Sampling method

The sampling method for Part II of the study is stratified random sampling according to the definition by Polit and Beck. (31) For this sampling method “the population is first divided into two or more strata”. In this study the sample will be divided by gender to ensure that an equal number of males and females are represented. Only after stratification will the sampling frame be randomised. The sampling frame is “the technical name for the list of elements from which the sample will be chosen.”(31) Randomisation is the process by which each member of the population has an equal opportunity of being chosen.

An alphabetical list of names of anaesthetists working at CMJAH will be requested from the Head of Department. The names on the list will be divided according to gender resulting in a sampling frame that comprises two lists.

With the help of the true random number service on the website random.org (32) a randomly selected number from 1 to 1 000 000 will be allocated to each name on the list of male anaesthetists and the same for each name on the list of female anaesthetists. The website random.org is operated by Randomness and Integrity Services Ltd. and it generates randomness using atmospheric noise and not algorithms or formulae.

It is important to use 1 000 000 possibilities, even though the sampling frame is only 63 anaesthetists to avoid allocating the same number twice. The randomly allocated numbers will be arranged in ascending order. The first 10 numbers on each list with the corresponding name of the anaesthetist will make up the study sample. If an anaesthetist on the list is excluded based on the inclusion and exclusion criteria (for example the anaesthetist has a beard), the same technique will be used to select another participant from the remainder of the sampling frame.

Sample size

For Part II a pilot study will be done with 20 anaesthetists working at CMJAH. A pilot study is a miniature version of a major study to assess feasibility. This can help the researcher to identify potential difficulties and snags in the data collection process that can be avoided or addressed in the actual study. (29)

Inclusion and exclusion criteria

The inclusion criteria for this part of the study are:

- anaesthetists working in the Department of Anaesthesiology at CMJAH
- who consent to take part in the study.

The exclusion criteria of Part II of this study are participants who:

- have facial hair that may hinder a proper seal (a beard, big moustache or sideburns that come between the skin and the FFR)
- wear apparel that will interfere with the seal of the FFR and that cannot be removed (for example external braces or synthetic hair extensions that extend behind the person's head prohibiting proper strap placement)
- have a medical condition such as shortness of breath, that precludes them from wearing a FFR
- have claustrophobia
- have a problem with tasting bitterness
- have a blocked nose
- have a known sensitivity to Bitrex®.

Collection of data

Data collection sheet

A data collection sheet (Appendix B) was compiled consisting of:

- demographics (gender)
- technique score sheet
- training received
- fit test outcome.

The technique scoring sheet and the fit test were adapted from the mandatory fit testing protocols as set out in the subpart on personal protective equipment in the Occupational Safety & Health Administration (OSHA) Standard 1910.134 Appendix A as published by the United States Department of Labor. (33)

Data collection process

Once the 20 members have been selected from the sampling frame they will be invited personally to participate on the three mornings of the study. They will be issued with the information letter (Appendix E) and consent form (Appendix F). If they agree to take part, time slots will be allocated to the 20 participants. They will be requested not to eat, chew gum, smoke or drink anything other than water for 30 minutes before their time slot.

Demographical data on the gender of the participants will also be documented. Data on the technique of the participants donning the FFR will be directly observed by the researcher. The participant will know that they are being observed but they will not know the scoring criteria.

After each participant has been scored on his or her technique of donning the FFR, he or she will receive individual training on the manufacturer's donning recommendations in an attempt to get the best fit possible. Thereafter the fit test is performed and the researcher will document the outcome of each test as pass or fail.

The fit test is performed by the researcher using a fit test kit (figure 5.1) that contains Bitrex® as the test solution.



Figure 5.1: The fit test kit (34)

The fit test kit contains a hood (the “enclosure”) with a 1.9 cm hole in front of the participant’s nose and mouth area. There are two nebulisers and two bottles in the kit, one with the standardised diluted Bitrex® (Denatonium Benzoate) threshold check solution and the other with the Bitrex® indicator solution at the normal concentration.

Firstly it will be ascertained that the participant can taste the Bitrex®. Taste threshold screening is performed with the threshold check solution, with the participant wearing the enclosure over the head and shoulders, but without wearing a FFR. The researcher shall spray a fine mist of the diluted Bitrex® solution into the enclosure with a nebuliser while the participant keeps his or her eyes closed. Only if the participant detects the bitter taste will he or she continue to the fit test.

The fit test is done with the participant wearing the FFR properly positioned and the enclosure donned. The indicator solution is nebulised into the enclosure while the participant breathes as indicated above. The participant will be guided through the following exercises (Figure 5.2):

- breathe normally
- breathe deeply
- turn the head slowly from side to side
- slowly move the head up and down
- count out loud
- bend over
- breathe normally again. (35)

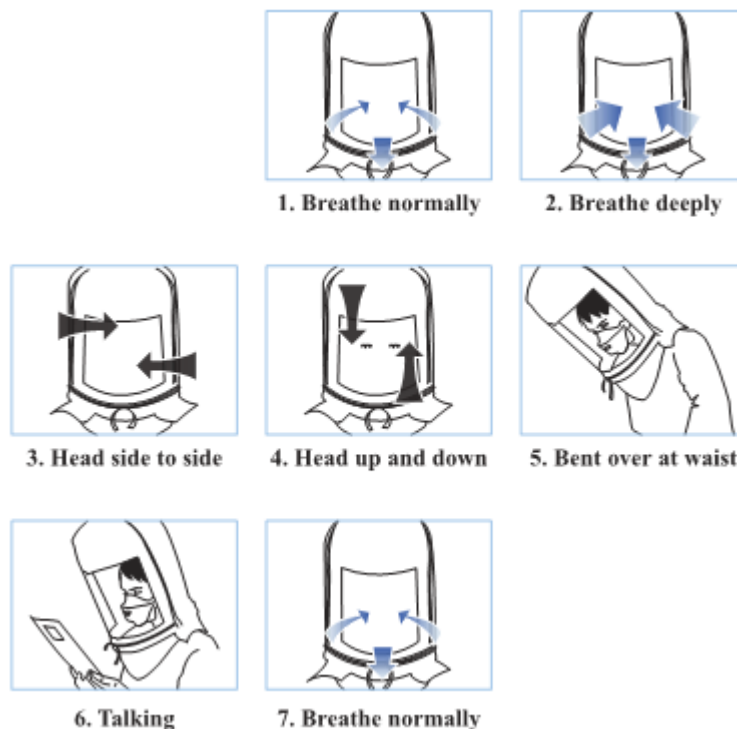


Figure 5.2: The seven exercises (35)

If the participant does not report tasting the Bitrex®, the test is passed. However, if the taste of Bitrex® is detected at any point during the exercises, the fit is incorrect and the fit test failed.

Data analysis

The mean and standard deviation will be used to describe the results of technique score sheet if the data follow Gaussian distribution, or the median with interquartile ranges will be used if data do not follow the Gaussian distribution. A frequency and percentage will be used to describe the outcome of the fit test.

As a secondary outcome the data from Part II of the study will also be compared in categories of fit test passed by males versus females using the Fishers Exact Test. A p-value of less than 0.05 will be considered significant.

5.8 Significance of the study

The emergence of MDR- and XDR-TB strains and the prevalence of HIV in South Africa make the ongoing battle against TB more relevant than ever. HCWs are disproportionately endangered (7, 19, 36). Even though administrative and architectural measures of preventing TB transmission are very effective, their application to a theatre environment are difficult and expensive. Due to the proximity of anaesthetists to the airways of patients with potentially undiagnosed TB presenting for surgery they are at risk of occupational TB infection. They are almost exclusively dependent on a perfectly fitting N95 FFR as their barrier of defence against occupational TB. The anaesthetist may still be at risk if there is leakage between the FFR and the skin, or if compliance with the use of the FFR in applicable situations is poor.

The results from Part I of the study may influence current practice. If the results show that the anaesthetists have poor compliance with use of the FFR, this may be addressed by a training session to ultimately improve safety.

If the results from Part II show that donning technique is poor this may be addressed at the same training session. If results from the fit test show that a number of participants failed the fit test despite adequate technique, the implication could be that either the model or size of FFR is incorrect for those individual participants. Currently in CMJAH no alternative size or model FFR is available. This information will be communicated to the Head of Department of Anaesthesiology. This may help to motivate the procurement of a choice of models of FFR in order to enhance the safety of anaesthetists at risk of TB transmission. This study may also motivate that more fit tests be done in the department.

5.9 Validity and reliability of the study

The concept of validity is explained by Botma et al (37) as “the degree measurement reflects a true value”. The concept of reliability is about the dependability, regularity and consistency of the results. (37)

The validity and reliability of this study will be ensured by:

- using an appropriate study design
- using previously published questionnaires
- using local experts to ensure face validity for the South African context
- having a single data collector to guarantee uniform instructions and collection
- analysing data with the assistance of a biostatistician.

5.10 Potential limitations of the study

According to Creswell (28) limitations are the potential weaknesses of the study.

Part I of the study is limited by the convenience sampling method, as the population may be over or under represented. The contextual design may restrict the extent to which the results can be generalised to other contexts.

The yield of questionnaires is limited to the response rate of participants, which may influence how representative the sample is.

The limitations of the direct observation component of Part II of the study are that the researcher is present while the anaesthetists don the FFR. Their awareness of being observed while putting on the FFR may influence behaviour. They may take more care in donning the mask than they would in the real-life situation that happens in the operating room.

5.11 Project outline

Activity	May 2015	June 2015	August 2015	Nov 2015	Dec 2015	Jan 2016	Feb 2016	Mar 2016	April 2016
Proposal preparation									
Literature review									
Proposal submission									
Ethics and postgrad approval									
Data collection									
Data analysis									
Writing article									
Submission									

5.12 Financial plan

Statement	Cost for 1	Number required	Total
Binding	R50	2	R100
Paper and printing	R1	1000	R1000
Test kit	R4 357.74	1	R4357.74
Filtering facepiece respirators	R200	1 box	R200
Total			R5657.74

The cost of paper and printing was incurred by the Department of Anaesthesiology.

The fit test kit was borrowed from Quali-Med.

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Appendix A: Part I data collection sheet

Anaesthetist compliance and comfort in use of N95 filtering facepiece respirator questionnaire

Section 1: Demographics

1. Please indicate your professional designation using an X:

Consultant	Career medical officer	Registrar	Medical officer
------------	------------------------	-----------	-----------------

2. Please indicate your gender:

Male	Female
------	--------

Section 2: Compliance with use of N95 filtering facepiece respirator questionnaire

3. Have you ever used a filtering facepiece respirator to protect yourself against TB transmission?

Yes	No
-----	----

4. If your answer for Question 3 is "Yes" please continue the questionnaire by indicating the statement most applicable to your current practice:

Compliance score

Statement	Never	Almost never	Occasionally	Often	Almost always	Always
I wear an N95 respirator when there is the possibility of an infectious airborne disease.	0	1	2	3	4	5
I perform a self-fit check after putting on my N95 respirator.	0	1	2	3	4	5
I wash my hands before removing my N95 respirator.	0	1	2	3	4	5
I discard my N95 respirator immediately after use.	0	1	2	3	4	5
I take my N95 respirator off after I leave the room.	0	1	2	3	4	5

Section 3: Comfort of N95 filtering facepiece respirator use score

4. If your answer for Question 3 is “Yes”, please indicate the statement regarding how comfortable using the N95 filtering facepiece respirator is for you:

Comfort score

Statement	Never	Seldom	Often	Always
The N95 respirator is uncomfortable.	0	1	2	3
The N95 respirator makes me short of breath.	0	1	2	3
The N95 respirator makes me claustrophobic.	0	1	2	3
The N95 respirator makes me feel dizzy.	0	1	2	3
The N95 respirator makes it difficult to communicate.	0	1	2	3
The N95 respirator gives me a rash.	0	1	2	3
The N95 respirator makes me hot and sweaty.	0	1	2	3

Thank you for taking the time to complete this questionnaire.

Appendix B: Part II data collection sheet

Demographics

Gender:

Male	Female
------	--------

Criteria for adequacy of respirator fit technique score sheet

Criteria	Yes	No
proper chin placement inside FFR		
adequate strap tension		
adequate upper strap placement		
adequate lower strap placement		
fit across nasal bridge		
respirator remains fixed (does not slip)		
evaluate FFR fit and position in mirror		
perform a self-fit check		
Total out of 8		
Training received:	Yes	No

Outcome of fit test

Outcome	Pass	Fail
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Appendix C: Letter to the CEO

501 Mentone Court

44 Riviera Road

Killarney

2193

5 July 2015

To the Chief Executive Officer of Charlotte Maxeke Johannesburg Academic Hospital

Dear Sir / Madam

My name is Marthinet Niemandt and I am currently a registrar in the Department of Anaesthesiology. I would like to do a study with the title **Use and fit of filtering facepiece respirators in a Department of Anaesthesiology.**

The aim of Part I of the study is to describe the compliance and the comfort of use of the N95 filtering facepiece respirator of the anaesthetists in the Department of Anaesthesiology at Charlotte Maxeke Johannesburg Academic Hospital. The aim of Part II of this study is to describe the donning technique and fit test of the N95 filtering facepiece respirator of the anaesthetists in the Department of Anaesthesiology at Charlotte Maxeke Johannesburg Academic Hospital.

I would like to request permission to investigate the objectives of the research proposal. There will be no cost to the hospital as result of the study.

Post-grad approval has been obtained. Ethical clearance (protocol number M150711) is pending CEO approval and corrections suggested by Human Research Ethics Committee (Medical) have been made.

I thank you in advance

Marthinet Niemandt

0834756911

marthinetniemandt@gmail.com

Appendix D: Information letter (Part I)

November 2015

Dear colleague

Hello, my name is Marthinet, I am a registrar in the Department of Anaesthesiology. This letter is an invitation to partake in my M Med research study titled: **Use and fit of filtering facepiece respirators in a Department of Anaesthesiology.**

The last barrier of defence that anaesthetists can rely on to protect themselves from transmission of tuberculosis is the use of respiratory protection devices. In the Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) a N95 filtering facepiece respirator is provided for this purpose. This measure is only effective if the right size and model is used appropriately. Comfort is an important factor that determines compliance with N95 filtering facepiece respirator use.

I am doing a two part study. The aim of this part of the study is to describe the compliance and comfort in the use of the N95 filtering facepiece respirator of the anaesthetists in the Department of Anaesthesiology at CMJAH.

Completing the questionnaire will imply consent to participate in the study. Participation is voluntary and anyone is free to withdraw from the study at any time without having to supply a reason.

Questionnaires are anonymous as no identifying data will be asked of you. Once the questionnaires are completed, they will be placed in a sealed data collection box. It will take less than 10 minutes to complete the questionnaire. The process is completely confidential and only my study supervisors and I will have access to the raw data.

If the results show poor compliance with the use of the filtering facepiece respirator that may put you at risk of acquiring TB at work, I shall organise a training session to educate the department on the correct use of the filtering facepiece respirator.

The Human Research Ethics Committee (Medical) (protocol number M150711) and the Post-graduate Committee of the University of the Witwatersrand have approved the study proposal.

If you have any questions with regards to the study, please contact me on 083 475 6911 or marthinetniemandt@gmail.com. The chairperson of the Human Research Ethics Committee is Prof Cleaton-Jones. He can be contacted on 011 717 1234.

Thank you for taking the time to read this letter.

Yours sincerely

Marthinet Niemandt

Appendix E: Information sheet (Part II)

November 2015

Dear colleague

Hello, my name is Marthinet, I am a registrar in the Department of Anaesthesiology. This letter is an invitation to you to partake in my M Med research study titled: **Use and fit of filtering facepiece respirators in a Department of Anaesthesiology.**

The last barrier of defence that anaesthetists can rely on to protect themselves from transmission of tuberculosis is the use of respiratory protection devices. In the Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) a N95 filtering facepiece respirator is provided for this purpose.

I am doing a two part study and the aim of this part of the study is to describe the donning technique and to do a fit test of the N95 filtering facepiece respirator with anaesthetists in the Department of Anaesthesiology at CMJAH.

You will be excluded from the study if you:

- have a medical condition such as shortness of breath or claustrophobia, that precludes you from wearing a N95 filtering facepiece respirator or a hood
- feel that you have a problem with tasting bitterness
- have a blocked nose
- have a known sensitivity to Bitrex®.

If you agree to participate, please choose a suitable 20 minute time slot on the sheet of paper supplied. Please do not eat, smoke, chew gum or drink anything other than water for 30 minutes for before your time slot as eating may affect your detection of the test solution.

A threshold screen shall be performed to ascertain that you are able to detect the taste of the test solution. You will wear an enclosure (a hood with a 1.9 cm hole in front of your nose and mouth area) over your head and shoulders. I will ask you to close your eyes. I will then spray a fine mist of diluted test solution into the enclosure and ask you to breathe through a slightly open mouth with your tongue extended. I will ask you if you can detect the taste of the solution.

Next I will ask you to don a N95 filtering facepiece respirator. While wearing the filtering facepiece respirator you will don the enclosure. I shall ask you to close your eyes again and spray the test solution into the hood. You will again be asked to let me know if you can detect the taste of the solution. I will give you very specific instructions about what is expected of you during the fit test.

Participation is voluntary and anyone is free to withdraw from the study at any time without having to supply a reason. Anonymity will not be possible in this study as the researcher will conduct the test, however the data generated will be documented and reported anonymously. There will be no negative consequences for participation regardless of the outcome. Only the researcher and supervisors will have access to the information and raw data therefore ensuring confidentiality.

If the results show the N95 filtering facepiece respirator provided does not fit your facial features, I shall report this possible safety hazard to the Head of Anaesthesiology.

The Human Research Ethics Committee (Medical) (protocol number M150711) and the Post-graduate Committee of the University of the Witwatersrand have approved the study proposal. If you have any questions with regards to the study, please contact me on 083 475 6911 or marthinetniemandt@gmail.com. The chairperson of the Human Research Ethics Committee is Prof Cleaton-Jones. He can be contacted on 011 717 1234.

Thank you for taking the time to read this information letter.

Yours sincerely

Marthinet Niemandt

Appendix F: Informed consent letter for Part II

Title: Use and fit of filtering facepiece respirators in a Department of Anaesthesiology
(Part II)

Principle researcher: Marthinet Niemandt

Telephone number: 083 475 6911

Email address: marthinetniemandt@gmail.com

Department of Anaesthesiology

Name of participant: _____

Nature of research: Participant will be a test subject for the fit test with the filtering facepiece respirator.

The study poses no risks to the participants. The potential benefits are that the participants will receive one on one training on the donning technique of the filtering facepiece respirator.

I, (name) _____, hereby agree to participate in the study titled **Use and fit of filtering facepiece respirators in a Department of Anaesthesiology.**

I acknowledge that:

- I have read this consent form and the information letter and I had the opportunity to ask questions about them
- I agree to my results being used for research purposes on condition that my privacy is respected
- I understand that I am under no obligation to take part in this study
- I understand I have the right to withdraw from this project at any stage.

Date: _____

Signature of participant: _____

Signature of principal investigator who sought consent: _____