# N95 RESPIRATORS FOR A DIVERSE POPULATION OF HEALTHCARE WORKERS:

# A MIXED-METHODS, PROSPECTIVE, PILOT AND FEASIBILITY STUDY

# N95 RESPIRATORS FOR A DIVERSE POPULATION OF HEALTHCARE WORKERS: A MIXED-METHODS, PROSPECTIVE, PILOT AND FEASIBILITY STUDY

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A thesis submitted to the School of Graduate Studies in partial fulfillment of the requirements for the degree of Master of Science in Health Research Methodology.

**Degree:** Master of Science (2022), McMaster University, Hamilton, Ontario

**Title:** N95 Respirator Fit for a Diverse Population of Healthcare Workers: A Mixed-Methods, Prospective, Pilot and Feasibility Study

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**Number of pages**: 82

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## ABSTRACT

**Introduction:** Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has had a global effect. While most of the transmission occurs through droplets produced by an infected individual, SARS-CoV-2 can be transmitted through virus-containing aerosols. The use of N95 respirators reduces the risk of infection; however, in the absence of standardized testing facilities, as well as supply chain and border challenges, Canadian healthcare workers (HCW) had to rely on United States (US) standards and respirators. In Canada, women represent 82% of HCWs, but most masks and respirators have been designed based on the anthropometrics of average men in the US and Europe. In the absence of a tight seal, female HCWs and any individual who does not fit the average male head and face, including individuals of different ethnicities, are at risk of contracting SARS-CoV-2 and other infectious diseases. Thus, there is a knowledge gap on the effects of gender and ethnicity on the fit of N95 respirators and the implications of poor fit on the physical and psychological well-being of HCWs.

**Objectives:** Primary: Feasibility of a multi-center mixed-method study, with a sample size of 100, 50% of participants self-identifying as non-white and having at least 1 characteristic of interest. Secondary: (1) Generate quantitative evidence on N95 fit using a PortaCount fit test, (2) describe participant-reported feelings on fit and breathability, and (3) evaluate the impacts of the pandemic and limited supply of N95's on a HCWs overall physical and mental well-being.

**Methods:** This study was a mixed-method prospective pilot and feasibility study consisting of (1) a quantitative fit test and (2) a qualitative survey on N95 fit and comfort, as perceived by HCWs. The quantitative fit was assessed using a TSI PortaCount test and facial measurements of bizygomatic breadth and Menton-Sellion length. In parallel, a survey was administered to collect sociodemographic information, gauge the HCW's assessment of N95 fit and comfort, and assess the impact of PPE- related challenges on the physical and mental well-being of HCWs.
**Analysis:** Primary: The sample size, the proportion of various HCWs, and the number of participants who completed both aspects of the study were reported using descriptive statistics. Secondary: The results of the quantitative fit test, as well as the domains assessed in the survey using Likert scales, were summarized using descriptive statistics. Additional patient-reported assessments were collated and presented to provide a comprehensive reflection of HCW's feelings and attitudes on respirator fit and comfort.

**Results:** Following a study amendment to increase eligible sites, 37 of the 41 (90.2%) approached HCWs consented to participate, 36 of the 41 (97.3%) were successfully fitted, and all 36 HCWs completed the survey. Compared to the other included HCWs, female HCWs who identified as non-White had the lowest mean fit factor. Differences in Menton-sellion length and bizygomatic breadth were also observed between both male and female HCWs and between white and non-White HCWs. These results were corroborated by the survey data. On average, female HCWs reported lower scores in all measured domains, and the majority of HCWs reported physical discomfort, including headaches and itching, and negative impacts on their psychological well-being, as a result of fit, availability, and prolonged use of N95.

**Conclusion:** Despite the challenges of conducting research in the context of the COVID-19 pandemic, we have identified gender and ethnicity as key factors in the fit of N95 respirators and the negative implications of existing respirator designs on the physical and psychological well-being of HCWs. Future studies, including a larger mixed-method study, and respirator designs should consider the effects of gender and ethnicity to ensure that they reflect the diverse demographic of HCWs.

**ACKNOWLEDGEMENTS**

First and foremost, I would like to express my sincere gratitude to my supervisor and mentor, Dr. Alison Fox-Robichaud. I have had the privilege of working with her since the second year of my undergraduate studies, but over the last two years especially, I have been in complete awe of her dedication to research, even amidst a global pandemic. Thank you for your unwavering support and ongoing encouragement.

To my committee members, Dr. Lisa Schwartz and Dr. Myrna Dolovich, thank you for your expertise, enthusiasm, and support for this project. Without your dedication to this project and expert advice on how to navigate the challenges we faced; this work would not have been possible.

To Jeff Mallany and Bonnie Peacock, I would like to thank you both for your willingness to support this research project, despite how busy you were and the immense responsibility you held. Put simply, your resilience and sheer enthusiasm for the work you do was inspiring. It has been a pleasure learning from you both.

To my professors in the Health Research Methodology program, thank you for teaching with compassion, for reinforcing the relevance of our work, and for challenging us to go beyond research norms.

I would like to thank CIHR for funding this research project and the larger body of research designed to evaluate and challenge existing PPE to protect against airborne bacteria and viruses. I would also like to thank Dr. Zeinab Hosseinidoust and the rest of the team contributing to the various aspects of this project for their support and technical expertise needed to ground this work.

Lastly, I would like to thank members of the Fox-Robichaud lab and fellow graduate students in the HRM program. Thank you for helping to navigate the last two years, for celebrating even the smallest of successes, and for your ongoing encouragement.

I would like to end by saying, for the people I have thanked above, simply saying “thank you” does not feel like enough. Each of you has supported me and this work in ways that I could not have imagined and taught me so much along the way. I can only hope to embody these lessons and insights as I continue my academic career. Thank you.

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**List of Figures and Tables**

**List of Abbreviations**

| | |
|---|---|
| AGP | Aerosol-generating procedures |
| COVID-19 | Coronavirus disease |
| CSA | Canadian Standards Association |
| HCW | Healthcare workers |
| HGH | Hamilton General hospital |
| JH | Juravinski hospital |
| MCH | McMaster Children's hospital |
| NIOSH | National Institute for Occupational Safety and Health |
| PPE | Personal protective equipment |
| SARS-CoV-2 | Severe acute respiratory syndrome coronavirus 2 |
| SD | Standard deviation |
| US | United States |
| WHO | World Health Organization |

# CHAPTER 1: INTRODUCTION

## 1.1 Coronavirus Disease Pandemic

Coronavirus disease (COVID-19) has had a global effect, with more than 522 million confirmed cases and 6 million deaths reported worldwide, to date.[1] Canada has seen more than 3.8 million cases and 41,000 deaths.[2] Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19, is a respiratory virus with a range of symptoms from mild, non-respiratory symptoms to severe acute respiratory illness, sepsis, and death.[3] Symptoms include fever, fatigue, nausea, vomiting, and in some cases chemosensory dysfunction, the loss of smell and taste.[4] Although the number of weekly cases and associated deaths has recently decreased[1], COVID-19 transmission has been an ongoing concern, particularly in healthcare settings with increasing highly transmissible variants.[5]

SARS-CoV-2 can be transmitted by droplets, aerosols, and, in some instances, through direct contact with contaminated surfaces, referred to as fomites. Most transmission occurs by droplets, produced when an infected individual coughs or sneezes and is in close proximity to another person. Expired respiratory droplets range from 5 to 10μm in size and typically fall within 1 meter of the individual; however, droplets can temporarily stay in the air.[6,7] Contact transmission occurs when an individual comes into direct contact with surfaces contaminated by droplets containing SARS-CoV-2.[4] In healthcare settings, SARS-CoV-2 can be aerosolized during aerosol-generating procedures (AGP) and can remain airborne for up to 3 hours. In this setting, aerosolized viral particles less than 5μm in size, can pass through the pores of surgical masks, especially in AGPs that require healthcare workers (HCW) to be in close proximity to the patient.[6,8] Strategies to reduce the spread of COVID-19 in high-risk settings must account for various modes of transmission and, in particular, settings where aerosolization can occur.[3]

### 1.2 Health Safety Measures in Healthcare Settings

To mitigate the spread of COVID-19, health safety measures were implemented in community and healthcare settings. Public health measures, including travel restrictions, social and physical distancing, widespread masking, along with contact tracing and testing, were effective in limiting the spread of COVID-19.[9] However, in healthcare settings where the risk of infection is increased[10], preventing the spread of infection between HCWs and patients required effective use of personal protective equipment, along with other health safety measures.[11]

Personal protective equipment (PPE), defined as any equipment used to reduce exposure to hazards[12], includes gloves, gowns, goggles, face shields, surgical masks, and N95 respirators. To protect against SARS-CoV-2, which is spread by droplets or aerosols produced when an individual coughs or sneezes, surgical masks and respiratory protective equipment are particularly important. Surgical masks consist of finely woven layered fabric designed to prevent the spread of droplets originating from the wearer, but do not meet the Canadian Standards Association (CSA) standard for respiratory protection. However, N95s are an essential form of respiratory protection as they offer a higher level of protection in airborne settings, compared to cloth or surgical masks, and have better filtration efficiency.[13] Early evidence suggested that the use of masks is associated with a significant reduction in the risk of infection, with N95s providing greater protection compared to disposable medical masks and reusable 12 to 16-layer cotton masks.[9] Thus, the World Health Organization (WHO) released guidelines on the use of medical masks and N95s in healthcare settings to limit COVID-19 transmission.[3] However, during the early phases of the pandemic, the supply of PPE was insufficient, particularly medical masks and respirators, due to high demand and disruptions in the global supply chain.[14]

According to WHO modelling, approximately 89 million masks are required monthly as part of the COVID-19 response, and without adequate access to well-fitted respirators, HCWs are at risk of contracting COVID-19. Prior to the increased production of PPE, 87% of nurses reported reusing masks or respirators and 27% reported exposure to COVID-19 patients without appropriate PPE, contributing to more than 3600 deaths in the United States.[15,16] Similarly, in Italy, where approximately 10% of HCWs were infected with SARS-CoV-2, 22% reported inadequate access to PPE. [17,18] While the shortages of medical masks and N95 respirators were of initial concern, appropriate strategies to limit the use and increase access to respiratory protective equipment[19] were implemented to mitigate these concerns in Canada. However, issues around properly fitted masks and respirators predate the pandemic.

The majority of current PPE, including masks and respirators, have been designed based on the anthropometrics of average men in the United States (US) and Europe.[20,21] Studies by Zhuang and Bradtmiller and Hsio et al. demonstrate clear differences between male and female anthropometrics, including head circumference, and a disconnect between the data used to design existing PPE and the US workforce.[22,23] The reliance on historical anthropometric data, based on average American and European men, poses additional challenges for other ethnic groups. In an international study of facial morphology, Farkas et al. found significant differences in nose height and width between Caucasian North Americans compared to Asian and Black ethnic groups, and significantly greater bizygomatic width in Caucasian men and Asians, among other differences.[24] As a result, most women, ethnic groups, and men who do not meet these standards, including individuals with facial hair, are challenged to find well-fitted and comfortable PPE.

In Canada, women represent 82% of HCWs[25], and with the vast majority of PPE designed for the average male head and face, they may be forced to wear poorly fitting PPE for

long periods of time. The inability to access appropriately fitting protection not only increases the risk of COVID-19, but, can lead to physical and psychological discomfort.[26] Existing PPE does not fit the diverse demographic of Canadian healthcare workers and is ineffectively serving its purpose.

### 1.3 N95 Respirators

In the presence of SARS-CoV-2, an airborne infectious agent that can be transmitted by aerosols, N95 respirators offer the greatest protection and are an essential form of respiratory protection.[9,27] According to the National Institute for Occupational Safety and Health (NIOSH), the national body that regulates N95s in the US and Canada, N95s must be closely fitted to the face and have at least 95% filtration efficiency to prevent inhalation of airborne particles less than 0.3μm in size.[28] A lack of standardized testing facilities, standards, and regulatory frameworks, in Canada, as well as supply chain and border challenges, forced HCWs to rely on US standards, and N95s. This exacerbated issues of access and fit, as the current standards do not reflect the diverse demographic of healthcare workers in Canada.

To provide adequate protection, N95s must be tightly fitted. Fit testing, evaluated qualitatively or quantitatively, is the process used to verify that a respirator forms a seal and provides the wearer with the expected protection.[29] Qualitative fit testing consists of a series of seven exercises (e.g., turning head side to side, moving head up and down, and bending over), is pass or fail, and is assessed based on the individual's ability to taste the test agent. Quantitative fit testing consists of the same seven physical exercises; however, unlike the qualitative test, it objectively measures the leakage around the face seal.[30] In the quantitative fit test, a particle generator is used to generate the ambient particle count and facilitates a comparison between the

concentration of airborne particles inside and outside the respirator. This is referred to as the fit factor, a measure of how well an N95 forms a seal around a person's face, and thus the reduction in the airborne concentration of the contaminant.[29,31] In the absence of a tight fit or an appropriate seal, N95s do not provide the required protection and put HCWs at risk of contracting COVID-19.[21]

Although the fit of N95s is important to protect against infectious diseases, ill-fitted respirators also affect the comfort and breathability, especially when worn for extended periods of time.[21,26,32] Concerns around difficulties breathing, skin irritation, heat and moisture build-up, and difficulties communicating or understanding others have been previously identified.[32] These problems were more frequently reported in women[26] and it is likely that they disproportionately impact any individual who does not fit the average male head and face, including individuals of different ethnicities. Ergonomic risk factors, such as poorly fitting PPE, impact the safety, comfort, and psychological well-being of HCWs, and as a result, can hinder patient care.[32,33] With respirators designed for the average American and European head and face, anthropometric differences between men, women and members of various ethnic groups, and a lack of evidence on the fit of N95s in Canada, Canadian HCWs are at risk of being exposed to infectious aerosols, such as SARS-CoV-2.

### 1.4 Rationale

SARS-CoV2 is transmitted through virus-containing aerosols, and thus personal protective equipment, specifically N95s, must provide an effective barrier against these infectious aerosols. The efficacy of N95s depends on how well it fits. Considering gender and ethnic diversity throughout the design, testing, and implementation phases has the potential to improve the fit, comfort, and breathability of N95s, thereby increasing user compliance and safety. Therefore, it is necessary to generate data on N95 fit and comfort that reflects the diversity of Canadian HCWs.

This mixed-methods pilot study will assess the feasibility of examining the fit of N95s in a diverse population of HCWs. Additionally, outcomes of fit testing, qualitative measures of HCW-reported feelings on N95 fit, breathability and comfort, and the impacts of PPE-related challenges on the physical and mental health of HCWs will be analyzed.

This project is part of a larger research study that aims to generate knowledge and evidence to inform the creation of a national standard that addresses material testing, material reuse, and PPE fit in Canada.

# CHAPTER 2: METHODS

## 2.1 Objectives

The objectives and outcome measures of this study are shown in **Table 1**.

The **primary objective** of this study was to determine the feasibility of examining the fit of N95s in a diverse population of HCWs, defined as:

(1) The ability to recruit a sample size of 100 healthcare workers within 4 months, where 50% of participants self-identify as being non-white, identify as female, or have at least 1 of the following characteristics: religious head covering (e.g., hijab, turban), glasses, and/or facial hair.

(2) The ability to obtain a consent rate of $\geq$ 80% in approached HCWs.

(3) The ability to generate quantitative evidence on the fit of N95 respirators in all 100 HCWs.

(4) The ability to collect HCW-reported assessments of N95 fit and the effects of COVID-19 and PPE shortages on their overall well-being.

The **secondary objectives** are to:

(1) Assess the outcomes of fit testing to determine the protection provided by N95s in a diverse sample of HCWs and specifically to identify any differences between HCWs who conform to facial norms and those who do not.

(2) Describe qualitative measures of participant-reported feelings on N95 fit, breathability, and overall comfort.

(3) Evaluate the impacts of COVID-19 and the limited availability of N95s on the physical and mental well-being of HCWs of diverse ethnic backgrounds.

**Table 1:** Objectives, outcome measures, and analysis for N95 pilot and feasibility study

| Objective | Outcome | Measure of Outcome |
|---|---|---|
| **Primary Objectives** | | |
| 1. Recruitment. | A sample size of 100 HCWs recruited within 4 months and 50% of the participants meet the following criteria:<br>● Self-identify as non-white<br>● Have at least one of the following characteristics: religious head covering (e.g., Hijab, Turban), glasses and/or facial hair (e.g., beard and/or mustache), and<br>● Identify as female | Count, proportions, and descriptive statistics (where appropriate). |
| 2. Consent | Consent rate of ≥80% in approached healthcare workers. | Proportion |
| 3. To perform the PortaCount fit test on all the included participants. | Successful PortaCount Fit Test: Full completion of a fit test or partial completion with a reason why the test was ended early. | Proportion and any changes to the current protocol |
| 4. To collect HCW reported feelings of N95 fit and the impacts of COVID-19 and associated PPE shortages on overall well-being. | Successful HCW-reported data collection: Completion of the survey, defined as at least 80% of the questions have been fully answered. | Proportion |
| **Secondary Objectives** | | |
| 1. To assess outcomes of PortaCount fit test to understand the protection N95s provide in a diverse sample of HCWs | Portacount fit test output (fit factor for all 7 tests and overall fit factor). | Descriptive statistics (mean ± SD) |
| 2. To describe participant-reported measures of N95 fit. | Participant-reported assessment of overall fit, comfort, and breathability. | Description of the results reported, thematic analysis, and. where appropriate, descriptive statistics. |
| 3. To describe any reported negative impacts of the pandemic and the limited availability of N95s on physical and mental well-being of HCWs. | Participant-reported impacts of COVID-19 on their physical and mental wellbeing. | |

## 2.2 Study Design

In the absence of knowledge on N95 fit that reflects the diversity of Canadian HCWs, it is necessary to collect both quantitative and qualitative data to generate the breadth and depth of knowledge required to develop standards and respirators that reflect this diversity.[34]

The described study is a prospective mixed-method pilot and feasibility study designed to assess the qualitative and quantitative fit, comfort, and breathability of N95s in a diverse population of HCWs. A convergent parallel design was used in which qualitative and quantitative data were collected in parallel, analyzed separately, and then merged for interpretation.[35,36] The collection of both data sets allowed objective measures of the fit of N95s (quantitative) and an analysis of themes regarding how HCWs feel about the fit, comfort, and breathability of N95s (qualitative). Incorporation of the results of the quantitative fit test with the qualitative data of the survey occurred in the interpretation phase, along with data on physical characteristics, gender, and ethnicity.

## 2.3 Study Methods

*Quantitative Study Methods*

For N95s to provide adequate protection, fit testing, and training are essential. Prior to all fit tests, HCWs were instructed on how to properly don and doff a respirator, complete a fit check, and had to complete a health assessment.

To assess the fit of an N95, a trained professional performed a quantitative fit test, using the TSI PortaCount Respirator Fit Tester, according to the NIOSH standard testing procedures[37] and the Hamilton Health Science respiratory protection protocol **(Appendix 1**). The quantitative fit test consisted of seven exercises designed to assess the amount of leakage into the respirator throughout the exercises. The overall fit factor compares the ratio of particles outside the respirator to those inside the respirator. The results of the PortaCount test for each of the following exercises were recorded: normal breathing (performed at the start and end of the test), deep breathing, turning the head side-to-side, nodding the head up and down, speaking out loud, and bending over. If the individual failed the test or the fit test was unsuccessful with the first respirator, the fit test was stopped, reported as an unsuccessful fit, and the machine was set up for the next respirator. Each fit test took approximately 10 to 30 minutes, depending on the number of tests required to fit the individual.

The 1870 + Health Care Particulate Respirator model (3M) was used for the first fit test. If the fit was unsuccessful, the DC 365 (Honeywell), followed by the 1860 (3M), 1860s (3M), and 1804s (3M) were tested. Following a failed fit test with the 1870+, the decision on which respirator to fit next was based on the individuals' perceived face width and length, as judged by the fit tester. If the individual was not fitted to one of the above respirators, they were fitted with a reusable elastomeric half-facepiece respirator (3M, 6000 series).

After completing a successful fit test, the bizygomatic breadth, defined as the maximum horizontal breadth of the face, and the Menton-Sellion length, defined as the distance between the Menton and Sellion landmarks, were measured using the VWR traceable sliding callipers (Model: 12777-830) **(Figure 1).** Both measures were recorded in millimetres for each participant, according to the NIOSH testing procedures.[38] These facial measurements were mapped onto the NIOSH bivariate panel **(Appendix 2, Attachment 8.5)** to determine the distribution of HCWs in each of the panels. These panels correspond to a range of face widths and lengths, and recommended number of participants to include when testing new respirators. These recommended numbers are based on the anthropometric database used to develop the bivariate panel and specifically to ensure that respirator designs reflect the user population.

The results of the fit test and the anthropometric measures were recorded in our data abstraction form, developed based on the Hamilton Health Sciences Respirator User Screening Assessment Form **(Appendix 3).**

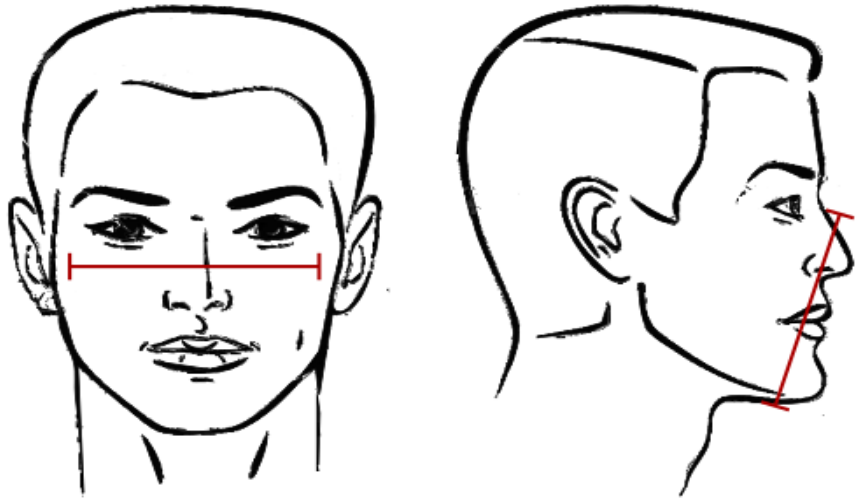


**Figure 1.** Anthropometric measures

*Qualitative Study Methods*

Although objective measures of N95 fit are important, understanding the perceived fit, comfort, and breathability of respirators from the perspective of HCWs is necessary, particularly when respirators are worn for long periods of time. To determine the diversity of experiences with wearing surgical masks and N95s, qualitative description, which seeks to provide a rich description of the phenomenon from the perspective of those involved (i.e., frontline healthcare workers), was used.[39,40] Specifically, a paper-based survey was designed and administered to frontline HCWs who underwent a quantitative fit test **(Appendix 4)**.

The survey was designed to gauge the HCW's assessment of (1) fit, comfort, and breathability of N95s and (2) the impact of PPE-related challenges on their physical and mental health, using open and closed-ended questions. The survey was divided into 3 parts that included participant demographics, fit and breathability of N95s and surgical masks, and physical and mental health. The demographic section included sex, gender, ethnicity, presence of headwear (e.g., hijab or turban), facial hair, and glasses. The definitions of sex, gender, and ethnicity were included in the survey to facilitate accurate responses. The HCWs were able to select more than one ethnicity or self-identify if the included categories did not reflect how they would identify. For the remaining 2 sections of the survey, closed-ended questions on N95 and surgical mask fit, comfort, and breathability, as well as PPE-related impacts on the physical and mental health of HCWs, were evaluated using 5-point Likert scales. Each question or series of related questions was followed by open-ended questions to collect qualitative, HCW-reported experiences of N95 fit to supplement the results of the close-ended questions, identify additional information not captured in the close-ended questions, and to assess the feasibility of collecting in-depth

qualitative data. For all the questions included, the HCWs had the option of selecting "prefer not to answer".

Domains, including gender, ethnicity, physical and mental well-being, were included based on frequently reported challenges in the literature[41,42], and the ongoing impacts of the COVID-19 pandemic on the overall well-being of front-line HCWs.[32] However, to assess the suitability of the questions, readability, and overall clarity, the survey was pilot tested in a sample of critical care healthcare workers (n = 3). Minor changes were made to improve the clarity of the questions. No questions were added or removed, and no other significant changes were made.

### 2.4 Setting

Potential participants included healthcare workers, defined as a healthcare providers (e.g., physician, nurse, respiratory therapist, etc.) or staff members, at a major teaching hospital (Hamilton General Hospital) in Hamilton, Ontario, Canada. This site has a high acute and emergency care burden, was under significant strain due to COVID-19 cases, and importantly, had the equipment and testing facilities to complete a quantitative fit test. Participants may work only at Hamilton General Hospital or at more than one Hamilton Health Sciences site and / or other healthcare facilities.

### 2.5 Recruitment and Participants

Convenience and purposive sampling strategies were used to recruit participants who were readily accessible, willing to participate, and would facilitate an analysis of the effects of gender and ethnicity on the fit of N95s.[43] Specifically, HCWs who underwent a routine fit test, and who had the time, and willingness to participate were approached for participation. The target population was healthcare workers, with equal representation of sex, and 50% of the participants met at least one of the following criteria:

- Self-identify as non-white
- Have one or more of the following characteristics: religious head covering (e.g., Hijab, Turban), glasses, and/or facial hair (e.g., beard).
- Identify as female

An identical sample of HCWs was selected for the qualitative and quantitative phases of the study, which occurred simultaneously. The decision to have the same and equal number of HCWs in both phases was necessary to facilitate direct comparisons between the quantitative and qualitative data sets.[35,44]

During the four-month study period, study posters, with a specific call for HCWs that met our diversity metrics, were posted outside the fit test clinic. This helped increase awareness and informed the staff about the ongoing study.

Participants were restricted to HCWs who worked on-site during the study period due to pandemic-related restrictions.

*Inclusion Criteria*

- 18 years of age or older
- Healthcare Provider or staff member at HGH
- Informed consent to participate in the fit test and complete the survey.

And 50% of the sample must also meet at least one of the following conditions:

- Self-identity as being non-white
- Have at least one of the following characteristics: religious head covering (e.g., Hijab, Turban), glasses and/or facial hair (e.g., beard and/or mustache)
- Identify as female

*Exclusion Criteria*

- Unable to safely complete a PortaCount fit test

**2.6 Data Management**

Data containing personal identifiers were not collected. De-identified data are stored in a locked drawer in a locked institution. REDCap, a secure web platform for building and managing online databases, will be used for long-term storage of the data.[45] All data will be destroyed after 5 years.

## 2.7 Analysis

*Co-primary Outcomes*

The co-primary outcomes are described in **Table 1**.

*Secondary Outcomes*

(1) Quantitative Fit Test Results

The results of the quantitative fit test are described with descriptive statistics. Specifically, the results for each of the seven exercises and the overall fit factor are reported as mean ± standard deviation (SD). These results are presented in aggregate, by gender, and by ethnicity. All data analysis was performed using *SPSS Statistics Version 27* (IBM, Chicago, IL).

Due to the small sample size, and risk of detecting a significant difference between males and females or the various ethnic groups, when in fact there was no difference (i.e., Type II error), no inferential statistics were run.[46]

(2) Measure of N95 Fit; and (3) Impacts related to PPE on Physical and Mental Health

Domains evaluated in the survey using Likert scales are summarized using medians and frequencies, where appropriate.[47]

Qualitative description was used to guide the reporting and analysis of the open-ended survey results, to ensure that the reported data directly reflect what the HCWs said, and how it was said.[39] Qualitative content analysis limits the amount of interpretation, and instead seeks to report the data from the perspective of the participants and provide a description of the patterns and regularities/irregularities organized in a way that reflects the data collected.[39,40] Thus, HCW-reported data on N95s were narratively summarized, and reported in tables, organized by N95 fit, comfort, and breathability and their impacts on the physical and mental health of HCWs.

Together, these results will provide a comprehensive reflection of HCW-reported feelings and attitudes on N95 respirator fit, and comfort as well as the impacts of the COVID-19 pandemic, including respirator shortages, on the physical and mental health of HCW's.

*Quantitative and Qualitative Data Integration*

Integration, defined as the point when the quantitative and qualitative data interface, is a key tenant in mixed-method designs, and in convergent studies, occurs following an independent analysis of the two datasets.[35] In this study, integration involved merging the results of the quantitative fit test, and qualitative survey, to provide a more robust analysis and understanding of experiences wearing N95s, than that provided by the quantitative or qualitative data alone.

To represent the convergent integration, a combination of data display, whereby quantitative and qualitative data are displayed using tables, and data integration were used to illustrate how quantitative and qualitative converge and diverge. Using narrative synthesis[35], the results of the quantitative statistical analysis were reported along with the themes from the qualitative analysis. These data were also summarized in the form of a "statistics-by-theme joint display"[48], where de-identified quotes are reported along with relevant numeric results and socio-demographic information collected in the two phases of the study. The results of this integration were reported in the discussion of our study.

## 2.8 Validity

Important to any research study is the management of threats to the validity of the study. Specific to mixed-method designs, validity refers to addressing threats to drawing correct inferences and assessments of the integrated data and varies according to the study design used.[35] Based on the threats to validity, in convergent designs, outlined by Creswell and Clark, **Table 2**, provides a list of validity threats necessary to consider and the specific strategies used in this study to address these threats.

**Table 2:** Threats to validity in mixed-method convergent designs

| Validity Threats | Strategies to Address Threats |
|---|---|
| Having unequal quantitative and qualitative sample sizes. | To limit this threat to validity, an equal sample size for the quantitative and qualitative data collection was used. Therefore, only participants who completed both the quantitative fit test and the survey were included in our analysis. |
| Keeping results from the different databases separate. | In addition to the analysis plan for the quantitative and qualitative datasets, strategies to facilitate data integration and analysis are described in Section 2.6, to ensure that both data sets are considered alongside each other. |
| Failing to resolve disconfirming results. | Both expected results (i.e., results that are in line with the existing literature on N95s and surgical masks) and unexpected results were explored in the analysis and reporting of the results. In line with the qualitative research paradigm, this approach recognizes the subjectivity of HCW experiences and allows for the consideration of multiple possible explanations of the results and experiences. |

Source: Adapted from Creswell, J., & Plano Clark, V. (2018). Chapter 7Analyzing and Interpreting Data in Mixed Methods Research (p. 251). In J. Creswell & V. Plano Clark (Eds). *Designing and conducting mixed methods research (3rd ed.)*. Thousand Oaks, CA: Sage.

### 2.9 Ethics

This study was approved by the Hamilton Integrated Research Ethics Board (HiREB) on April 1st, 2021 (project # 12776).

The risks involved in participating in this study were minimal. The PortaCount fit test was performed according to standard testing procedures and was the same as what is normally done when fitting HCWs to an N95s. However, if at any point during the fit test the HCW experienced any discomfort, the test was immediately stopped. Given the potentially sensitive nature of some of the questions, the HCWs had the option of selecting "prefer not to answer" and/or completing the survey on their own time, sealing it, and having it delivered to the research team via the secure, internal mailing system. Although the risks of this study were minimal, as part of the informed consent process, potential harms, risks, and benefits were described in detail.

Additionally, since this study was conducted during the COVID-19 pandemic, it was important to ensure that the research did not "compromise the public health response to [the] outbreak or the provision of clinical care."[49] In terms of recruitment, this meant that HCWs were only approached for study participation if (1) there was no line-up at the fit test clinic, (2) the HCW did not express time constraints or the need to return to clinical duty, and (3) the addition of one more person to the room, while other fit tests were ongoing, did not exceed the capacity limit. Potential participants who were available for this study were also limited to HCWs who attended the clinic to be refitted, and thus did not include individuals being fitted for research purposes only.

## 2.10 Funding

This work was funded by the Canadian Institute for Health Services Research (CIHR) for one year beginning June 1st, 2020. FS was supported by an Ontario Graduate Fellowship Award.

# CHAPTER 3: RESULTS

## 3.1 Study Amendment

Study recruitment began on January 4th at Hamilton General Hospital (HGH). However, due to the significant strain on the fit test clinic (i.e., wait times ≥ an hour), no participants were recruited until January 14th. Following two months of very minimal recruitment, a study amendment was submitted to the HiREB on February 27th, to expand the eligible sites. This amendment was designed to increase study recruitment by addressing (1) the strain on the fit test clinic, (2) the number of days the fit test clinic was run (on average only 1 day/week at HGH), and (3) the limited staff qualified to perform a PortaCount Fit test. Ultimately, the amendment was necessary in large part due to the challenges associated with the COVID-19 pandemic in hospital settings, and by extension the challenges of conducting research in this context. The amendment was approved on March 6th, and the last participant was recruited on May 6th. Key study dates are summarized in **Figure 2**.

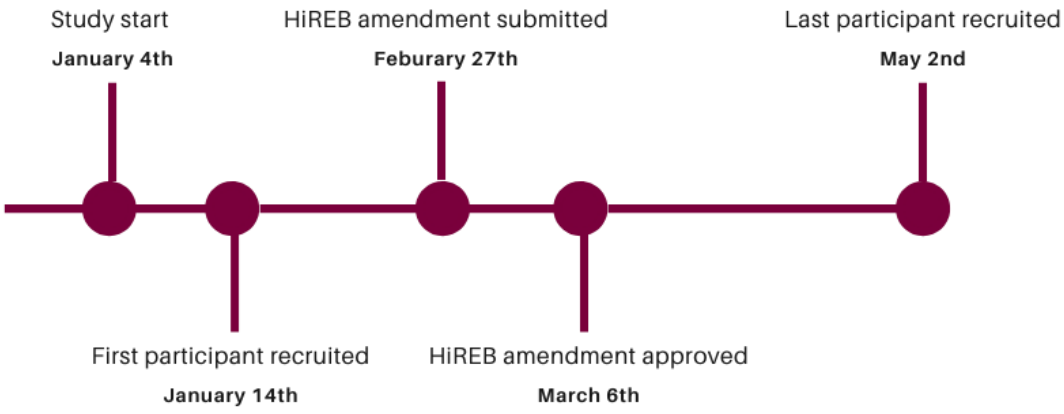


**Figure 2.** Study timeline

### 3.2 Feasibility Results

Feasibility results were collected up to May 6th, 2022. The flow of potentially eligible participants, beginning with the total number of fit tests conducted between January 4th and May 6th at Hamilton General Hospital (HGH), and between March 14th and May 6th, at Juravinski Hospital (JH) and McMaster Children's Hospital (MCH), are shown in **Figure 3**.

In most cases (n = 612), we were unable to approach potentially eligible HCWs, due to time constraints, either on the part of the HCW or the fit test clinic, and in some cases due to equipment failure. The quantitative fit test required setup time, could be done with only one person at a time, and had to be cleaned between uses. In contrast, using the qualitative fit test method, three to four HCWs could be fitted simultaneously, and when there was a line or multiple HCWs coming in at the same time, this was the only feasible option. At the HGH and MCH study sites, the TSI PortaCount machine also malfunctioned and had to be sent out for repairs. On these days, HCWs were not approached for participation. In two cases, study participants were unable to complete all study components and in one case, this was due to the PortaCount machine malfunctioning halfway through the test.

The results of the primary objectives, designed to assess the feasibility of conducting this study, are summarized in **Table 3**. Overall, study recruitment was well below the target (100 HCWs), with only 36 of the target 100 (36%) HCWs enrolled in the study. The primary reasons for low enrollment were the increased need for fit tests, the limited amount of time HCWs had, and for the first two months of the study, the limited number of days the fit test clinic was run. There were some additional challenges with equipment failure and the time required to have it repaired. Study recruitment increased slightly following the addition of two study sites; however, challenges persisted, and the recruitment rate was low with only 36 of the 653 (5.5%) potentially

eligible HCWs recruited. No other reasons, beyond time, were reported by HCWs or observed by the study team. Study recruitment over time is shown in **Figure 4**.

In the sample of HCWs approached for inclusion in the study, 37 of the 41 (90.2%) HCWs consented to participate in the study and 36 of the 41 (97.3%) were successfully fitted via the quantitative method. Additionally, 23 of the 36 (63.9%) included HCWs were fitted on the first try, while the remaining 13 required more than one fit test. One HCW was could not be fitted using the quantitative method due to equipment failure. All 36 HCWs successfully completed the survey, defined as at least 80% of the questions answered; however, on average, only 50% of the open-ended qualitative questions were answered.

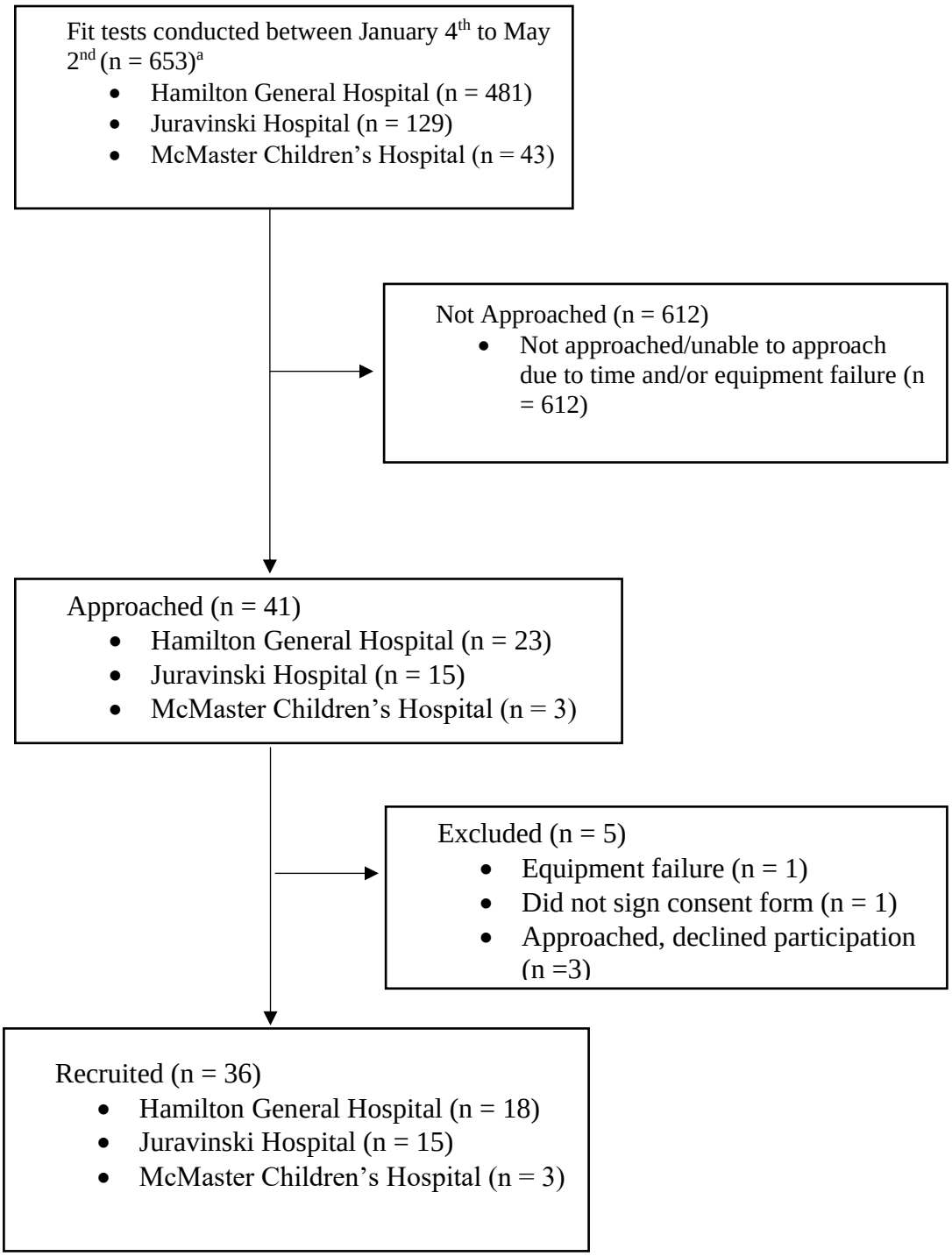


**Figure 3.** Study flow diagram

[a]Recruitment began at Juravinski and McMaster Children's Hospital on March 10th. The total number of fit tests completed at each of these sites prior to March 10th is not reported.

**Table 3:** Feasibility outcomes

| Outcome | Outcome Description | Proportion (%) |
|---|---|---|
| Recruitment | A sample size of 100 HCWs recruited within 4 months and 50% meet one of the following criteria:<br>• Self-identify as non-white<br>• Have one or more of the following characteristics: religious head covering, glasses, and/or facial hair<br>• Identify as female | 36/100 (36%)<br><br>Proportion of eligible HCWs: 36/653 (5.5%)<br><br>Characteristics of included participants are reported in **Table 4**. |
| Consent | Consent rate of ≥ 80% in approached HCWs. | 37/41 (90.2%) |
| Fit Test | Successful completion of a PortaCount fit test or partial completion with a reason for why the test was ended. | 36/37 (97.3%)<br><br>Proportion of successful fit tests on the first attempt:<br>23/37 (62.2%) |
| Survey | Completion of the survey, defined as at least 80% of the questions have been fully responded to. | 36/36 (100%) |

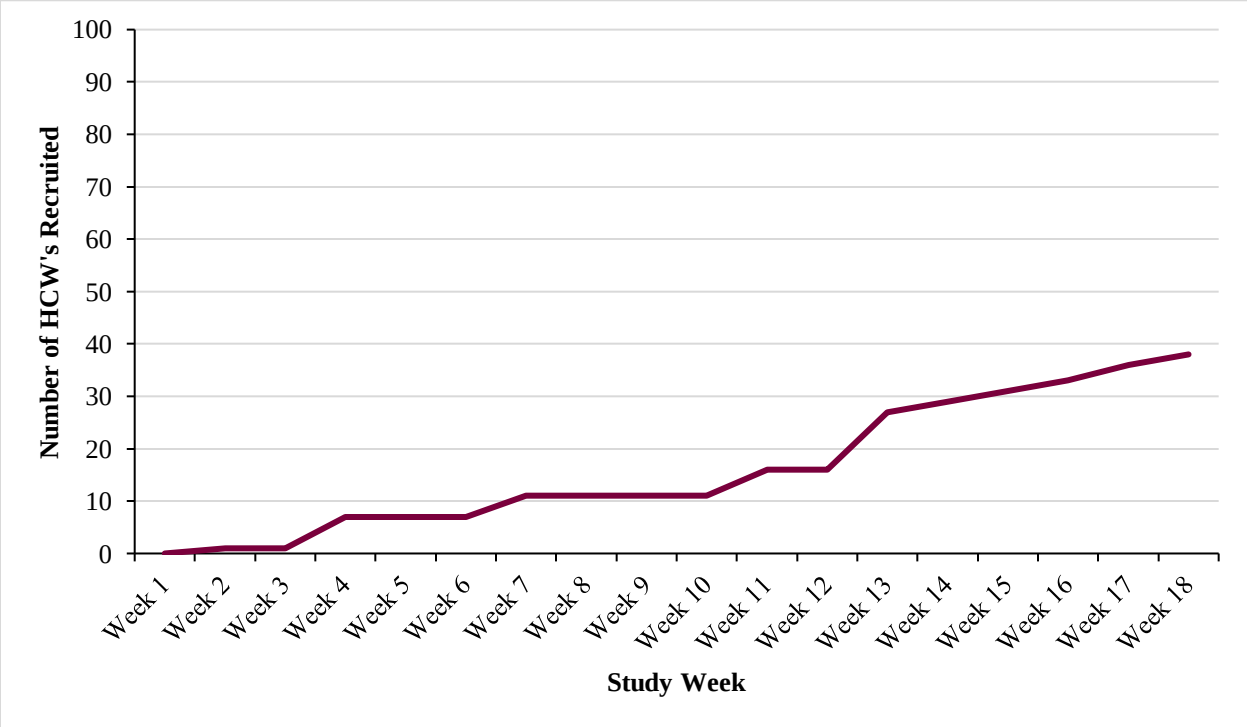


**Figure 4**. Study recruitment

### 3.3 Pilot Study Results

*Characteristics of the included HCWs*

As of May 6th, 36 HCWs were successfully recruited and completed the quantitative fit test and survey. The characteristics of the included participants are reported in **Table 4**. The age of the included participants ranged from 20 to 55 years, and the mean age was 32. 6 of the 36 (16.7%) HCWs identified as male and 30 of the 36 (83.3%) identified as female. No other gender identities were reported. Of the 36 included HCWs, 35 self-reported their ethnicities, 19 (52.8%) identified as White (Caucasian), 4 as Filipino (11.1%), 3 as Chinese (8.3%) and 2 as Black (5.6%). There was also one HCW in each of the following ethnic groups: Latin American (2.8%), Polish (2.8%), South Asian (2.8%) Southeast Asian (2.8%) and Vietnamese (2.8%). Polish and Vietnamese were not included as ethnic categories in the original survey; however, participants selected "prefer to self-identify" and responses were reported verbatim. Two HCWs selected more than one ethnic category, specifically one HCW identified as White (Caucasian) and Indigenous, and the other as White (Caucasian) and Latin American. One HCW did not respond to this question. In this study, no HCWs with religious head coverings or facial hair were included. In the context of COVID-19, we were unable to fit test individuals with facial hair as no fit tests were conducted for research purposes only. Standard fit testing procedures stipulate that the individual must be clean shaved at the time of the fit test. 16 of the 36 HCWs reported wearing glasses on a regular basis.

**Table 4:** Characteristics of the included participants (n = 36)

| **Variable** | **N (%)** |
|---|---|
| **Age,** (SD) | 31.97 (10.8) |
| **Gender** | |
| Male | 6/36 (16.7) |
| Female | 30/36 (83.3) |
| **Ethnicity** | |
| White (Caucasian) | 19/36 (52.8) |
| Black | 2/36 (5.6) |
| Chinese | 3/36 (8.3) |
| Filipino | 4/36 (11.1) |
| Latin American | 1/36 (2.8) |
| Polish* | 1/36 (2.8) |
| South Asian | 1/36 (2.8) |
| Southeast Asian | 1/36 (2.8) |
| Vietnamese* | 1/36 (2.8) |
| Mixed ethnicity | 2/36 (5.6) |
| **Physical Characteristics** | |
| Religious head covering | 0/36 (0) |
| Glasses | 16/36 (44.4) |
| Facial hair† | 0/36 (0) |

*SD* Standard deviation. *These ethnic categories were not included in the survey. The participants selected "prefer to self-identify". Responses are displayed as listed by participants. †The fit test protocol requires individuals to be clean-shaven. For safety reasons, and in the context of COVID-19, we were unable to include HCWs with facial hair.

*Results of the quantitative fit test*

All 36 of the included HCWs were fit tested; however, only 35 were included in the analysis. One HCW was fitted to a P100, the results of which are out of range, relative to the N95 respirator fit test. Among the 35 included HCWs, 27 (75%) were fitted to a 3M 1870+, 4 (11.2%) were fitted to a Honeywell DC 365, 3 (8.3%) were fitted to a 3M 1804s, and 1 (2.8%) was fitted to the 3M 1860s. An average of 1.67 fit tests per HCW were required to obtain a successful fit. The overall mean fit factor for all HCWs was 173, however, male HCWs had a mean fit factor of 184 compared to female HCWs, who on average, had a fit factor of 170. Unsurprisingly, White HCWs had a fit factor of 178, approximately 11 points higher than their non-White counterparts. Both the menton-sellion length, 122.87 vs 111.40, and the bizygomatic breadth, 121.93 vs 109.26, were longer in males compared to females. White HCWs had a slightly longer menton-sellion length, and non-White HCWs had a higher bizygomatic breadth value, compared to non-White and White HCWs, respectively.

To assess the combined effects of gender and ethnicity, the results of the quantitative fit test are summarized by gender and ethnicity in **Table 5**. On average, non-White male HCWs required the greatest number of fit tests to be fitted, compared to White males, and both White and non-White females. In contrast, both White and non-White males had a higher overall fit factor compared to their female White and non-White counterparts. Specifically, White males had a mean fit factor of 200, the maximum score attainable, and non-White males had a fit factor of 175, compared to White and non-White females who had mean fit factors of 175 and 165, respectively. In each of the four groups, the highest fit scores were observed in the first two static exercises, normal breathing, and deep breathing, after which the scores began to decline. Across the seven exercises, White males had the highest scores, followed closely by non-White males,

except in the talking–out-loud and bending-over exercises. In these two exercises, non-White females had the highest scores, with fit values of 196 and 174. Overall, female HCWs consistently had lower mean scores compared to males, and in four of the seven exercises, non-White females had lower scores compared to White females.

In addition to the fit test results, two anthropometric measures, menton-sellion length and bizygomatic breadth, were reported for all included HCWs. Within the male HCWs group, the menton-sellion length was longer in White males compared to non-White males, and the bizygomatic breadth showed the opposite trend. Non-White female HCWs had the shortest menton-sellion length and bizygomatic breadth, with mean values of 108.99mm and 107.82mm, compared to White female and male HCWs. When these values were assigned to the NIOSH bivariate panel, 27 of the 36 (75%) HCWs were out of range, 4 of the 36 (11.1%) were assigned to panel 6, 3 (8.3%) were assigned to panel 3, 1 (2.8%) was assigned to panel 4, and 1 (2.8%) was assigned to panel 1. The facial measurements of the 36 included HCWs are displayed alongside the NIOSH bivariate panel in **Figure 5**.

Together, these results demonstrate differences in fit factor and anthropometric measures between males and females, and between White and non-White identifying HCWs. Ultimately, female non-White HCWs had the lowest mean fit factor, the shortest menton-sellion length, and bizygomatic breadth, compared to the other included HCWs. Most HCWs included in this study could not be assigned to the NIOSH bivariate panel, reflecting differences in the anthropometric values of the HCWs in this study and those used to generate the bivariate panel.

**Table 5:** Summary of quantitative fit test results

| | Male (n = 6) | | Female (n = 29)* | |
|---|---|---|---|---|
| **Variable** | Non-White | White | Non-White | White |
| **Number of fit tests,** Mean (SD) | 2.25 (1.5) | 1 (0) | 1.62 (0.9) | 1.65 (1.1) |
| **Fit Factor,** Mean (SD) | 175 (32) | 200 (0) | 165 (30) | 175 (31) |
| Normal breathing | 200 (0) | 200 (0) | 185 (29) | 199 (5) |
| Deep breathing | 200 (0) | 200 (0) | 189 (26) | 189 (33) |
| Head side to side | 200 (0) | 200 (0) | 174 (49) | 180 (42) |
| Head up and down | 199 (1.5) | 200 (0) | 167 (55) | 161 (60) |
| Talking out loud | 168 (52) | 200 (0) | 196 (16) | 187 (30) |
| Bending over | 157 (66) | 200 (0) | 174 (52) | 180 (36) |
| Normal breathing | 173 (53) | 200 (0) | 168 (51) | 188 (23) |
| **Anthropometric Measures,** Mean (SD) | | | | |
| Menton-sellion length | 122.07 (9.6) | 124.46 (9.0) | 108.88 (11.3) | 113.32 (7.3) |
| Bizygomatic breadth | 126.46 (4.7) | 112.87 (6.4) | 107.82 (9.1) | 110.36 (11.0) |

*SD* Standard deviation. *mm* Millimeters. *One female participant was excluded from the quantitative analysis because they were fitted to a P100.

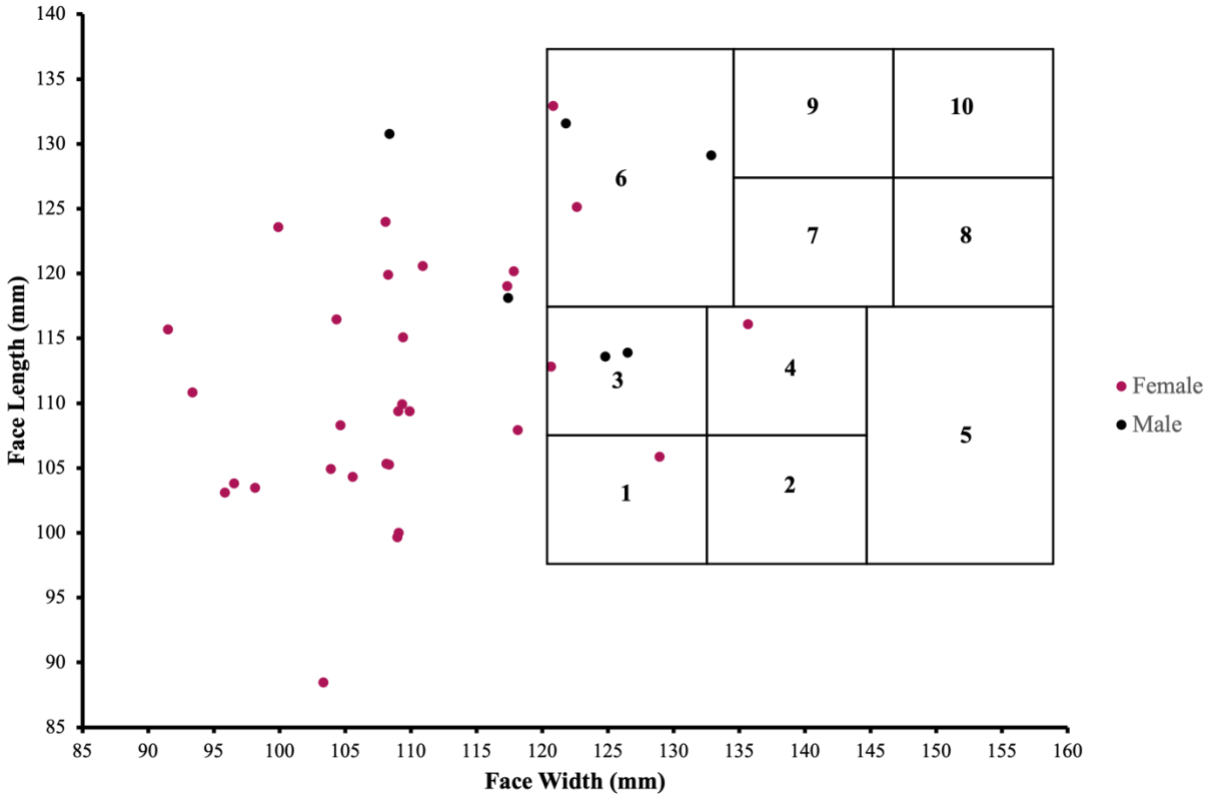


**Figure 5**. **Facial anthropometric measurements**. The facial measurements of the 36 included HCWs are displayed alongside the NIOSH bivariate panel. These panels correspond to a range of face widths (120.5 – 158.5 mm) and lengths (98.5 – 138.5mm) and recommend number of participants to include from each panel when testing new respirators. Twenty-seven of the thirty-six (75%) included HCWs in this study were out of range, demonstrating differences in this sample and the testing standards.

*Qualitative survey results: N95 respirators and surgical masks*

All 36 included HCWs completed the survey and responded to at least 80% of the questions. On a scale of one to ten, where one is poor and ten is excellent, included HCWs, on average, reported their experiences with N95s as a 6. There were no differences in reported experiences between white and non-white HCWs, however male HCWs had a slightly higher average score of 6.5, compared to female HCWs. 28 of the 36 (77.8%) HCWs reported experiencing physical discomfort, 23 (63.9%) experienced pressure/pain, 14 (38.9%) experienced headaches, and 12 (33.3%) reported experiencing itching as a result of wearing an

N95 respirator. Less frequent concerns included dizziness, reported by 8 (22.2%) HCWs, and nausea, reported by 2 (5.6%) HCWs.

A summary of the quantitative and qualitative measures of N95 and surgical mask fit, comfort, and breathability, grouped by gender and ethnicity, are reported in **Tables 6a** and **6b**, respectively. On a five-point Likert scale, where 0 is poor and 4 is excellent or very good, HCWs were asked to rate the fit, comfort, and breathability of N95s and surgical masks. Regarding the fit of N95s, both male and female HCWs had a median value of 3, corresponding to an agreement with the statement "N95 respirators fit me well". While male HCWs reported the comfort of N95 respirators as a 2, female HCWs reported the comfort of N95s as a 1 out of 5. This was reflected in the open responses, with one female HCW stating that "With the 1860s mask, it was extremely uncomfortable, difficult to breathe in. I would say it fit fine, but everything else was not great." In terms of breathability, male HCWs reported an average score of 3, compared to females who reported an average score of 2. Aside from the perceived fit of N95s, females reported lower measures of N95 comfort and breathability. In stark contrast to the N95 fit, comfort, and breathability measures, male and female HCWs rated the fit, comfort, and breathability of surgical masks as better than N95s. In all three domains, male HCWs reported an average score of 4 out of 5, and female HCWs reported an average score of 3 out of 5. However, despite the average score of 4 out of 5 reported by the male HCWs, a male HCW reported that they "prefer N95 – less fogging up", referring to the seal formed by an N95 and often absent when wearing a surgical mask. Female HCWs frequently reported surgical masks being too big as well. For example, a female HCW reported "Feels loose, not providing enough protection, but they are comfortable" and another stated, "most surgical masks are a bit big on me". Although

male and female HCWs perceived the fit, comfort and breathability of respirators and masks differently, both rated the comfort and breathability of surgical masks higher compared to N95s.

When comparing the experiences of wearing N95s between white and non-white HCWs, the median scores for fit and breathability were the same. In line with these quantitative values, HCWs in each of these groups reported similar concerns, including respirators being overly tight and causing red marks on their face when worn for prolonged periods of time. In terms of comfort, the median score in white HCWs was 1 compared to a median score of 2 in non-white HCWs. However, both groups reported feelings of tightness and negative experiences exacerbated by wearing glasses, or unique facial characteristics. For example, a HCW who self-identified as white stated "Find it challenging to wear with my glasses. Find my mask a bit awkward on my face. Breathable but give me headaches when I wear all day (but I am generally prone to headaches)." Similarly, a HCW who self-identified as Vietnamese reported that it was "difficult finding appropriately sized masks due to small nasal bridge." There were no reported differences in perceived fit, comfort, or breathability of surgical masks between white and non-white HCWs. Concerns around the fit of surgical masks and the associated challenges continued to be reported. For example, a HCW said: "Some movement, chin will pull mask below the nose. Some do not pinch well at nose to stay snug.", and similarly, another reported that "only challenge is about fit. I have a small face, so I find myself adjusting the mask frequently."

In summary, surgical masks were reported to be more comfortable and breathable compared to N95s, but the fit of surgical masks and N95s was similar. On average, female HCWs reported lower scores across most domains, and there were minimal differences between white and non-white HCWs. Frequently reported concerns included pain, specifically at the nasal

bridge and behind the ears, and poor fit that resulted in significant movement on the individual's face and fogging of glasses.

**Table 6a:** Summary of survey results, reported by gender

| Domain | Median (IQR) | | Domain descriptions & illustrative examples | |
|---|---|---|---|---|
| | Male | Female | Male (n = 6) | Female (n = 29) |
| **N95 Respirators** | | | | |
| Fit | 3 (1) | 3 (1) | "I use the 1860 N95 and have issues with the nose clamp." "Nose pain – bridge of nose" "Prolonged use was uncomfortable" | "Hard to get proper fit, some slide & move on face. Drawing blood – required to bend head to chest → lots of movement." |
| Comfort | 2 (1) | 1 (1) | | "Uncomfortable after long periods of time. Difficult to get a comfortable seal across the nose." |
| Breathability | 3 (1) | 2 (2) | | "With the 1860s mask it was extremely uncomfortable, difficult to breath in. I would say it fit fine, but everything else was not great." |
| **Surgical Masks** | | | | |
| Fit | 4 (1) | 3 (1) | "Prefer N95 – less fogging up" "No challenges with surgical masks" | "Most surgical masks are a bit big on me" |
| Comfort | 4 (2) | 3 (0) | | "Feels loose, not providing enough protection but they are comfortable." |
| Breathability | 4 (2) | 3 (1) | | "Wearing a surgical mask for a 12 hour shift is hard to breath." |

*IQR* Interquartile range.

**Table 6b:** Summary of survey results, reported by ethnicity

| Domain | Median (IQR) | | Domain descriptions & illustrative examples | |
|---|---|---|---|---|
| | White | Non-White | White (n = 19) | Non-White (n = 17) |
| **N95 Respirators** | | | | |
| Fit | 3 (1) | 3 (1) | "Fit tightly to point where causes facial markings, redness + bruising. Especially at bridge of nose." | "They feel tight but move around, not well formed to nose and chin." |
| Comfort | 1 (1) | 2 (1) | "Find it challenging to wear with my glasses. Find my mask a bit awkward on my face. | "Difficult finding appropriately sized masks due to small nasal bridge." |
| Breathability | 2 (2) | 2 (2) | Breathable but gives me headaches when I wear all day (but I am generally prone to headaches)." | "Tight and quite uncomfortable." |
| **Surgical Masks** | | | | |
| Fit | 3 (1) | 3 (2) | | "Only challenge is about fit. I have a small face, so I find myself adjusting the mask frequently." |
| Comfort | 3 (1) | 3 (1) | "Breathable, fit me well. No problem wearing for extended periods." | |
| Breathability | 3 (1) | 3 (1) | "Some movement, chin will pull mask below nose. Some do not pinch well at nose to stay snug." "Fogging of glasses" | "Usually, a little too big. Can be hard to breath on exertion." "Ears – the hoops irritate my ears wearing them all day" |

*IQR* Interquartile range.

*Qualitative survey results: mental health*

In addition to the experiences of wearing N95s, and the perceived fit, comfort, and breathability of respirators and surgical masks, the impact of these experiences on HCWs mental health was also assessed. 8 (22.2%) of the 36 HCWs reported negative impacts due to prolonged use of N95s, 13 (36.1%) reported negative impacts due to limited access during the early stages of the pandemic, and 4 (11.1%) reported negative impacts on their mental health due to the fit of N95s. Although the number of responses to the open-ended questions related to mental health were limited, HCWs reported the following experiences as having negative impacts to their mental health and well-being:

> "Ability to communicate with patients – unable to fully understand some patients while wearing a mask – I listen with my eyes."

> "Very uncomfortable. Left to debate whether to wear mask (N95 – 1860s) + be in pain or to protect mental health at work. I feel like we shouldn't have to choose."

> "Worrying that the N95 not working or leaking and potentially getting COVID-19,"

These direct excerpts illustrate the negative impacts of existing N95s on the mental health of healthcare workers, and importantly the breadth of these impacts, including their ability to communicate with patients, feel safe while at work and their overall comfort.

# CHAPTER 4 DISCUSSION AND CONCLUSIONS

## 4.1 Discussion

With the onset of the COVID-19 pandemic, the shortage of PPE and the requirement to wear masks for prolonged periods of time, there was a critical need to evaluate N95s and surgical masks, in the Canadian context. This study aimed to explore the fit, comfort, and breathability of N95s and surgical masks in a diverse population of HCWs, and the first, to our knowledge, to compare fit testing outcomes with qualitative descriptions from the perspective of front-line HCWs. This was a prospective mixed methods pilot and feasibility study in which the co-primary objectives were to evaluate the feasibility of recruiting 100 HCWs, 50% of whom met the diversity criteria, a consent rate of at least 80% in HCWs approached, and the ability to collect quantitative fit test data and qualitative survey data. Although we were unable to approach the majority of potentially eligible HCWs who came to the fit test clinic, due to the increased need for fit tests and limited time, 37 of the 4190.2% approached HCWs consented to participate, 36 of the 41 (97.3%) were successfully fitted via the quantitative fit test, and all 36 (100%) included HCWs completed the survey. These results were obtained following a study amendment to expand eligible study sites, thus increasing the number of days for study recruitment, and decreasing the strain on the fit test clinic and staff.

In addition to the primary feasibility outcomes, we evaluated the results of the quantitative N95 fit test, and the survey data, of the 36 included HCWs. Although few studies have looked at the effects of both gender and ethnicity on N95 fit, and none have compared the results of N95 fit tests with HCW-reported qualitative description, the key findings of this study reflect the existing literature. When comparing the results between male and female HCWs, we found that, on average, male HCWs had a higher fit factor compared to female HCWs. In a study

that examined the fit factor in a group of HCWs, Wardhan et al. found that women had higher fit failure rates, defined as a fit factor less than 100, compared to men.[41] These findings are consistent with studies by McMahon et al.[50] and Lee et al.[51], which demonstrated a 10% difference in fit failure rate between males and females, with females having a higher fit failure rate. In line with previous studies comparing anthropometric measures between males and females, we also identified differences in Menton-sellion length and bizygomatic breath, key measures used to inform the design of N95s, between males and females. Specifically, females had shorter Menton-sellion length and bizygomatic breadth, with average values of 111.40 mm and 109.26 mm, compared to 122.87 mm and 121.93 mm in male HCWs. Although differences in N95 fit between men and women have been widely reported[42,50,51], few studies have explored the effects of ethnicity.[52]

When stratified by ethnicity, White HCWs had a higher fit factor compared to non-White HCWs, and both White and non-White males had higher fit factors, compared to their female counterparts. These differences in fit factor, as well as the observed differences in anthropometric measures, corroborate previous, albeit few, studies that examine the effects of ethnicity on the fit and comfort of respirators. For example, during the first wave of the COVID-19 pandemic, Green et al. analyzed the outcomes of fit tests across National Health Service (NHS) hospitals in the United Kingdom. In addition to demonstrating differences in fit failure rates between men and women, they found that Black, Asian, and Minority Ethnic (BAME) HCWs had significantly higher fit failure rates compared to non-BAME HCWs.[42] Similarly, Chopra et al. found that females and BAME participants had lower fit factor scores and fit test pass rates, which was attributed to differences in facial features. Specifically, they identified 14 standardized anthropometric measures that were significantly smaller for females. Despite

limited disaggregated data on facial measurements of BAME individuals, they also reported differences in facial geometry, face size, and nose measurements between Asian, Black, and Caucasian individuals.[52] These differences in fit failure rates between men, women, and various ethnic groups can be explained by differences in head and face anthropometrics, as these studies have demonstrated significant differences between genders[22,23] and ethnicities.[24,52]

The results of our study, corroborated by the existing literature, demonstrate differences in N95 fit and anthropometric measures, between males and females, and between White and non-White HCWs, highlighting a clear need to consider gender and ethnicity in the design of N95s. These findings were reaffirmed by the HCW reported measures of N95 respirator fit, comfort, and breathability reported in the survey, as female HCWs had lower scores in most measured domains. The majority of HCWs reported experiencing physical discomfort, including pain, headaches and itching, and a negative impact on their mental health due to prolonged use of N95s, limited access in the early phases of the pandemic, and the fit of existing respirators. Together, these studies highlight the importance of gender and ethnicity in the fit of N95 respirators, the existing knowledge gap, and as a result the lack of access to respirators that match the diverse demographic of HCWs in Canada. Importantly, the qualitative data from the survey demonstrate the widespread impact of existing PPE, including negative impacts to the well-being of HCWs and their ability to care for patients.

This study was limited by the number of HCWs we were able to recruit and the shortened study period. Specifically, the increased need for fit tests and the decreased capacity to engage in research among HCWs strained by the pandemic limited the pool of potentially eligible HCWs, and thus our ability to purposefully recruit individuals with religious head coverings, for example. The small sample size, specifically in the quantitative arm of our study, also limited our

analyses and our ability to run inferential statistics and report statistical differences. To address low recruitment, a study amendment was submitted to increase study sites; however, many of the challenges were the result of the COVID-19 pandemic and persisted even after the amendment. Despite these limitations, our study has several strengths: (1) this study of N95s in a diverse sample of HCWs, particularly in the absence of Canadian standards and respirators, is timely (2) used rigorous and objective methodology for conducting fit tests, and (3) included the collection of quantitative and qualitative data on N95 fit, comfort, and breathability. The collection of quantitative and qualitative data, an important strength of mixed-method studies, facilitated a comparison between the results of the fit test and the experiences of front-line HCWs to capture additional nuance that would otherwise have been missed.

In summary, we identified differences in the outcomes of the quantitative fit test and perceived measure of N95 and surgical mask fit between males, females, and various ethnic groups. Thus, despite the challenges of conducting research in the context of the COVID-19 pandemic, we have identified gender and ethnicity as key factors that contribute to the fit and comfort of N95s. With female HCWs making up approximately 82% of the current healthcare workforce, and the marked increase in individuals who identify as a visible minority, the challenges around N95s and other PPE, including the negative impacts to physical and psychological well-being, will persist in the absence of equitable designs. Future studies, including a larger mixed-method study to assess the fit and comfort of current respirators, are necessary to inform evidence-based testing, and new Canadian standards for N95s. Specifically, future studies should (1) employ strategies for recruiting a truly diverse sample of HCWs, (2) including additional anthropometric measures that better account for face and head shape, and (3) an exploration of factors such as occupation and duration of wear that may contribute to the

fit and comfort of N95 respirators. Together, the results of this pilot study and future studies will help inform equitable designs and standards for N95 respirators.

### 4.2 Conclusions

The COVID-19 pandemic has highlighted and exacerbated concerns around the fit, comfort, and breathability of PPE, and specifically N95s. In Canada, there remains a knowledge gap on the effects of gender and ethnicity on the fit of N95s and the implications of existing designs on the well-being of HCWs. This study used a mixed-methods approach to evaluate the results of the quantitative fit test, and qualitative data from front-line HCWs on the perceived fit and comfort of N95s. To date, we have presented the feasibility results of this prospective study, and pilot data, highlighting the differences in fit between males, females, and various ethnic groups, and the disproportionate impacts on the physical and mental well-being of female and non-White HCWs. The results of this study can be used to design a larger prospective mixed-methods study, and ultimately, inform improvements to existing respirators, and new standards in Canada. To our knowledge, this is the first study to incorporate N95 fit testing data alongside HCW-reported measures and has identified key factors that influence the fit of N95 respirators. It has become clear that masks and respirators are essential for protection against infectious diseases, and thus to protect front-line HCWs and patients against SARS-CoV-2 and other infectious diseases, masks and respirators must be designed to reflect the diversity of Canadian HCWs.

## References


1. Weekly epidemiological update on COVID-19 - 25 May 2022. Accessed June 13, 2022. https://www.who.int/publications/m/item/weekly-epidemiological-update-on-covid-19---25-may-2022

2. Canada PHA of. Coronavirus disease (COVID-19) outbreak updates, symptoms, prevention, travel, preparation. aem. Published September 13, 2020. Accessed February 3, 2021. https://www.canada.ca/en/public-health/services/diseases/coronavirus-disease-covid-19.html

3. Advice on the use of masks in the community, during home care and in healthcare settings in the context of the novel coronavirus (COVID-19) outbreak. Accessed January 26, 2022. https://www.who.int/publications-detail-redirect/advice-on-the-use-of-masks-in-the-community-during-home-care-and-in-healthcare-settings-in-the-context-of-the-novel-coronavirus-(2019-ncov)-outbreak

4. Guo G, Ye L, Pan K, et al. New Insights of Emerging SARS-CoV-2: Epidemiology, Etiology, Clinical Features, Clinical Treatment, and Prevention. *Front Cell Dev Biol*. 2020;8. Accessed June 13, 2022. https://www.frontiersin.org/article/10.3389/fcell.2020.00410

5. Christie A, Brooks JT, Hicks LA, Sauber-Schatz EK, Yoder JS, Honein MA. Guidance for Implementing COVID-19 Prevention Strategies in the Context of Varying Community Transmission Levels and Vaccination Coverage. *Morb Mortal Wkly Rep*. 2021;70(30):1044-1047. doi:10.15585/mmwr.mm7030e2

6. Howard BE. High-Risk Aerosol-Generating Procedures in COVID-19: Respiratory Protective Equipment Considerations. *Otolaryngol Neck Surg*. 2020;163(1):98-103. doi:10.1177/0194599820927335

7. Morawska L, Cao J. Airborne transmission of SARS-CoV-2: The world should face the reality. *Environ Int*. 2020;139:105730. doi:10.1016/j.envint.2020.105730

8. D'Silva DF, McCulloch TJ, Lim JS, Smith SS, Carayannis D. Extubation of patients with COVID-19. *Br J Anaesth*. 2020;125(1):e192-e195.

9. Chu DK, Akl EA, Duda S, et al. Physical distancing, face masks, and eye protection to prevent person-to-person transmission of SARS-CoV-2 and COVID-19: a systematic review and meta-analysis. *The lancet*. 2020;395(10242):1973-1987.

10. Salzberger B, Buder F, Lampl B, et al. Epidemiology of SARS-CoV-2. *Infection*. 2021;49(2):233-239.

11. Livingston E, Desai A, Berkwits M. Sourcing Personal Protective Equipment During the COVID-19 Pandemic. *JAMA*. 2020;323(19):1912. doi:10.1001/jama.2020.5317

12. Personal Protective Equipment - Overview | Occupational Safety and Health Administration. Accessed June 21, 2022. https://www.osha.gov/personal-protective-equipment

13. CDC. Masks and Respirators. Centers for Disease Control and Prevention. Published February 11, 2020. Accessed July 15, 2022. http://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/types-of-masks.html

14. GPMB. Accessed June 22, 2022. https://www.gpmb.org

15. Ayton D, Soh SE, Berkovic D, et al. Experiences of personal protective equipment by Australian healthcare workers during the COVID-19 pandemic, 2020: A cross-sectional study. *PloS One*. 2022;17(6):e0269484.

16. New survey of nurses provides frontline proof of widespread employer, government disregard for nurse and patient safety, mainly through lack of optimal PPE. National Nurses United. Published May 20, 2020. Accessed June 14, 2022. https://www.nationalnursesunited.org/press/new-survey-results

17. Nava S, Tonelli R, Clini EM. *An Italian Sacrifice to the COVID-19 Epidemic*. Vol 55. Eur Respiratory Soc; 2020.

18. Felice C, Di Tanna GL, Zanus G, Grossi U. Impact of COVID-19 outbreak on healthcare workers in Italy: results from a national E-survey. *J Community Health*. 2020;45(4):675-683.

19. Canada H. COVID-19 medical masks and respirators. Published October 20, 2020. Accessed June 22, 2022. https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/personal-protective-equipment/medical-masks-respirators.html

20. PPEandwomenguidance.pdf. Accessed June 22, 2022. https://www.tuc.org.uk/sites/default/files/PPEandwomenguidance.pdf

21. Janson DJ, Clift BC, Dhokia V. PPE fit of healthcare workers during the COVID-19 pandemic. *Appl Ergon*. 2022;99:103610. doi:10.1016/j.apergo.2021.103610

22. Zhuang Z, Bradtmiller B. Head-and-face anthropometric survey of US respirator users. *J Occup Environ Hyg*. 2005;2(11):567-576.

23. Hsiao H, Whitestone J, Kau TY, Whisler R, Routley JG, Wilbur M. Sizing Firefighters: Method and Implications. *Hum Factors*. 2014;56(5):873-910. doi:10.1177/0018720813516359

24. Farkas LG, Katic MJ, Forrest CR. International anthropometric study of facial morphology in various ethnic groups/races. *J Craniofac Surg*. 2005;16(4):615-646.

25. Bourgeault IL, James Y, Lawford K, Lundine J. Empowering women leaders in health: a gap analysis of the state of knowledge. *Can J Physician Leadersh*. 2018;5(2):1.

26. Çiriş Yildiz C, Ulaşli Kaban H, Tanriverdi FŞ. COVID-19 pandemic and personal protective equipment: Evaluation of equipment comfort and user attitude. *Arch Environ Occup Health*. 2022;77(1):1-8. doi:10.1080/19338244.2020.1828247

27. Plana D, Tian E, Cramer AK, et al. Assessing the filtration efficiency and regulatory status of N95s and nontraditional filtering face-piece respirators available during the COVID-19 pandemic. *BMC Infect Dis*. 2021;21(1):712. doi:10.1186/s12879-021-06008-8

28. NIOSH guide to the selection and use of particulate respirators certified under 42 CFR 84. Published online October 6, 2020. doi:10.26616/NIOSHPUB96101

29. Fit Test FAQs | NPPTL | NIOSH | CDC. Published December 28, 2021. Accessed June 27, 2022. http://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/respsource3fittest.html

30. Fit Testing | Center for Respiratory Protection | Respiratory Protection | 3M - US. Accessed June 27, 2022. https://www.3m.com/3M/en_US/respiratory-protection-us/support/center-for-respiratory-protection/fit-testing/

31. Hospital respiratory protection program toolkit: resources for respirator program administrators. Published online April 6, 2022. doi:10.26616/NIOSHPUB2015117

32. Cloet A, Griffin L, Yu M, Durfee W. Design considerations for protective mask development: A remote mask usability evaluation. *Appl Ergon*. 2022;102:103751.

33. Tawfik DS, Scheid A, Profit J, et al. Evidence relating healthcare provider burnout and quality of care: A systematic review and meta-analysis. *Ann Intern Med*. 2019;171(8):555-567. doi:10.7326/M19-1152

34. Creswell JW, Klassen AC, Plano Clark VL, Smith KC. Best practices for mixed methods research in the health sciences. *Bethesda Md Natl Inst Health*. 2011;2013:541-545.

35. Creswell JW, Clark VLP. *Designing and Conducting Mixed Methods Research*. Sage publications; 2017.

36. Tariq S, Woodman J. Using mixed methods in health research. *JRSM Short Rep*. 2013;4(6):2042533313479197.

37. Healthcare Respiratory Protection Resources, Fit Testing | NPPTL | NIOSH | CDC. Published February 5, 2021. Accessed July 6, 2022. http://www.cdc.gov/niosh/npptl/hospresptoolkit/fittesting.html

38. NIOSH Conformity Assessment Interpretation Notice (CA 2019-1011) | NPPTL | NIOSH | CDC. Published March 10, 2022. Accessed July 6, 2022. http://www.cdc.gov/niosh/npptl/resources/pressrel/letters/conformityinterp/CA-2019-1011.html

39. Bradshaw C, Atkinson S, Doody O. Employing a Qualitative Description Approach in Health Care Research. *Glob Qual Nurs Res*. 2017;4:2333393617742282. doi:10.1177/2333393617742282

40. Sandelowski M. Whatever happened to qualitative description? *Res Nurs Health*. 2000;23(4):334-340. doi:https://doi.org/10.1002/1098-240X(200008)23:4<334::AID-NUR9>3.0.CO;2-G

41. Wardhan R, Brennan MM, Brown HL, Creech TB. Does a Modified Adhesive Respirator Improve the Face Seal for Health Care Workers Who Previously Failed a Fit Test?: A Pilot Study During the Coronavirus Disease 2019 Pandemic. *Aa Pract*. 2020;14(8):e01264. doi:10.1213/XAA.0000000000001264

42. Green S, Gani A, Bailey M, Brown O, Hing CB. Fit-testing of respiratory protective equipment in the UK during the initial response to the COVID-19 pandemic. *J Hosp Infect*. 2021;113:180-186. doi:10.1016/j.jhin.2021.04.024

43. Etikan I, Musa SA, Alkassim RS. Comparison of convenience sampling and purposive sampling. *Am J Theor Appl Stat*. 2016;5(1):1-4.

44. Onwuegbuzie A, Collins K. A Typology of Mixed Methods Sampling Designs in Social Science Research. *Qual Rep*. Published online January 15, 2015. doi:10.46743/2160-3715/2007.1638

45. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)—a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform*. 2009;42(2):377-381.

46. Allua S, Thompson CB. Inferential statistics. *Air Med J*. 2009;28(4):168-171.

47. Slattery EL, Voelker CC, Nussenbaum B, Rich JT, Paniello RC, Neely JG. A practical guide to surveys and questionnaires. *Otolaryngol--Head Neck Surg*. 2011;144(6):831-837.

48. Guetterman TC, Fetters MD, Creswell JW. Integrating quantitative and qualitative results in health science mixed methods research through joint displays. *Ann Fam Med*. 2015;13(6):554-561.

49. Organization WH. Guidance for managing ethical issues in infectious disease outbreaks. Published online 2016.

50. McMahon E, Wada K, Dufresne A. Implementing fit testing for N95 filtering facepiece respirators: Practical information from a large cohort of hospital workers. *Am J Infect Control*. 2008;36(4):298-300. doi:10.1016/j.ajic.2007.10.014

51. Lee K, Slavcev A, Nicas M. Respiratory Protection Against Mycobacterium tuberculosis: Quantitative Fit Test Outcomes for Five Type N95 Filtering-Facepiece Respirators. *J Occup Environ Hyg*. 2004;1(1):22-28. doi:10.1080/15459620490250026

52. Chopra J, Abiakam N, Kim H, Metcalf C, Worsley P, Cheong Y. The influence of gender and ethnicity on facemasks and respiratory protective equipment fit: a systematic review and meta-analysis. *BMJ Glob Health*. 2021;6(11):e005537. doi:10.1136/bmjgh-2021-005537

**Posting Date: 2018-12-07**
**Posting History Dates:** 2003-09-10, 2004-12-22, 2005-11-22, 2006-12-20, 2006-12-20, 2007-11-08, 2008-12-01, 2010-08-23, 2010-12-06, 2011-08-18, 2013-01-30; 2013-11-18; 2017-12-05
Next Review Date: 2019-12-07

Title: **HSW - Respiratory Protection Protocol**

**Applies to: Hamilton Health Sciences staff, Hospital Affiliates, members of the Medical, Dental and Midwifery Staff.**

## 1.0 Purpose

Respiratory protection is a personal protective device used to protect workers from atmospheric hazards such as biological, chemical or particulate hazards. The type of respirator required to provide protection to the worker is dependant on the nature and concentration of the hazard.

The purpose of this protocol is to outline the responsibilities of workplace parties for the identification of atmospheric hazards in the workplace and the selection, use and care of appropriate respiratory protection. Included in the appendices of this protocol are the supporting materials (specific fit testing procedures, training materials, screening assessment form and queries) to implement this protocol.

## 2.0 Equipment

N95 disposable half-face respirators
P100 disposable half-face respirators
Full or Half Face Elastomeric Respirators
Fit testing hood
Challenge solution and nebulizers
TSI Portacount/N95 Companion

## 3.0 Policy Statements

**3.1** All HHS staff who require specialized respiratory protection to prevent exposure to other airborne hazards are required to have a valid fit test (within 2 years) for each type of respirator they have been fitted to.

**3.2** All patient facing HHS staff who are required to wear an N95 mask to perform their job duties are required to have a valid N95 Fit test (within 2 years).

**3.3** All members of the medical and midwifery staff who are involved in direct patient care are required to have a valid N95 Fit test (within 2 years).

**3.4** All HHS staff along with Members of the Medical and Midwifery Staff shall use respiratory protection in accordance with the training received.

## 4.0 Responsibilities

### 4.1 Program Director is responsible to:

4.1.1 Understand and ensure compliance with this protocol.
4.1.2 Ensure managers, supervisors and staff within their portfolio adhere to the respiratory protection protocol as required.

### 4.2 Manager/Supervisor is responsible to:

4.2.1 Understand and ensure compliance with this protocol.
4.2.2 Conduct, with the assistance of Health, Safety & Wellness and / or Infection Prevention and Control, a hazard assessment of their area, identifying biological, chemical and particulate hazards to determine the most appropriate respiratory protection required.

4.2.3 Provide employees opportunities to be trained and fit tested. Appointments for respiratory training and fit testing can be booked online (Click Here). **NOTE:** Ensure staff are clean shaven where the respirator seals to the face and not to consume anything by mouth (except water) or smoke 15 minutes prior to the fit test.
4.2.4 Maintain an adequate supply of all models of respirators as required by their department.
4.2.5 Ensure that employees have access to the appropriate models of respirator at the point of care (Clincal) or before exposure to the hazard (Non-clinical) and are using their respirators as instructed. **NOTE:** Ensure staff are clean shaven where the respirator seals to the face.
4.2.6 Regularly review the fit testing records of all employees within their department.
4.2.7 Notify Health, Safety & Wellness and / or Infection Prevention and Control of any employee concerns or changes in the workplace that would impact the use of a respirator.

**4.3 Infection Prevention and Control is responsible to:**
4.3.1 Consult with provincial authorities and best practice guidelines such as the Provincial Infectious Diseases Advisory Committee (PIDAC) to identify the appropriate circumstances and types of respiratory protection to prevent exposure to airborne infectious disease.
4.3.2 Identify departments, areas or personnel who require an N95 for infection prevention and control purposes.
4.3.3 Develop and deliver training as related to the donning and doffing of Personal Protective Equipment (PPE) for Droplet/Contact, Airborne or Airborne/Contact Precautions.
4.3.4 Notify Health, Safety & Wellness of any changes in the workplace that would impact the use of a respirator.

**4.4 Health, Safety & Wellness is responsible to:**
4.4.1 Assist Managers / Supervisors in conducting biological, chemical and particulate hazard assessments which may require respiratory protection as requested.
4.4.2 Provide managers with information on the selection, use and maintenance of respiratory protection which addresses the atmospheric hazards identified based on best practice guidelines.
4.4.3 Facilitate, coordinate and/or conduct fit testing using the procedure outlined in Appendix 5 and 6.
4.4.4 Maintain fit testing records for HHS staff in the Cority database.
4.4.5 Conduct medical clearance exam on employees who self identify conditions or symptoms which would prevent respirator use on the Respirator User Screening Assessment Form (Appendix 1).
4.4.6 Refer employees to Occupational Health Physician as necessary.
4.4.7 Document medical clearance and/or restrictions on the Respirator User Screening Assessment Form (Appendix 1) and communicate the results to the respirator user, the manager and Health & Ability management as appropriate.
4.4.8 Conduct or schedule fit testing as required during pre-placement medical assessments.
4.4.9 Maintain a corporate list of all departments which require N95 fit testing.

**4.5 Respirator User is responsible to:**
4.5.1 Understand and comply with this protocol.
4.5.2 Complete the Respirator User Screening Assessment Form (Appendix 1) prior to fit testing and identify the presence of any conditions or symptoms which would prevent them from wearing a respirator.
4.5.2 Participate in the fit testing procedure prior to initial respirator use and every 2 years, or whenever there is a physical change that would affect the fit of the respirator.

4.5.3 Refrain from eating, drinking, chewing gum or smoking 15 minutes prior to the fit test.
4.5.4 Be clean shaven where the respirator seals to the face on the day of the fit test and everytime they are required to don a respirator.
4.5.5 Select only respirators for which they have a valid fit test and use respirators as per the training received including donning, seal check and doffing.
4.5.6 Report to Manager/Supervisor any conditions in the workplace or personal physical changes that may prevent the safe use of the respirator.
4.5.7 Affix sticker on the back of their ID badge to identify the respirator they can safely wear.
4.5.8 Submit copy of the fit test record card to credentialing for record keeping (for members of the Medical and Midwifery Staff only).

**4.6 Credentialling is responsible to:**
4.6.1 Maintain a database of Medical and Midwifery Staff who are required to have a valid N95 Fit test (within 2 years).
4.6.2 Report fit testing compliance to Chiefs.

**4.7 Medical Practice Chiefs are responsible to:**
4.7.1 Ensure all members of the medical and midwifery staff who are involved in direct patient care have a valid N95 Fit test (within 2 years).
4.7.2 Review requests from medical staff to be exempted from being tested on or wearing an N95 respirator. Exemptions shall be made based on an assessment of:
a) the scope of practice of the requesting physician,
b) whether sufficient medical staff are available to allow the requesting physician to be excluded from from patient care requiring an N95.

**4.8 Fit Test Procedure**
4.8.1 The employee/physician or midwife completes the Respirator User Screening Assessment Form (Appendix 1).
4.8.2 The employee/physician or midwife reports to Employee Health Services for further health assessment if indicating on the Respirator User Screening Form the presence of any conditions or symptoms that would prevent them from wearing a respirator.
4.8.3 Prior to fit testing, employees/physicians or midwives are reminded to be clean shaven where the respirator seals to the face and not to consume anything by mouth 15 minutes prior to the fit test (except water).
4.8.4 Respirator User Screening Form (Health surveillance questionnaire) is collected by the fit tester and reviewed for completeness and any medical clearance/restrictions documented.
4.8.5 Information related to the Maintenance, Use, Care and Limitations of the respirator will be discussed with the employee ( Appendix 2, 3 or 4 depending on respirator type).
4.8.6 The qualitative (Appendix 5) or quantitative (Appendix 6) fit testing procedure will be followed to complete the fit test.

**5.0 Documentation**
Respirator User Screening Form
Fit Test Log Sheet
Fit Test Card
N95 Employee Handout
P100 Employee Handout
Fit Testing Record (data base)
Fit Test Sticker

**Posting Date: 2018-12-07**
**Posting History Dates:** 2003-09-10, 2004-12-22, 2005-11-22, 2006-12-20, 2006-12-20, 2007-11-08, 2008-12-01, 2010-08-23, 2010-12-06, 2011-08-18, 2013-01-30; 2013-11-18; 2017-12-05
Next Review Date: 2019-12-07

Title: **HSW - Respiratory Protection Protocol**

## 6.0 Definitions

**Challenge Agent:** A taste threshold screening product, either saccharin or bitrex, which is intended to determine whether the individual being tested can detect the taste.

**Maximum Use Concentration (MUC):** Is the assigned protection factor of the respirator X the occupational exposure limit of the airborne agent.

**Qualitative Fit Test:** A pass/fail method that relies on the subject's sensory response to detect a challenge agent in order to assess the adequacy of respirator fit.

**Quantitative Fit Test:** A test method that uses an instrument to assess the amount of leakage into the respirator in order to assess the adequacy of respirator fit.

**Respirator:** A device to protect the user from inhaling a hazardous atmosphere.

**Threshold Check Test:** A test intended to determine whether the individual being tested can detect the taste of saccharin or bitrex before donning the respirator.

**User Seal Check:** An action conducted by the respirator user to determine if the respirator is properly sealed to the face.

## 7.0 Cross References

HSW - Health and Safety Policy Statement
HSW - Footwear and Personal Protective Equipment
IC – Precautions for Aerosol Generating Medical Procedures IC - Communicable Diseases
Index - Clinical Syndromes and Conditions with Required Level of Precautions
IC- Routine Practice Policy
IC – Additional Precautions Policy
702013 Respirator User Screening Assessment (For EHS to order from Moore)

## 8.0 External References

R.S.O. 1990 Occupational Health and Safety Act
CSA Z94.4-11 Selection, Use and Care of Respirators

## 9.0 Developed By

Health, Safety and Wellness

## 10.0 In Consultation With

Infection Prevention and Control
Joint Health and Safety Committees

## 11.0 Approved By

Director – Health, Safety and Wellness
Manager – Safety (reviewed 2018)

| Keyword Assignment | Fit test, N95, P100, Half face, Full face, Respirator, worksafe |
|---|---|

**Posting Date: 2018-12-07**
**Posting History Dates:** 2003-09-10, 2004-12-22, 2005-11-22, 2006-12-20, 2006-12-20, 2007-11-08, 2008-12-01, 2010-08-23, 2010-12-06, 2011-08-18, 2013-01-30; 2013-11-18; 2017-12-05
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Title: **HSW - Respiratory Protection Protocol**

**Appendix 1** - This form is available through the Moore Forms Ordering Warehouse.

## 702013 Respirator User Screening Assessment - Sample Form

Hamilton Health Sciences

702013 (2015-02)

RESPIRATOR USER SCREENING ASSESSMENT

**GENERAL INFORMATION**

Date (yyyy/mm/dd) _____

Employee: Last Name _____ First Name _____ Employee ID # _____

Extension _____ Department _____ Occupation: _____

Are you a Credentialed Professional Staff Physician? ☐ Yes ☐ No Are you a resident? ☐ Yes ☐ No

Primary Work Site: ☐ Chedoke ☐ General ☐ JHCC ☐ MUMC ☐ SPH ☐ WLMH ☐ Other _____

Conditions of Respirator Use: ☐ Airborne Isolations ☐ Dust ☐ Other _____

Frequency of use: ☐ Daily ☐ Weekly ☐ Monthly ☐ Yearly ☐ Other: _____

Duration of use: ☐ Less than 15 min. ☐ Greater than 15 min. ☐ Greater than 2 hours ☐ Variable

Other types of personal protective equipment required (specify) _____

**HEALTH ASSESSMENT**

1. Do you have any of the following conditions or symptoms that you feel would make it unsafe to wear a respirator?
***(Do Not disclose your personal medical information on this form)*** ☐ Yes ☐ No

- shortness of breath
- heart problems
- chronic bronchitis
- claustrophobia
- chest pain on exertion
- dizziness / nausea
- hypertension
- neuromuscular disease
- fainting spells
- lung disease
- panic attacks
- asthma
- breathing difficulties
- emphysema

2. Do you have any concerns about your future ability to use a respirator safely? ☐ Yes ☐ No
3. Have you had previous difficulty while using a respirator? ☐ Yes ☐ No
4. Have you had pneumonia or bronchitis in the last 6 weeks? ☐ Yes ☐ No

**If you have answered YES to any of the 4 above questions, further assessment by a healthcare professional is required prior to respirator use. Please contact EHS (Employee Health Services) for an appointment.**

5. Have you previously failed a fit test and are now returning to be re-tested? ☐ Yes ☐ No
6. Are you on a medical surveillance program for isocyanates or asbestos through HHS? ☐ Yes ☐ No

What mask were you previously fitted for? ☐ 8210 ☐ 8110s ☐ 1860 ☐ 1860s ☐ 1870 ☐ 9105 ☐ 9105s ☐ Other: _____

**(Employee to complete this section, following Fit Test)**

I, _____ (employee printed name) acknowledge that I have been fitted for a respirator and I have been given adequate training in the following areas:

☐ Donning (putting on) ☐ Seal Check (confirming fit of mask)
☐ Doffing (removal the mask) ☐ Limitations of Use (when to use mask)

Signature of Respirator User _____ Date (yyyy/mm/dd) _____

**For Employee Health Services Only**

**Assessment Date** *(yyyy/mm/dd)* _____

**Respirator use permitted:** ☐ Yes ☐ No _____ *(Printed Name)* _____ *(Signature and Designation)*

**FIT TEST**

**Method**: ☐ Portacount ☐ Bitrex ☐ Saccharin **Sensitivity:** ☐ 10/5 ☐ 20/10 ☐ 30/15

Fit Tester to record results as follows:

Qualitative – Enter pass (✓) or fail (X) - or - Quantitative – Enter the protection factor

| Mask → | | | | | |
|---|---|---|---|---|---|
| Normal Breathing | | | | | |
| Deep Breathing | | | | | |
| Head Side to Side | | | | | |
| Head Up and Down | | | | | |
| Talking Out Loud | | | | | |
| Bending Over | | | | | |
| Normal Breathing | | | | | |
| **FINAL RESULT** | | | | | |

**Fitted to:**

☐ 8210 ☐ 8110s ☐ 1860 ☐ 1860s ☐ 1870 ☐ 9105 ☐ 9105s ☐ Other: _____

Tester: _____ *(Printed Name)* _____ *(Signature and Designation)*

**FOR OFFICE USE ONLY:** (PS = PeopleSoft PSP = Physician Share Point)

Date Entered:

PS: _____ (yyyy/mm/dd) Non-PS: _____ (yyyy/mm/dd) PSP: _____ (yyyy/mm/dd) Initials: _____

***(Fit Testing Record is kept in Employee's Primary Work Site Department)***

## Appendix 2: N95 Employee Fact Sheet

### Donning and Doffing Instructions for an N95 Mask

**For styles: 3M 1860, 3M 18860S, 3M 8210 and 3M 8110S**
*(Images and instructions courtesy of: https://multimedia.3m.com/mws/media/894897O/health-care-respirator-1860-1860s-wearitrightposter-english.pdf)*

DONNING:
Perform hand hygiene**.** Lightly stretch straps on respirator before fitting mask to face. Remove make-up around mouth and nose area before using (friction with straps may cause skin irritations)


(1) Cup the respirator in your hand, with the nosepiece at your fingertips (nosepiece is indicated by metal strip), allowing the headbands to hang freely below your hand.
(2) Position the respirator under your chin with the nosepiece up.
(3) Pull the top strap over your head so it rests high on the back of your head.
(4) Pull the bottom strap over your head and position it around the neck below the ears. Untwist the straps and position the respirator low on your nose.
(5) Using both hands, mold the nosepiece to the shape of your nose by pushing inward while moving your fingertips down both sides of the nosepiece.
(6) Perform a User Seal Check prior to each wearing. Place both hands completely over the respirator and exhale sharply. Be careful not to disturb the position of the respirator. If air leaks around the nose, adjust the nosepiece as described in Step 5. If air leaks at the respirator edges, adjust the straps back along the sides of your head. Perform the seal check again. If you cannot achieve a proper fit, inform your supervisor.

DOFFING:
Perform hand hygiene**.**

(1) Without touching the respirator, lift the bottom strap from around your neck up and over your head.
(2) Lift off the top strap. Do not touch the respirator.
(3) Discard the respirator.

**For Pleated Style: 3M 1870, V-Flex and AOS Masks**
*(Images and instructions courtesy of: https://multimedia.3m.com/mws/media/1641960/wear-it-right-particulate-respirator-surgical-mask-1870.pdf)*

DONNING:
Perform hand hygiene**.** Lightly stretch straps on respirator before fitting mask to face. Remove make-up around mouth and nose area before using (friction with straps may cause skin irritations).


(1) Remove respirator from packaging and hold with straps facing upward. Place the bottom strap under the center flaps next to the ATTENTION statement.
(2) Fully open top and bottom panels, bending the nosepiece around the thumb at center of foam. Straps should separate when panels are opened. Make certain bottom panel is unfolded and completely opened.

(3) Place respirator on your face so that the foam rests on your nose and the bottom panel is under the chin.
(4) Hold the bottom panel and pull the top strap to position it high on the back of your head. Then pull the bottom strap over your head and position it around the neck and below the ears.
(5) Adjust for a comfortable fit by pulling top panel toward the bridge of the nose and bottom panel under the chin.
(6) Place your fingertips from both hands at the top of the metal nosepiece. Using two hands, mold the nose area to the shape of your nose while moving your fingertips down both sides of the nosepiece.
(7) Perform a User Seal Check prior to each wearing. Place both hands over the respirator and inhale then exhale gently. If air leaks around your nose, adjust the nosepiece as described in Step 6. If air leaks around respirator edges, adjust the panels and position of straps to ensure edges fit against the face. If a proper seal cannot be obtained, inform your supervisor.

DOFFING:
Perform hand hygiene**.**

(1) Without touching the respirator, slowly lift the bottom strap from around your neck up over your head.
(2) Lift off the top strap. Do not touch the respirator.
(3) Discard the respirator.

## Limitations of N95 respirators

N95 respirators are aerosol-arresting respirators. Like other aerosol-arresting respirators, they have the following limitations:

1. They do not provide protection against hazardous gases or vapours.
2. They do not supply oxygen, so they cannot be used in oxygen deficient environment.
3. They are not suitable for oil-containing aerosols or for environment where oil is present in the air. This is because oil may reduce the filter efficiency of N95 filters.

N95 respirators provide the user with inadequate or little protection in the following circumstances:

- If facial hair is present, which interferes with the seal of the respirators. (Small moustaches and small goatees may be acceptable if they do not interfere with the seal of the mask; full beards are not acceptable.)
- If the respirator has become damaged or altered.

- If the concentration of the hazardous airborne aerosol in the environment concentration exceeds the maximum use concentration (MUC)[1].

N95 respirators may also have restrictions on their useful life; the manufacturer should be consulted for detailed instructions.

## General Time Use Limitations of N95 respirators

Aerosol filters, which include disposable N95 respirators, generally become more efficient as particles are collected and plug the spaces between the filters. N95 respirators should be discarded when the user notices an increase in breathing resistance or once they become damaged, altered or unhygienic.



[1] MUC = assigned protection factor of the respirator x the occupational exposure limit of the airborne agent

## Appendix 3: P100 Employee Fact Sheet

### Donning and Doffing Instructions for a P100 Mask

**For Style: 3M 8293 P100 respirators**

*(Images and instructions courtesy of: https://multimedia.3m.com/mws/media/298547O/3m-particulate-respirator-p100-user-instructions.pdf)*

DONNING:

Perform hand hygiene**.**

Fig. 1

Fig. 2

Fig. 3a

Fig. 3b

Fig. 4

Fig. 5

(1) Thread the top elastic strap through the top buckle. Repeat for the bottom elastic strap. Place the bottom elastic strap around the head, just below the ears. Untwist the strap.

(2) Pull the top strap over your head, resting it above the ears at the top back of your head.

(3) Adjust the strap tension by pulling the straps (3a). Strap tension may be decreased without removing respirator from the head by pushing out on the back of the buckle (3b).

(4) Place fingertips from both hands at the top of the metal nosepiece. Mold the nose area to the shape of your nose by pushing inward while moving your fingertips down both sides of the nosepiece.

(5) Perform a User Seal Check prior to each wearing. Place both hands completely over the respirator and inhale sharply. Be careful not to disturb the position of the respirator. A negative pressure should be felt inside the respirator. If any leakage is detected, readjust the position of the respirator according to Steps #3 and #4. If you cannot achieve a proper fit, inform your supervisor.

DOFFING:
(1) Decrease strap tension by pushing out on the back of the buckle.
(2) Cup respirator in hand to maintain position on face and pull bottom strap over head.
(3) Still holding the respirator in position, pull top strap over head and remove respirator.

## Limitations of P100 respirators

P100 respirators are aerosol-arresting respirators. Like other aerosol-arresting respirators, they have the following limitations:

1. They do not provide protection against hazardous gases or vapours.
2. They do not supply oxygen, so they cannot be used in oxygen deficient environment.

P100 respirators provide the user with inadequate or little protection in the following circumstances:

- If facial hair is present which interferes with the seal of the respirators. (Small moustaches and small goatees may be acceptable if they do not interfere with the seal of the mask; full beards are not acceptable.)
- If the respirator has become damaged or altered.
- If the concentration of the hazardous airborne aerosol in the environment concentration exceeds the maximum use concentration (MUC)[2].

P100 respirators may also have restrictions on their useful life; the manufacturer should be consulted for detailed instructions.

## General Time Use Limitations of P100 respirators

Aerosol filters, which include disposable P100 respirators, generally become more efficient as particles are collected and plug the spaces between the filters. P100 filters should be changed when the user notices an increase in breathing resistance, or once they become damaged, altered or unhygienic.

## Differences between N95 Respirators and P100 Respirators

N95" and "P100" are two of the nine series of the respirator filters certified by NIOSH[3]. There are two major differences between N95 filters and P100 filters:

[2] MUC = assigned protection factor of the respirator x the occupational exposure limit of the airborne agent

[3] NIOSH: the National Institute for Occupational Safety and Health of the USA

1. P100 filters have better filter efficiency than N95 filters.[4]
2. For oil-containing aerosols or for environment where oil is present in the air, P100 filters may be used but N95 filters should not be used. This is because oil may reduce the filter efficiency of N95 filters.



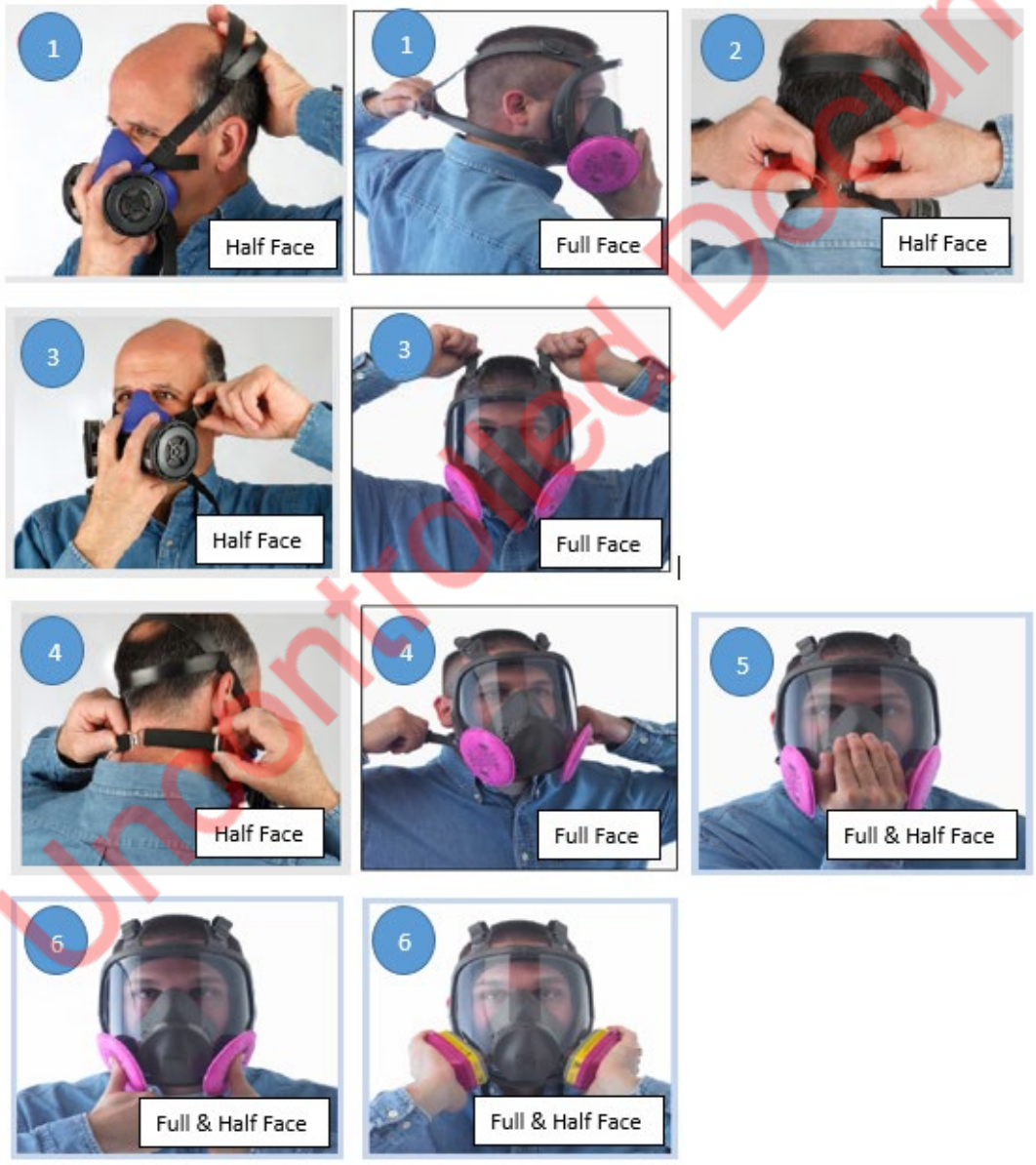
[4] For the particles (in 0.2 – 0.4 μm range) used in NIOSH test, the filter efficiency is 95% for N95 filters and is 99.97% for P100 filters.

# Appendix 4: Half-Face and Full-Face Employee Fact Sheet

## Donning and Doffing Instructions for a Half-Face Mask

### For Style: North 7700 Series and 3M 6000 Series

*(Images and instructions courtesy of: https://multimedia.3m.com/mws/media/64513O/wear-it-right-elastomeric-full-facepiece-4-strap-respirator.pdf AND https://www.honeywellsafety.com/Supplementary/Documents_and_Downloads/Respiratory_Protection/Single_Use_(Disposable)_Respirators/4294997403/1033.aspx)*



(1) Adjust the respirator head straps and clips to their full outward position. With one hand holding the respirator, place your chin inside the chin cup and the top of the respirator over your nose.
(2) *For Half-Masks ONLY*: Hook the bottom headband behind your neck, below your ears, and adjust the position of the facepiece on your face for best fit and comfort.
(3) Tighten the upper head straps in small, equal increments to ensure the top half of the respirator is tightened evenly and centered on your face.
(4) Tighten the lower head straps by pulling evenly on the end straps in the back of the respirator until the entire respirator is snug, comfortable and centered on your face.
(5) Positive pressure seal check: Place the palm of your hand over the exhalation valve so it is completely sealed and exhale gently. If you have a good seal, the facepiece will be pushed away from your face very slightly.
(6) Negative pressure seal check: Place the palm of each hand over the two cartridges or filters so they are completely sealed and inhale. Hold your breath for 5 seconds. If you have a good seal, the facepiece will be pulled inward toward your face.

DOFFING:
(1) Loosen straps from top to bottom. Be gentle so as not to damage elasticity of the straps.
(2) Grasp respirator on the bottom and remove upward over top of the head.
(3)

## Limitations of Half-face and Full-face respirators

Half-face and Full-face respirators have limitations in the following circumstances:

1. They do not supply oxygen, so they must not be used in oxygen deficient environment.
2. If the respirator has become damaged or altered.
3. If the concentration of the hazardous airborne aerosol in the environment concentration exceeds the maximum use concentration (MUC)[5].
4. For gas/vapour removing respirators, no protection is provided against particulate contaminants
5. For particulate removing respirators, protection is provided against non-volatile particulates only

Note: The appropriate type of canister, cartridge, or filter shall be selected for the particular atmosphere and conditions.

[5] MUC = assigned protection factor of the respirator x the occupational exposure limit of the airborne agent

## General Time Use Limitations of Half-Face and Full-Face respirators

*Gas/vapour-removing cartridges or canisters* equipped with an end-of-service-life indicator shall be replaced when the indicator dictates. Cartridges or canisters not equipped with an end-of-service-life indicator shall be replaced based on an established schedule that ensures the cartridge is changed before the service life has ended. The respirator manufacturer should be consulted for guidance on the effectiveness of any specific respirator or air-purifying element against the contaminant for which protection is needed. At any time, should workers detect odour or experience any irritation symptoms of the contaminant before the end of the change-out schedule, HSW shall be informed and shall re-evaluate the use of this respirator, i.e., the change-out schedule, the workplace concentrations, or other use conditions.

*Particulate filters* shall be replaced if :

a) they become damaged or unhygienic; or
b) based on the employer's change-out schedule; or
c) when breathing becomes difficult; or
d) as recommended by the manufacturer.

In environments containing only oil aerosols, P-series filters usually should be replaced after 40 hours of use or 30 days, whichever is first.

## Care and Maintenance of Half-Face and Full-Face Respirators

Each respirator shall be properly maintained to retain its original effectiveness. This shall include:

(a) Cleaning

Respirators shall be cleaned as follows:
Remove filters, cartridges, or canisters. Disassemble facepieces by removing all component parts (i.e. inhalation/exhalation valves). Wash components in warm water with a mild detergent. Rinse components thoroughly in clean, warm, preferably running water. Components should be hand-dried with a clean, lint-free cloth or air-dried. Reassemble the facepiece, replacing filters, cartridges, and canisters where necessary. Finally ensure that all components work properly before use.

(b) Inspection

Users shall inspect their respirators before and after each use. Respirator inspection shall include, where applicable, the following:

- condition of component parts (e.g., facepiece, head harness, valves, filters, cartridges, canisters, etc.);
- tightness of connections;
- end-of-service-life indicator; and

- shelf-life dates

(c) Storage

Respirators shall be stored in a manner that will protect them against dust, ozone, sunlight, heat, extreme cold, excessive moisture, vermin, damaging chemicals, oils, greases, or any other potential hazard that can have a detrimental effect on the respirator. Respirators shall be stored in a manner that will prevent deformation of rubber or other elastomeric parts.

## Appendix 5: Qualitative Fit testing Method[6]

### Sensitivity Test :

Prior to the fit test, the fit tester needs to determine the threshold of the mask user to either bitrex or saccharine.

1) Ask the employee to wear the fit test hood without a mask.
2) Introduce 5 aspirations at a time into the hood of either the Bitrex threshold solution or the saccharine threshold solution.
3) Ask the user to indicate when they taste the substance ( Bitrex: Bitter, Saccharine:Sweet)
4) Provide the user with a drink of water to cleanse their palette.
5) Record the number of aspirations and the substance on the Pre-screening sheet.

### Fit Test:

Based on the sensitivity test, the user is to be put into the low, medium or high threshold categories.

| Sensitivity Result | Category | Fit test Initial Dose | Fit test maintenance Dose |
|---|---|---|---|
| 1-10 | Low | 10 | 5 |
| 11-20 | Medium | 20 | 10 |
| 21-30 | High | 30 | 15 |

1) Instruct the user of the limitations and donning technique for the mask.
2) Ensure that the user adjusts the nosepiece and performs a seal check.
3) Have the user put on the fit testing hood.
4) Instruct the user that there are 7 tests which take 30 seconds each.
    a. Provide the Initial dose of the Bitrex or Saccharine fit test solution instruct the user to **BREATHE NORMALLY**
    b. Provide maintenance dose and instruct the user to **BREATHE DEEPLY**
    c. Provide maintenance dose and instruct the user to **TURN HEAD SIDE TO SIDE** (Taking a full inhalation and exhalation at the shoulders)
    d. Provide maintenance dose and instruct the user to **MOVE HEAD UP AND DOWN** (Inhaling in the up position and exhaling at the down position)
    e. Provide maintenance dose and instruct the user to **SPEAK OUTLOUD**
    f. Provide maintenance dose and instruct the user to **LEAN FORWARD/BEND OVER** (Subject is to bend at a comfortable pace, pausing long enough to take 2 breaths at each extreme position)
    g. Provide maintenance dose and instruct the user to **BREATHE NORMALLY**

[6] CSA Z94.4-11, Selection, Use and Care of Respiratory Protection

5) If the user completes all 7 tests without tasting the solution they pass. Please note that the fit test solution is much stronger than the threshold check so the user should taste the solution with a similar intensity to the threshold check if it is a true failure.
6) Instruct the user on proper doffing.
7) Insure that the Prescreening form is completed, dated and signed by the worker, and that they receive a card and sticker.
8) The forms are entered into Cority as soon as possible.

## Appendix 6: Quantitative Fit testing Methodology[7]

## TSI Portacount Setup

The TSI Portacount is to be set up and maintained as per the manufacturers instructions.

a) Sampling probes must be inserted into disposable respirators and attached to the sample tube. In the case of N95 respirators this must be connected to the N95 companion, for P100 respirators it is attached directly to the Portacount unit.
b) Sample adapters must be installed on all elastomeric masks. The adapter must match the manufacturer of the mask and connect directly to the portacount through the sample tube. The filter ports on the adapter and on the mask must be fitted with 100 series filters to complete the test.

## Fit Test

1) Instruct the user in the limitations and donning technique for the mask.
2) Ensure that the user adjusts the nosepiece and performs a seal check.
3) Instruct the user that there are 7 tests which each take 90 seconds. The results of the each test will be displayed on the screen during the next test and are recorded on the back of the prescreening form.

    a) Start the test and instruct the user to **BREATHE NORMALLY.**
    b) When the Second test starts instruct the user to **BREATHE DEEPLY**
    c) When the Third test starts instruct the user to **TURN HEAD SIDE TO SIDE** (Taking a full inhalation and exhalation at the shoulders)
    d) When the Fourth test starts instruct the user to **MOVE HEAD UP AND DOWN** (Inhaling in the up position and exhaling at the down position)
    e) When the Fifth test starts instruct the user to **SPEAK OUTLOUD**
    f) When the Sixth test starts instruct the user to **LEAN FORWARD/BEND OVER** (Subject is to bend at a comfortable pace, pausing long enough to take 2 breaths at each extreme position)
    g) When the Seventh test starts instruct the user to **BREATHE NORMALLY**

[7] CSA Z94.4-11 Selection, Use and Care of Respiratory Protection.

1) The Portacount will generate a Pass/Fail based on an assigned protection factor.
2) Instruct the user on proper doffing.
3) Ensure that the Prescreening form is completed, dated and signed by the worker, and that they receive a card and sticker.
4) The forms are entered into Cority as soon as possible

## Appendix 7: Fit Test Records through Cority

Fit Test Compliance Reports:
A report will be provided to all units with mandatory respiratory protection requiremetns. The report will provide the Employee Name, Fit test Model, Expiry date and current status.

Errors in the Record:
Through your review you may identify errors in the record. If that is the case the following steps should be taken.

| Nature of Error | Resolution |
| --- | --- |
| Staff are identified as Not Valid or No Test and have a current fit test sticker or card.<br><br>OR<br><br>There is a discrepancy in the record in terms of the date/ model of the mask tested. | The Manager can email Safety@hhsc.ca with the employee's name, ID number, site, date of the test, and the mask model. Then HSW will review paper records to determine if there has been an omission. Only records that can be confirmed as valid will be amended, others will have to be re-test. |
| Staff that are not in my unit appear on the report. | Fit test Compliance Report from Cority pulls this the department data from myHR. Contract Human Resources to correct the record. |

National Institute for Occupational Safety and Health
National Personal Protective Technology Laboratory
626 Cochrans Mill Road
Pittsburgh, PA 15236

| Procedure No. RCT-APR-STP-0005-05a-06 | Revision: 3.0 | Date: 20 December 2018 |
|---|---|---|

# DETERMINATION OF QUALITATIVE ISOAMYL ACETATE (IAA) FACEPIECE FIT, AIR-PURIFYING RESPIRATORS STANDARD TESTING PROCEDURE (STP)



## 1. PURPOSE

This test establishes the procedure for ensuring that the level of protection provided by the Isoamyl Acetate facepiece fit test requirements on air-purifying respirators submitted for Approval or Extension of Approval meet the minimum certification standards set forth in 42 CFR Part 84, Subpart G, Section 84.63(a)(c), Subpart I, Section 84.124, and Subpart L, Section 84.205, Subpart KK, Section 84.1135 Volume 60, Number 110, June 8, 1995.

## 2. GENERAL

This STP describes the Determination of Qualitative Isoamyl Acetate (IAA) Facepiece Fit Test Air-Purifying Respirators test in sufficient detail that a person knowledgeable in the appropriate technical field can select equipment with the necessary resolution, conduct the test, and determine whether or not the product passes the test.

## 3. EQUIPMENT/MATERIAL

3.1. The list of necessary test equipment and materials follows:

3.1.1. Large viewable chamber with interlocking double doors and exhaust system, approximately 9.7' x 12.2' x 8' in size.

3.1.2. Tire pump

3.1.3. Isoamyl acetate, 99%.

3.1.4. Tiered wick.

3.1.5. Graduated cylinder, 100 ml.

3.1.6. Sliding measurement calipers, Seritex model GPM 104, 0-200 mm length, as shown in Attachment 8.2.

3.1.7. Spreading measurement calipers, Seritex model GPM 106, 0-300 mm width, as shown in Attachment 8.3.

3.1.8. Facepiece, mouthpiece, hood, or helmet equipped with a cartridge or canister with organic vapor protection.

4. TESTING REQUIREMENTS AND CONDITIONS

4.1. Prior to beginning any testing, all measuring equipment to be used must have been calibrated in accordance with the testing laboratory's calibration procedure and schedule. All measuring equipment utilized for this testing must have been calibrated using a method traceable to the International System of Units (SI) when available.

4.2. General facepiece fit test requirements for gas mask, chemical cartridge, mouthpiece, and powered air-purifying respirators.

4.2.1. The fit test shall be performed using a panel of test subjects of various facial sizes measured according to the NIOSH Bivariate Panel (NIOSH Panel) requirements. The measured face length and face width are used to designate the subject's NIOSH Panel cell number, as illustrated in Attachment 8.5.

4.2.1.1. Face Width is the Bizygomatic Breadth measurement (Attachment 8.4), using the spreading measurement calipers.

4.2.1.2. Face Length is the Menton-Sellion measurement (Attachment 8.4), using the sliding measurement calipers.

4.2.2. Prior to fit testing, test subjects shall be subjected to the odor threshold screening as follows:

4.2.2.1. Prepare a stock solution by adding 1 ml isoamyl acetate to 800 ml of distilled water and shake for 30 seconds. This solution is stable for two days.

4.2.2.2. To a 1 liter volumetric add 0.4 ml stock solution to 500 ml distilled water. To an identical volumetric add 500 ml distilled water. Mark both samples with an identifying marker known only to the test operator. The solutions must be made fresh daily.

4.2.2.3. The following instructions shall be typed on a card and placed on the table in front of the two test jars (i.e. 1 and 2): "The purpose of this test is to determine if you can smell banana oil at a low concentration. The two bottles in front of you contain water. One of these bottles also contains a small amount of banana oil. Be sure the covers are on tight, and then shake each bottle for two seconds. Unscrew the lid of each bottle, one at a time, and sniff at the mouth of the bottle. Indicate to the test operator which bottle contains banana oil."

4.2.2.4. If the test subject correctly identifies the jar containing the odor test solution, the subject shall continue with the fit testing.

4.2.2.5. The screening shall be conducted in an isoamyl acetate free environment.

4.2.3. Any gas mask, chemical cartridge, powered air purifying, or mouthbit respirator part which must be removed to perform the facepiece or mouthpiece fit test shall be replaceable without special tools and without disturbing the facepiece or mouthpiece fit.

4.2.4. Each wearer shall enter the chamber containing 100 ppm isoamyl acetate for half-mask respirators and 500 ppm for full facepieces, mouthpieces, hoods, and helmets.

4.2.5. The respirator or mouthpiece may be adjusted, according to the manufacturer's user instructions, prior to entering the chamber, if necessary; however, upon entry into the test chamber the facepiece or mouthpiece shall not be adjusted.

4.2.6. If a respirator comes in multiple sizes, a test subject may only achieve a pass in one size, except when testing an extra-small or extra-large facepiece, in accordance with 4.3.2.

4.2.7. If a test subject is unable to achieve a user seal check after three donning attempts, it is considered a failed trial; however, if the facepiece model comes in multiple sizes they may attempt to don an alternate size.

4.2.8. If a test subject is able to achieve the required user seal checks; but, prior to starting the test, the subject detects the IAA, the subject shall be removed to an IAA-free atmosphere and permitted to don the respirator again. After two attempts the trial is considered a failure. However, if the facepiece model comes in multiple sizes they may attempt to don an alternate size.

4.3. Test subject selection

4.3.1. For respirators designed and manufactured in one, two or three unique facepiece sizes, the fit test will be conducted with 18 individual test subjects using the NIOSH Panel (Appendix 8.5). See Table 1 for the suggested test subject distribution in relation to the NIOSH Panel (NIOSH is allowing flexibility in the use of subjects from well-populated panel cells. NIOSH will attempt to test at least one subject from each cell, but no more than four subjects may be tested per cell).

Table 1: Suggested test subject distribution to be used for Isoamyl Acetate fit testing in relation to the NIOSH Panel

| NIOSH Panel – Cell Number | Number of Test Subjects |
|---|---|
| 1 | 1 |
| 2 | 1 |
| 3 | 2 |
| 4 | 4 |
| 5 | 1 |
| 6 | 1 |
| 7 | 4 |
| 8 | 2 |
| 9 | 1 |
| 10 | 1 |

4.3.1.1. Respirators designed and constructed in one unique size, a subject failing to achieve a pass is considered a failure.

4.3.1.2. Respirators designed and constructed in two unique sizes.

4.3.1.2.1. Subjects in panel cells 1-4 and cell 6 shall be tested first wearing the smaller sized respirator. If the subject does not pass in the smaller sized respirator, the subject can be tested again wearing the larger sized respirator.

4.3.1.2.2. Subjects in panel cells 7-10 and cell 5 shall be tested first wearing the larger sized respirator. If the subject does not pass in the larger sized respirator, the subject can be tested again wearing the smaller sized respirator.

4.3.1.2.3. A subject failing to achieve a pass in either of the sizes available for testing is considered a failure.

4.3.1.3. Respirators designed and constructed in three unique sizes.

4.3.1.3.1. Subjects in panel cells 1 and 2 shall be tested wearing the smaller size initially.

4.3.1.3.2. Subjects in panel cells 3-7 shall be tested wearing the regular/medium size initially.

4.3.1.3.3. Subjects in panel cells 8, 9, and 10 shall be tested wearing the larger size initially.

4.3.1.3.4. If a subject does not pass in the first respirator size, the subject will be retested in the next available size. A subject failing in the smaller sized respirator, can try the medium, and then larger sized respirator. A subject failing in the medium

sized respirator can try the smaller and larger sized respirators. A subject failing in the larger sized respirator can try the medium, then the smaller sized respirator. A subject failing to achieve a pass in any of the sizes available for testing is considered a failure. The test administrator may determine whether or not the third trial is worthy of completion. If the subject failed to achieve a pass in the small and medium sized respirator, trying the large may not be necessary since the large may be too big for the subject. If the subject failed to achieve a pass in the large and medium sized respirator, trying the small may not be necessary since the small may be too small for the subject.

4.3.2. For respirators designed and manufactured in four or five unique face piece sizes, the panel fit test will be conducted on 21 and 24 member panels, respectively, using the NIOSH Panel (Appendix 8.5). No more than four subjects may be tested per cell. Four individual test failures will be allowed; the number of test failures is not increased with the increased number of test subjects.

4.3.2.2. Subjects in panel cells 1 and 2 shall be tested wearing the small size first.

4.3.2.3. Subjects in panel cells 3-7 shall be tested wearing the regular/medium size first.

4.3.2.4. Subjects in panel cells 8, 9, and 10 shall be tested wearing the large size first.

4.3.2.5. For each additional size facepiece, such as an extra-small (XS) or extra-large (XL), there will be an additional 3 subjects tested.

4.3.2.5.1. Testing an additional size designated as extra-small shall include testing an additional three subjects from panel cells 1-3 and must include one positive test utilizing a subject from panel cell 1. If three subjects from cell 1 are unable to pass the XS, the project will be denied.

4.3.2.5.2. Testing an additional size designated as extra-large shall include testing an additional three subjects from panel cells 5-10 and must include one positive test utilizing a subject from panel cell 10. If three subjects from cell 10 are unable to pass the XL, the project will be denied.

4.3.2.6. If a subject does not pass in the first respirator size, the subject will be retested in the next available size, reference 4.3.1.3.4 if more detail is required.

5. PROCEDURE

5.1. Follow individual instruction manuals if any, for set up, calibration, and maintenance of equipment used in this procedure prior to beginning any testing. Malfunctioning equipment must be repaired or replaced and properly set up and calibrated before starting all tests.

5.2. Determine the amount of isoamyl acetate required to produce the concentration desired according to the size and volume of the test chamber using the following formula.

$$C = \frac{V \otimes \frac{22.4}{MW} \frac{T}{273} \frac{760}{P} x10^6}{V_t}$$

Where: V = volume in ml of isoamyl acetate required in ml
C = concentration in ppm of isoamyl acetate desired in chamber
MW = molecular weight of isoamyl acetate
T = chamber temperature in degrees Kelvin
P = chamber pressure (760 mm Hg)
$\otimes$ = density of isoamyl acetate in g/ml
$V_t$ = volume of chamber in liters

5.2.1. For the NIOSH test chamber: using the graduated cylinder, distribute onto the tiered wick 16 ml isoamyl acetate for halfmask respirators or 80 ml isoamyl acetate for full facepiece, hoods, helmets and mouthbit respirators.

5.3. Allow 20 minutes for equalization of the concentration in the chamber.

5.4. In an isoamyl acetate free environment, allow the test subject to read the manufacturers donning instructions and perform positive or negative user seal check procedures.

5.5. The test subject will don the respirator and perform a user seal check per the manufacturer's user instructions. If the test subject cannot obtain a successful user seal check, he/she will not be sent into the chamber. Upon obtaining a successful user seal check, the subject will enter the chamber.

5.6. For all IAA fit tests, the test subject shall enter the test chamber and remain in the test chamber for 8 minutes while performing the following activities:

5.6.1. Two (2) minutes nodding up and down, and turning head side to side.

5.6.2. Two (2) minutes callisthenic arm movements.

5.6.3. Two (2) minutes running in place.

5.6.4. Two (2) minutes pumping with tire pump.

5.7. The test subject must not detect the odor of IAA when they enter the chamber and perform the required exercises. If on initial entry into the IAA chamber, the subject immediately (before the required exercises begin) detects the odor of IAA, the subject will immediately exit the chamber, adjust the respirator, perform a second user seal check, and if successful, re-enter the chamber.

5.8. Upon completion of the above activities the test subject will exit the chamber and verbally notify the test operator as to the performance of the respirator with any remarks pertinent to the fit or performance of the respirator.

5.9. If the subject detects the banana type odor of isoamyl acetate during any exercise they will indicate a thumbs down motion and will be removed from the chamber. Once removed, a user seal check will be performed and the facepiece harness or tension mechanism will be checked for their tightness.

## 6. PASS/FAIL CRITERIA

6.1. The criteria for passing this test is set forth in 42 CFR Part 84, Subpart G, Section 84.63(a)(c), Subpart I, Section 84.124, Subpart L, Section 84.205, and Subpart KK, Section 84.1135 and Section 84.1142.

6.2. The number of test failures will not exceed four.

6.3. If an overall pass is achieved, but three subjects report the same issue about the comfort of the facepiece, the test will be considered a failure.

## 7. RECORDS/TEST SHEETS

7.1. All test data collected will be recorded on the appropriate Determination of Qualitative Isoamyl Acetate (IAA) Facepiece Fit IAA Test data sheet.

## 8. ATTACHMENTS

8.1. Facepiece Fit IAA Test Data Sheet.

8.2. Sliding Calipers

8.3. Spreading Calipers

8.4. Anthropometric Measurements

8.5. NIOSH Panel

## Attachment 8.1: Facepiece Fit IAA Test Data Sheet

**National Institute for Occupational Safety and Health**
**Respirator Branch**
**Test Data Sheet**

**Task Number:** TN-NNNNN
**Reference No.:** CFR Reference number
**Test:** Facepiece Fit IAA Test
**STP No.:** 5, 5.1 or 6
**Manufacturer:**
**Item Tested:** Facepiece with OV Cartridge

**Concentration = XXX ppm isoamyl acetate vapor**

| Subject | Facesize | Result |
|---|---|---|
| A | 1 | PASS |
| B | 2 | PASS |
| C | 4 | PASS |
| D | 3 | PASS |
| E | 10 | PASS |
| F | 8 | PASS |
| G | 7 | PASS |
| H | 9 | PASS |
| I | 5 | PASS |
| J | 6 | PASS |
| K | 4 | PASS |
| L | 7 | PASS |

**Overall Result:** PASS

**Comments:**

Was all equipment verified to be in calibration throughout all testing? ◉ Yes ○ No

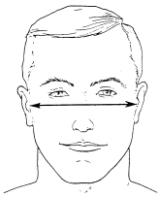
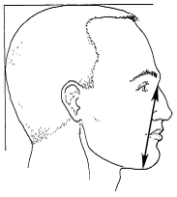
**Signature:** **Date:** _____

**Engineering Technician**

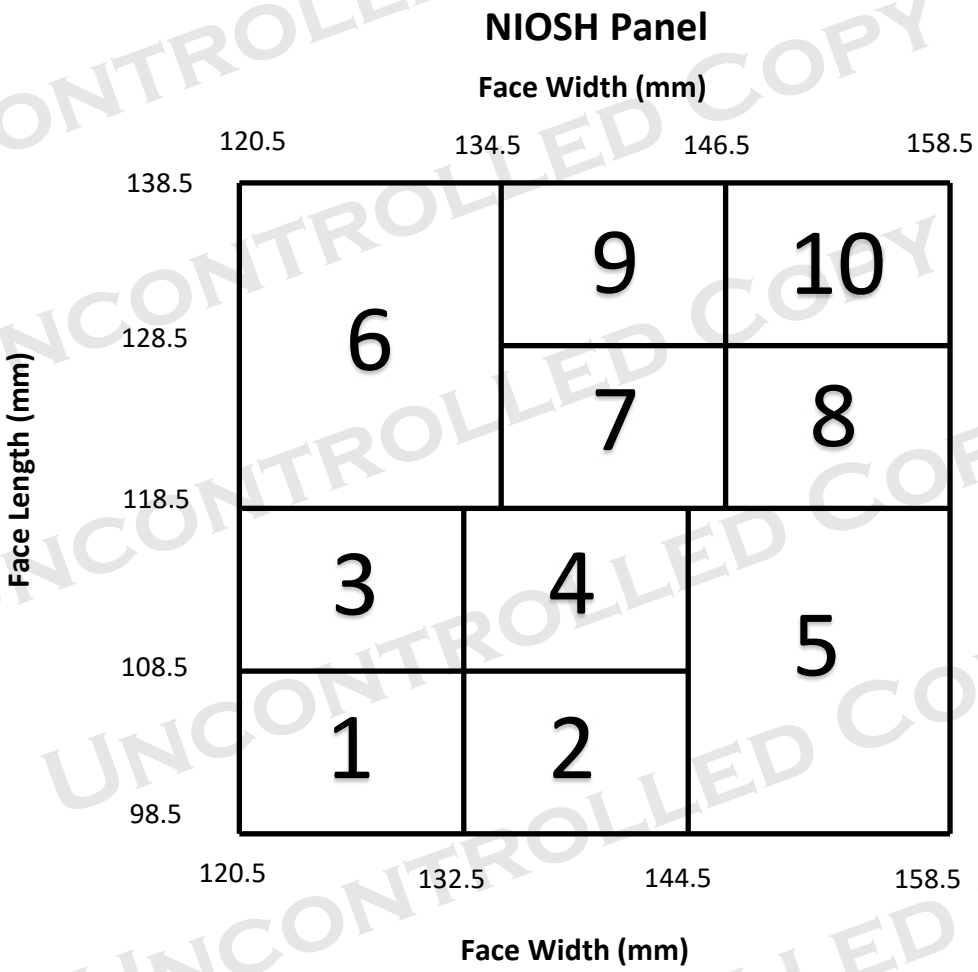
**Attachment 8.2: Sliding Calipers**

**Attachment 8.3: Spreading Calipers**

**Attachment 8.4: Anthropometric Measurements**

| Description | Definition | Diagram |
|---|---|---|
| **Bizygomatic Breadth** | Maximum horizontal breadth of the face as measured with a spreading caliper between the zygomatic arches. |  |
| **Menton–Sellion Length** | Distance as measured with a sliding caliper in the midsagittal plane between the menton landmark and the sellion landmark. |  |

**Attachment 8.5: NIOSH Bivariate Panel (NIOSH PANEL)**



# Revision History

| Revision | Date | Reason for Revision |
|---|---|---|
| | February 1996 | NIOSH has reduced the IDLH for isoamyl acetate in the Pocket Guide to Chemical Hazards from 3000 ppm to 1000 ppm. This resulted in the NIOSH STP being run at the IDLH concentration contrary to good work practices, and OSHA standards which stipulate the "concentrations during the test shall not exceed an OSHA permissible exposure limit, the ACGIH threshold limit values, or any known recommended exposure limit, when there is no OSHA PEL or ACGIH TLV, and not create a health or physical hazard for the test subject or operator." In the face of these facts, the test concentration was reduced to the OSHA PEL and NIOSH REL of 500 ppm with commitment to revisit the appropriateness of the test, and of isoamyl acetate as the test agent of choice in future regulation change modules. |
| 1.0 | 16 January 2002 | Historic document |
| 1.1 | 3 June 2005 | Update header and format to reflect lab move from Morgantown, WV No changes to method |
| 2.0 | 20 March 2008 | Correct errors in sections 4.3.3.2 and 5.2 and update to reflect new file naming procedures and changes announced in Letter to All Manufacturers dated 18 May 2005. |
| 3.0 | 20 December 2018 | Changes throughout the document to incorporate a new anthropometric panel referred to as the NIOSH Panel. |

Patient Study ID #: __ __-__ __ __

## N95 FIT TEST DATA FORM

The following data collection form has been modified from the Hamilton Health Sciences "Respirator User Screening Assessment (2015-02)" and is ONLY intended for research purposes.

**Date of Assessment (yyyy – mm – dd) __ ___ __ ___ - __ __ - __ __**

### Part I. General Information

**Please select the appropriate response for each question.**

1. Are you a healthcare professional and/or staff member at HHS? ☐ Yes ☐ No

2. What is your current role/title? (e.g., staff physician, nurse, resident etc.) Please specify: _____

3. Conditions of Respirator Use
   - ☐ Airborne isolations
   - ☐ Dust
   - ☐ Other (please specify): _____

4. Frequency of use
   - ☐ Daily
   - ☐ Weekly
   - ☐ Monthly
   - ☐ Other (please specify): _____

5. Duration of use
   - ☐ Less than 15 min.
   - ☐ Greater than 15 min.
   - ☐ Other (please specify): _____
   - ☐ Greater than 2 hours.
   - ☐ Variable

### Part II. Health Assessment

**Please select the appropriate response for each question.**

6. Do you have any of the following conditions or symptoms that you feel would make it unsafe to wear a respirator or complete a fit test? ☐ Yes ☐ No
Please do not disclose any personal medical information on this form.

- Shortness of breath
- Heart problems
- Chronic bronchitis
- Claustrophobia
- Chest pain on exertion
- Dizziness/nausea
- Hypertension
- Neuromuscular disease
- Fainting spells
- Lung disease
- Panic attack
- Asthma
- Breathing difficulties
- Emphysema

7. Have you previously had difficulty completing a fit test? ☐ Yes ☐ No

If you answered "Yes" to either question 6 or 7, further assessment by a healthcare professional is required before fit testing and respirator use.

8. Have you previously been fit tested? ☐ Yes ☐ No

Patient Study ID #: __ __-__ __ __

If you have undergone a fit test before, please answer the following:

8. What was the overall fit factor? _____

9. What mask were you fitted for?

☐ 8210 ☐ 8110s ☐ 1860
☐ 1860s ☐ 1870 ☐ 9105
☐ 9105s ☐ 1840s ☐ DC 365
☐ Other (please specify): _____

To be filled out by the participant **before** the fit test:

I, _____ acknowledge that this fit test is only for research purposes and to use a respirator safely, I must adhere to standard fit testing protocols set out by my employer (i.e., Hamilton Health Sciences) and be adequately trained. Please note, safe respirator use includes the requirement to be clean-shaven within 24 hours of the fit test and a seal check whenever a respirator is donned. If you have any questions regarding safe respirator use, please contact Employee Health Services.

**Part III: Fit Test**

10. Quantitative Fit Test (enter protection factor)

| | **Mask Type** | | | | |
|---|---|---|---|---|---|
| | | | | | |
| Activity | | | | | |
| Normal Breathing | | | | | |
| Deep Breathing | | | | | |
| Head Side to Side | | | | | |
| Head Up and Down | | | | | |
| Talking Out Loud | | | | | |
| Bending Over | | | | | |
| Normal Breathing | | | | | |
| **Final Result** | | | | | |

11. Fitted to:

☐ 8210 ☐ 8110s ☐ 1860
☐ 1860s ☐ 1870 ☐ 9105
☐ 9105s ☐ 1840s ☐ DC 365
☐ Other (please specify): _____

12. Facial Measurements

a. Face length(mm): _____

b. Face width(mm): _____

13. Face measurement (mm): _____

**Full Name (Printed):** _____ **Signature and Designation:** _____

## N95 FIT SURVEY

**Part I. Participant Demographics**

**Please select the appropriate response for each question.**

**1. Occupation**
(e.g., staff physician, nurse, resident etc.)

_____
☐ Prefer not to answer

**2. Sex**
Sex (biological) refers to the sex assigned at birth. Sex is typically assigned based on a person's reproductive system. [1]

☐ Male
☐ Female
☐ Prefer not to answer

**3. Gender**
Gender refers to the gender that a person internally feels ('gender identity' along the gender spectrum) and/or the gender a person publicly expresses ('gender expression') in their daily life.[2]

_____
☐ Prefer not to answer

**4. Ethnicity.** Please select **all** that apply.
Ethnic origin refers to the ethnic or cultural origins of a person's ancestors.[3,4] Ethnicity consists of the cultural characteristics that identify a person as belonging to a particular group.[5]

☐ Indigenous (e.g., First Nations, Inuit and Métis)
☐ Arab/West Asian (e.g., Armenian, Egyptian, Iranian, Lebanese, Moroccan)
☐ Black (e.g., African, Haitian, Jamaican, Somali)
☐ Chinese
☐ Filipino
☐ Japanese
☐ Korean
☐ Latin American
☐ South Asian
☐ South East Asian
☐ White (Caucasian)
☐ Prefer to self-identify: _____
☐ Prefer not to answer

**5. Date of Birth** (YYYY-MM-DD): __ __ __ __- __ __ - __ __

The purpose of the following question is to determine which, if any, of the following characteristics may/have had an impact on the fit or comfort of **N95 respirators** and/or **surgical masks.**

**6. Please select all the characteristics that apply to you.**

| | **Yes** | **No** |
|---|---|---|
| A. Religious head covering (e.g., Hijab, Turban) | ☐ | ☐ |
| B. Glasses | ☐ | ☐ |
| C. Facial Hair | ☐ | ☐ |
| D. Other characteristics (that you feel have impacted the fit) | ☐ | ☐ |

Please specify any additional characteristics here: _____

E. Prefer not to answer ☐

**Part II. N95 Respirator & Surgical Mask Fit and Breathability**

**N95 Respirators**

**Please select the appropriate response for each question.**

7. Have you previously been fit tested for an N95 respirator? ☐ Yes ☐ No

| | Strongly Disagree | Disagree | Neutral | Agree | Strongly Agree | Not applicable |
|---|---|---|---|---|---|---|
| 8. **N95 respirators** fit me well. | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| 9. **N95 respirators** are comfortable. | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| 10**. N95 respirators** are breathable. | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

11. Based on your experiences of wearing an **N95 respirator**, please describe any challenges you have encountered regarding the fit, comfort, and breathability.

**Surgical Masks**

| | Strongly Disagree | Disagree | Neutral | Agree | Strongly Agree | Not Applicable |
|---|---|---|---|---|---|---|
| 12. **Surgical masks** fit me well | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| 13. **Surgical masks** are comfortable | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| 14**. Surgical masks** are breathable | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

15. Based on your experiences of wearing a **surgical mask**, please describe any challenges you have encountered regarding the fit, comfort, and breathability.

## Part III. Physical and Mental Health

The following section is designed to better understand your experiences with wearing masks and N95 respirators for extended periods of time, and how this has impacted your physical and/or mental health, if at all. After each set of questions (one each for physical and mental health), there are sections for you to share, in your own words, the impacts and any experiences that may not have captured in the questions.

16. On a scale of 1 to 10, with 1 being 'poor' and 10 being 'excellent', please rate your **overall** experience wearing an N95 respirator.

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|
| **Poor** | | | | | | | | | **Excellent** |

### Physical Health

17. When wearing an N95, have you experienced any **physical** discomfort?

- ☐ Yes
- ☐ No
- ☐ Prefer not to answer

18. If so, please specify which of the following **physical** discomforts you have experienced. Select all that apply.

| | **Yes** | **No** |
|---|---|---|
| A. Pressure/Pain | ☐ | ☐ |
| B. Itching | ☐ | ☐ |
| C. Nausea | ☐ | ☐ |
| D. Dizziness | ☐ | ☐ |
| E. Headaches | ☐ | ☐ |
| F. Other | ☐ | ☐ |

Please specify any additional discomforts here: _____

G. Prefer not to answer ☐

19. Are there any other **physical discomforts/symptoms** you have experienced either more frequently or directly as a result of wearing an N95 respirator for extended periods of time?

**For each of the following statements, please select the most appropriate response.**

| | Strongly Disagree | Disagree | Neutral | Agree | Strongly Agree | Prefer not to answer |
|---|---|---|---|---|---|---|
| 20. The use of PPE for prolonged periods of time at has negatively impacted my **mental health**. | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| 21. Limited access to appropriate PPE/PPE shortages have negatively affected my **mental health**. | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| 22. The fit of currently available N95s has negatively affected my **mental health**. | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |

23. Are there any other factors or experiences, related to the use of an N95 respirator, that you feel have impacted your **mental health**?

☐ Yes
☐ No
☐ Prefer not to answer

24. If you selected "Yes" to the above question, please describe the factors and/or experiences that have impacted your mental well-being in the box below.

25. Are there other factors related to the use of N95 respirators and/or experiences related to the use of N95s, during the COVID-19 pandemic, that have negatively impacted your physical and/or mental well-being?

☐ Yes
☐ No
☐ Prefer not to answer

If so, please specify in the space provided below:

26. Today's Date (YYYY/MM/DD): __ __ __ __- __ __ - __ __

Thank you for taking the time to fill out this survey! If you have any additional questions or concerns regarding the study, please contact the Principal Investigator, Dr. Fox-Robichaud at afoxrob@mcmaster.ca,
or Fatima Sheikh, at sheikf9@mcmaster.ca.

References

1. Government of Canada SC. Sex of person. Published February 1, 2018. Accessed March 16, 2021. https://www23.statcan.gc.ca/imdb/p3Var.pl?Function=DEC&Id=24101

2. Government of Canada SC. Classification of gender - M - Male gender. Published February 1, 2018. Accessed October 16, 2020. https://www23.statcan.gc.ca/imdb/p3VD.pl?Function=getVD&TVD=467245&CVD=467245&CLV=0&MLV=1&D=1

3. Government of Canada SC. Ethnic origin of person. Published December 2, 2015. Accessed March 18, 2021. https://www23.statcan.gc.ca/imdb/p3Var.pl?Function=DEC&Id=103475

4. Government of Canada SC. Previous standard - Race (ethnicity). Published July 15, 1998. Accessed March 16, 2021. https://www.statcan.gc.ca/eng/concepts/definitions/previous/preethnicity

5. Robinson A. Race vs. Ethnicity vs. Nationality: All You Need to Know. Accessed March 18, 2021. https://blog.prepscholar.com/race-vs-ethnicity-vs-nationality