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Strengthening N95 Filtering Facepiece Respirator Protection Programs by Evaluating the Contribution of Each of the Program Elements

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Strengthening N95 Filtering Facepiece Respirator Protection Programs by Evaluating the Contribution of Each of the Program Elements

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BULLETED POINTS

- The overall agreement found between the two Bitrex and Portacount fit-test methods is slight to moderate.
- There was no significant difference found between pass or failure rates associated with annual versus biennial fit-test frequencies for N95 filtering facepiece respirators (N95 FFRs) commonly used in healthcare. This suggests a lack of change in worker exposure if the fit-test frequency were to increase from an annual basis to a biennial basis
- N95 FFR donning skills did not differ significantly between staff fit-tested on an annual basis only, biennial basis only, or biennial basis but with an annual education component in between fit-tests in Year 3. There did seem to be an immediate positive effect of education on the fit-test outcome; however, at some point following that over the course of a year, this effect diminished.
- Regular usage of N95 FFRs resulted in a lower fit-test failure rate and increased the level of donning skills retained by staff using N95 FFRs.
- The user seal check was not found to be an appropriate surrogate for a fit-test in determining an adequate fit on an N95 FFR. If workers were to rely solely on the user seal check without being appropriately fit-tested, there is the potential they would not be adequately protected.

EXECUTIVE SUMMARY

When respirators are deemed necessary to be worn in a workplace to protect workers from airborne hazards, a respiratory protection program (RPP) must be implemented. Overall, there are four major elements of a RPP which are: 1) selection of respirators, 2) respirator user education and training, 3) inspection, cleaning, maintenance and storage of respirators and 4) respirator fit-testing. Although these elements are indicated as being essential, there are questions regarding the particulars. For example, how frequently should education and training be provided to ensure adequate knowledge translation? What is the optimal frequency for fit-testing to ensure that users are adequately protected? These concerns are especially critical in healthcare as 16,000 workers (in only two of the five BC health authorities) have been assessed to require the use of respirators, generally N95 filtering facepiece respirators (N95 FFR), for protection against bioaerosols. Such a large number of people requiring respirators involves a considerable amount of both time and resources. It would therefore be important to assess the relative importance of the RPP elements and, in turn, optimize the resources necessary to ensure that individuals have the appropriate respiratory protection.

The specific objectives of the study are:

1. Compare the outcomes between the qualitative (i.e. Bitrex) and quantitative (i.e. Portacount) fit-testing methods.
2. Determine if there is a significant difference between failure rates associated with annual versus biennial fit-test frequencies for N95 FFRs commonly used in healthcare.
3. Evaluate the level of N95 FFR donning skills retained by staff fit-tested on an annual basis only, biennial basis only, or biennial basis but with an annual education component in between fit-tests.

4. Determine the effect of regular usage on fit-test failure rates as well as on the level of donning and doffing skills retained by staff using N95 FFRs.
5. Evaluate the applicability of a user seal check as a surrogate for a fit-test in determining an adequate fit on an N95 FFR.

This was a multi-site study involving residential care facilities (as workers from these sites do not normally wear respirators and, therefore, would not be in contravention of the current WorkSafeBC Occupational Health and Safety Regulation requirement of annual fit-testing) and select acute care departments (deemed regular N95 FFR users). Each subject was given education/training, provided with a respirator and then fit-tested using both Bitrex and Portacount in year 1. If they passed both fit-tests, they were included for the remainder of the study. In subsequent years of the study, participants were divided into four groups and "treated" as per the table below.

Participant Study Groups

Group	Setting Selected From	Year 1		Year 2		Year 3
		Education/ Training	Fit-Test	Education/ Training	Fit-Test	Fit-Test
1	Residential Care	✓	✓	✓	✓	✓
2	Residential Care	✓	✓	✓		✓
3	Residential Care	✓	✓			✓
4	Acute Care	✓	✓	✓	✓	✓

The comparative analyses employed to meet the objectives are summarized in the table below:

Summary of Comparative Analyses Used to Assess Stated Objective

Objective	Description of comparison
1	Compare the QLFT and QNFT results for every single fit-test session
2	Compare fit-test pass rates in Year 3 between Group 1 and 3
3	Compare fit-test pass rates in Year 3 between Group 1, 2, and 3 (with Group 1 serving as the control)
4	Compare fit-test pass rates in Year 3 between Group 1 and 4
5	Compare the user seal check results and fit-test pass rates for every single fit-test session

The results for each objective are as follows:

Objective 1: The overall agreement between the Bitrex and Portacount fit-test methods is slight to moderate.

Objective 2: In Year 3, Group 1 and Group 3 had the same pass rates using the Bitrex method (56%). The Portacount pass rates were also very similar – 41% for Group 1 and 43% for Group 3. As such, there was no statistically significant difference found between pass or failure rates associated with annual versus biennial fit-test frequencies. This suggests a lack of change in worker exposure if the fit-test frequency were to increase from an annual basis to a biennial basis.

Objective 3: Regardless of the fit-test method, the pass rates were virtually identical between Groups 1, 2 and 3 in Year 3. This suggests that at that point in time, there was no positive or negative effect from whether the subject had received education, fit-testing, or both in the year prior compared to participants who had not received either intervention for a two-year period.

Objective 4: In Year 3, the pass rate among Group 4 participants (regular users) was 81% and 72% (Bitrex and Portacount, respectively) compared to Group 1 participants (non-users) with pass rates of 56% and 41% (Bitrex and Portacount, respectively). This data suggest that regular usage results in a higher fit-test pass rate.

Objective 5: Of the 784 subjects in this study population, 99.5% indicated that they felt they had an appropriate face seal after performing the user seal check. However, the subsequent respirator fit-test results had failure rates as high as 30% which demonstrate that the user seal check is not able to identify a poorly fitting respirator as defined by a fit-test. If workers were to rely solely on the user seal check without being appropriately fit-tested, there is the potential they would not be adequately protected.

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1. RESEARCH PROBLEM / CONTEXT

WorkSafeBC's Occupational Health and Safety Regulation (OHSR) section 5.55 (3), states that the use of personal protective equipment (PPE) as the primary means to control exposure is permitted only when: (a) substitution, or engineering or administrative controls are not practicable, or (b) additional protection is required because engineering or administrative controls are insufficient to reduce exposure below the applicable exposure limits, or (c) the exposure results from temporary or emergency conditions only.[1]

Healthcare workers often employ the use of respirators as PPE, specifically the N95 filtering facepiece respirator (N95 FFR), as all three aforementioned conditions are likely when caring for patients who are potentially ill with an airborne infectious disease.[2]

When respirators are required in the workplace, regulatory bodies including WorkSafeBC (WSBC), require the implementation of a respiratory protection program (RPP). Once the need is established through a risk assessment, the four major elements of a RPP are: 1) selection of respirators, 2) respirator user education and training, 3) inspection, cleaning, maintenance and storage of respirators and 4) respirator fit-testing.[1] Most jurisdictions in Canada, including British Columbia, make reference to CSA Standard *Z94.4 Selection, Care, and Use of Respirators (2002)* to fulfill elements of the RPP.[3] Each of the four elements of a RPP is outlined in detail in the following sections.

1.1. Elements of a Respiratory Protection Program

1.1.1. Selection of Respirators

The selection of a respirator is based on a number of criteria including an analysis of the airborne hazard(s), the physical characteristics of the work environment, the physical demands of the task, and the capabilities and limitations of various respirators.[4] The most common type

of respirator used in healthcare is the N95 FFR, which is classified as an air-purifying respirator. N95 FFRs are used by healthcare workers for protection against airborne bioaerosols, such as tuberculosis and measles.[5-8] N95 FFRs are not solely used in healthcare; they are also utilized in other industries for various workplace applications including, but not limited to, grinding, sanding, sweeping, bagging and other dusty operations.

The entire facepiece of the N95 FFR acts as the filtration mechanism to remove particulate from the air breathed in by the respirator user. The "N95" refers to the National Institute for Occupational Safety and Health (NIOSH) rating indicating the material is not resistant to oil mist and is at least 95% effective in filtering out 0.3 micron sized particles.[9] An N95 FFR has an assigned protection factor of 10.[1]

1.1.2. Respirator User Education and Training

Education and training on respirator usage is typically provided at the same time that a person is fit-tested. According to the CSA Standard, training shall consist of general knowledge principles (including reference to the RPP), instructions on the care and practical use of the respirator, and the limitations of the selected respirator. Respirator wearers are also taught the need to perform a 'user seal check' prior to using the respirator as it is deemed necessary to test for gross leaks. A user seal check is a subjective procedure that consists of placing both hands completely over the N95 FFR and inhaling and exhaling sharply. If an air leak is detected around the nose, the nosepiece is adjusted; if an air leak is detected at the respirator edges, the straps are adjusted.[10] According to the CSA Standard, training documents are to be maintained and refresher training shall be provided at least every two years.[3]

1.1.3. Inspection, Cleaning, Maintenance, and Storage of Respirators

The N95 FFRs used in the healthcare setting are designed to be disposable so the requirements for cleaning, maintaining and storage generally do not apply. However, these devices must be inspected prior to each use "to assure there are no holes in the breathing zone other than the punctures around staples (used to affix the straps to the facepiece) and no damage has occurred".[11] If there is evidence of damage, the respirator is simply discarded and a new one obtained.

1.1.4. Respirator Fit-Testing

A respirator cannot provide its optimal level of protection when it does not fit the user properly. Fit-testing ensures that the respirator provides an effective seal with the user's face, thereby providing appropriate protection. Several studies have documented the importance of fit-testing.[12-15]

There are two types of fit-testing methods for N95 FFRs: qualitative and quantitative. The qualitative fit test (QLFT) is a subjective pass/fail test, based on the ability of the respirator user to detect an airborne test agent. Two of the most common test agents are saccharin and denatonium benzoate (commercially available as Bitrex™).[14, 16-19] A quantitative fit-test (QNFT) uses an instrument to determine the degree of fit by measuring the particulate concentration outside the respirator and comparing this value to the particulate concentration inside. This results in an objective and numerical assessment of the fit-test factor. The most common QNFT for N95 FFRs is the TSI PORTACOUNT® Plus Respirator Fit Tester Model 8020 with an N95-Companion Model 8095 (Portacount).[14, 16-19] Regardless of which method is used, a fit-test involves the user wearing a respirator while simultaneously performing a series of breathing exercises designed to place stress on the respirator seal. The CSA Standard specifies a series of six exercises: normal breathing, deep breathing, turning head side-to-side, nodding head up-

and-down, talking out loud, and normal breathing. Each exercise must be at least 30 seconds in duration.

For a QLFT, if the user detects the test agent during any of the exercises, the fit-test is unsuccessful. A QNFT is successful if none of the individual exercises results in a fit factor (ratio of particulate levels outside versus inside the respirator) below the minimum protection factor required by the standards (i.e. 100) and the overall fit factor is not less than this minimum protection factor.[i]

A typical fit-test, in conjunction with the respirator education and training component, takes approximately 20 minutes to complete, assuming that the person passes the fit-test. Should a person fail a fit-test, the fit-test exercises must be repeated in their entirety either on the same respirator (after adjustment to ensure an adequate seal) or with another respirator model. Currently in British Columbia (BC), the OHS Regulation states that an individual must be fit-tested on an annual basis or sooner if there are structural changes to the face that could affect the fit of the selected respirator (e.g. broken nose, weight gain).[3]

1.2. Rationale and Significance of Research

1.2.1. Respirator User Education and Training: Frequency and Knowledge Retention

The CSA Standard does not provide guidance on how education / training is to be delivered. As a result, respiratory protection education / training is not standardized in BC. The most common method of education / training delivery is through verbal instruction to the respirator user by a qualified fit-tester. Evaluation of skill and capabilities of the respirator user is based upon professional judgment of the fit-tester within the 20-minute fit-test period. Except under

[i] The minimum protection factor is set at 10 times the applicable assigned protection factor of the relevant regulatory jurisdiction. WorkSafeBC has set an assigned protection factor of 10 for filtering facepieces[1]; therefore the minimum protection factor that must be achieved during a fit-test is 100.

rare situations, the majority of healthcare workers do not require the use of N95 FFRs on a daily basis. Because the infrequent use of N95 FFRs may affect workers knowledge retention over time, the frequency of respirator education / training for skill and knowledge recollection over time needs to be assessed.

1.2.2. Respirator Fit-Testing: Frequency

There are 217,400 healthcare workers in the province of British Columbia.[20] Within the two health authorities participating in this study, approximately 16,000 workers are currently required to be fit-tested annually based on assessments identifying them as being at risk of airborne exposure. The logistics and resources required to conduct fit-testing for these at-risk workers is quite daunting. Time must be spent to coordinate fit-test schedules with the various departments. As persons responsible for coordinating these fit-test schedules, the co-principal investigators of this study can state from experience that multiple efforts and approaches may need to be made to coordinate fit-testing with those departments that have high patient loads and/or staffing challenges to attempt to capture the largest number of staff with the greatest efficiency. At the same time, department managers need to coordinate staffing schedules to ensure that there are enough patient care providers while concurrently allowing workers time off to participate in a fit-test. There are also administrative requirements in coordinating fit-testing. This includes arranging for the necessary fit-testing equipment, acquiring the various respirator models, securing a fit-testing location and communicating and advertising fit-test sessions. Various supplies are also consumed at each fit-test. This includes at least one N95 FFR, fit-test solution or a fit-test probe adaptor, and paper for documentation per potential respirator user. The two health authorities participating in this study currently allocate over 10,000 hours per year in order to conduct these fit-tests. Based on the above information, this

results in approximately $368,000 and 9,200 hours per year devoted to respiratory fit-testing within Vancouver Coastal Health and Fraser Health alone (see Appendix A).

If the current version of the CSA Standard were implemented in British Columbia, which allows for fit-testing to be performed at least every two years, it could facilitate more appropriate allocation of resources. As a result, the resources currently spent on fit-testing every year could be diverted to other health and safety efforts within the health authorities. Unfortunately, no scientific study has evaluated the relative effectiveness of annual or biennial fit-testing in providing adequate protection to the respirator user.

1.2.3. Current Fit-Testing Methods in BC Healthcare

The 3M Bitter (Bitrex™) QLFT (Bitrex) is the primary method of fit-testing healthcare workers in BC.[21] One reason for using this method is that it does not require the expensive equipment needed for QNFTs. Another reason is the time frame required for the actual fit-test exercises; a QLFT requires 30-seconds per exercise whereas a QNFT (i.e. Portacount) generally requires 86-seconds per exercise, effectively tripling the overall time required for a fit-test. In addition, multiple individuals may be fit-tested concurrently using a QLFT whereas only one individual may be fit-tested at a time with a QNFT. However, Janssen et al. found a disagreement in results among these fit-test methods approximately 25% of the time.[16] The outcomes of the QLFT have yet to be correlated to the corresponding QNFT results with the N95 FFRs that are currently in use in healthcare in BC. This is important in order to qualify the reliability of the QLFT method.

1.2.4. Preparation for Pandemic Influenza and Surge Capacity Events

The results of this study would be very beneficial for the planning and preparation for pandemic influenza and surge capacity events. The importance of evidence-based respiratory protection programs was highlighted with the recent H1N1 pandemic.

During another pandemic, there may be a requirement to mobilize large numbers of staff, students, retired health care professionals, as well as volunteers and provide them with education / training and fit-testing on N95 FFRs. It will be essential during this period that the most efficient means of providing that necessary education / training and fit-testing be utilized.

Other surge capacity events may also require significant need for education / training and fit-testing of individuals on N95 FFRs, either due to the nature of the event, or the need to utilize a different model of respirator due to an inability to procure adequate supplies. It is therefore critical during such events that education / training and fit-testing be provided in the most efficient manner.

1.3. Critical Review of Existing Literature

1.3.1. Respirator User Education and Training: Frequency and Knowledge Retention

Research regarding respirator training is sparse. Coffey et al. argued that there is a need to better train respirator wearers so that their donnings are more consistent.[18] Clayton and Vaughn stated that fit-testing plays an important role in reinforcing training as users forget how to correctly don and use their respirators while Hannum et al. concluded that fit-testing as part of training marginally enhanced the ability of healthcare workers to wear respirators properly and pass a fit-test. [26, 27] Doffing safely and in the proper sequence is also important to prevent self-contamination.[28] According to section 8.8 of CSA Standard Z94.4-02, refresher training for

respirator users is to be provided at least every two years.[3] However, there are no references in the Standard to justify this stated time period.

1.3.2. Respirator Fit-testing: Frequency

The literature surrounding fit-test frequency is also extremely limited. The results of a study by Johanson and Morgan found that changing to a fit-test frequency greater than one year did not result in increased fit-test failure rates when compared with fit-tests conducted on an annual basis.[29] In their study, almost 2000 fit-tests were performed and then repeated at intervals over time. The highest failure rates on repeated fit-tests occurred 6 – 12 months after the initial fit-test. For fit-tests conducted at periods greater than 12 months after the initial fit-test, there was a significant decrease in fit-test failures. Johanson and Morgan concluded that the passage of time does not appear to result in an increase in fit-test failures. There have been no follow-up studies to corroborate or refute this conclusion. Regardless, the relevancy of the results is questionable as the study was conducted over 20 years ago on a class of respirators that no longer exist.

As mentioned previously, Canadian jurisdictions generally refer to the CSA Standard Z94.4 for respiratory protection guidance. Development of this Standard was overseen by a Technical Committee comprised of experts in the field of respiratory protection from across Canada. The purpose of the Committee was to "be assured that the latest advances in respiratory protection were reflected, the Subcommittee spent (sic) considerable time reviewing the latest research and the most current literature, including other relevant standards and regulations." [3]

In section 7.1.3 of the 2002 CSA Standard, it states that a fit-test shall be carried out "at least every two years; however, it is recommended that fit tests be conducted annually". The previous version of the standard (1993) had recommended that a fit-test should be carried out

annually. Personal correspondence with the Z94.4 Project Manager indicated that “the criteria was changed from a recommendation (a "should") to a mandatory requirement (a "shall")”.[30] According to the 94.4 Project Manager “[the] primary goal in this subject area was to convince employers and provincial regulators that in all cases retesting needed to be done.” [31] However, no scientific references could be provided as to whether or not a biennial fit-test was as protective as an annual fit-test.

In the United States, a fit-test frequency of one year was chosen based on consensus rather than scientific rigor according to a former NIOSH staff member.[32] In the UK, the current standard states that although it is good practice to do regular fit-tests especially when respiratory protection is frequently used as a primary means of control, a repeat fit-test is only considered necessary when the wearer loses or gains weight, undergoes any substantial dental work, or develops any facial changes around the faceseal area.[33] Across Canada, many provinces reference the CSA standard for fit-test frequency. With such differences across jurisdictions, clearly there is a need to establish an appropriate fit-testing frequency to achieve an adequate seal based on scientific evidence.

1.3.3. Respirator Fit-Testing: Errors associated with Fit-Testing

When conducting a fit-test, there are two types of potential error: (1) alpha error which is the error of failing a respirator that should pass (false negative), and (2) beta error which is the error of passing a respirator that should fail (false positive).[14] These errors are of concern because beta errors, and to some degree alpha errors, can result in individuals being assigned inadequately fitting respirators. Findings from a study by Coffey et al. indicate that when both types of errors were combined, the QNFT method had the lowest percentage of wearers being assigned a poor-fitting respirator.[14] Two limitations of this study were that it had a small sample

size and it did not examine the 3M model number 1870 – a common flat-folded respirator used at both Vancouver Coastal Health and Fraser Health. In fact, the authors state "the accuracy of fit-testing methods and the fitting characteristics of filtering-facepiece respirators need to be improved. Further research is needed to lower the percentage of subjects failing a fit-test".

In a more recent study, Coffey et al. went further and examined the fit-test errors of 15 new filtering facepiece respirators.[18] The authors concluded that the fit-test method errors may be dependent on the characteristics of the respirator model tested and that fit-test accuracy may vary from one respirator model to another.

In a study by MacKay and Davies, the authors found that fit-test failures recorded with the quantitative method were correctly identified 100% of the time with the Bitrex qualitative method. However, the authors noted that they used a significantly higher concentration of Bitrex than what is commercially available raising questions about the applicability of their results.[17] Another study comparing Bitrex and Portacount fit-test results found that the Bitrex method resulted in a significant greater number of failures where a Portacount established an acceptable fit.[34] Other studies have found varying degrees of correlation between the Bitrex and Portacount methods but none have assessed the 3M 1860 and 3M 1870 respirator models.[14, 18]

1.3.4. Frequency of Respirator Usage and Appropriate Fit

Although fit-testing is required to ensure appropriate selection, the actual impact of frequency of respirator usage on obtaining an appropriate fit for each donning is unknown. Crutchfield et al. found that multiple donnings of a respirator over a period of time affected respirator fit to a greater degree than fit-test exercises.[35] Therefore, one could expect, as concluded by Johanson

and Morgan, that the more an individual utilizes a respirator in the real-world setting, the better the fit that will be obtained.[29]

Findings by Salazar et al. "suggested that workers who had more experience using the respirator were more adept at assuring adequate protection and they were less stressed when donning their equipment".[36] However, this study examined a different style of respirator and was not conducted in a healthcare setting where it is known that there has been lack of compliance with using personal protective equipment.[37] The theory that regular respirator usage reduces fit-test failure rates has yet to be tested with the N95 FFRs that are commonly used in healthcare.

1.3.5. User Seal Check Versus Fit-Test

Since the Severe Acute Respiratory Syndrome (SARS) crisis in 2003, a number of groups have advocated the use of user seal checks to replace the time-consuming fit-test process.[38] The purpose of a seal check is for the user to subjectively evaluate if an adequate seal is achieved following the donning of a respirator. However, a user seal check is difficult to perform on filtering facepiece respirators.[39] One study concluded that the user seal check is restricted in its use as a surrogate for respirator fit-testing.[40] The value of these results to our jurisdiction is limited by the fact that their subjects were a very specific demographic group (Chinese females) and they did not examine the respirator models used in BC healthcare.

1.4. Study Objectives

1. Compare the outcomes between the Bitrex and Portacount fit-testing methods.
2. Determine if there is a significant difference between failure rates associated with annual versus biennial fit-test frequencies for N95 FFRs commonly used in healthcare.

3. Evaluate the level of N95 FFR donning skills retained by staff who are fit-tested on an annual basis only, biennial basis only, or biennial basis but with an annual education component in between fit-tests.
4. Determine the effect of regular usage on fit-test failure rates as well as on the level of donning and doffing skills retained by staff using N95 FFRs.
5. Evaluate the applicability of a user seal check as a surrogate for a fit-test in determining an adequate fit on an N95 FFR.

2. METHODOLOGY

2.1. Selection of participating sites and subjects

Approval from relevant ethics boards was obtained prior to commencement of study. All residential care facilities within Fraser Health, including those owned-and-operated and leased, were invited to participate. The two largest owned-and-operated residential care facilities within Vancouver Coastal Health were also invited to participate. Residential care workers were chosen as they do not normally work under airborne precaution situations and therefore do not require N95 FFRs. As study objective #2 was to assess the feasibility and protectiveness of a biennial fit-test frequency, it is essential to have participants that do wear an N95 FFR on a regular basis; otherwise they would require an annual fit-test as per the OHSR (i.e. if this cohort does not receive an annual fit-test, there is no contravention of the current OHSR).

Acute care staff from all emergency departments within Fraser Health was also invited to participate. To supplement the number of acute care workers in the study, select Respiratory Therapy departments at both participating health authorities were also asked invited to part of the study. The purpose of including acute care staff was to determine the effect of regular

usage on fit-test failure rates and on the level of donning and doffing skills retained by staff (Objective #4). The term "regular usage" in the context of this study refers to work positions where staff have a higher probability of exposure to airborne infectious agents and therefore require the use of an N95 FFR, on average at least once per month.

2.2. Subject recruitment methods

At most participating sites, a mutually-agreed upon date was established in which a presentation was given by members of our research team to all available staff. At the conclusion of the presentation, potential subjects were provided with a written summary of the study as well as a copy of the consent form (Appendix B). In instances where a departmental presentation could not be arranged, managers were given several copies of the initial letter of contact as well as the consent form and asked to disseminate the documents to their staff on behalf of the research team.

Completed consent forms were compiled in a central location at each department and were subsequently collected by members of the research team. While on site collecting the completed consent forms, members of our research team also actively recruited potential subjects by explaining the study to staff on a one-on-one basis and then seeking consent from these workers. All workers that provided their written consent were subsequently contacted by a member of the research team to schedule a mutually-convenient fit-test date.

Active recruitment of additional subjects as described earlier also took place while our research team was on-site conducting the fit-tests.

2.3. Study groups

Participants were divided into four groups. Groups 1 to 3 were randomly assigned from residential care settings and represent naïve users. Group 4 were selected from the acute care

departments and represent experienced users. Participants in all groups underwent an initial education and training session and fit-test in Year 1. The four groups were divided according to their subsequent involvement and received the interventions outlined in Table I.

The rationale for each group was as follows. Group 1 (the control group) represented the currently mandated education / training and fit-testing criteria in which staff requiring the use of N95 FFRs received both services on an annual basis. Group 2 participants received ONLY education / training in Year 2 (i.e. not fit-tested) to determine how this RPP element affected the retention of respirator usage skills. Group 3 received neither education/training nor fit-testing in Year 2 in order to evaluate Objective#2.

Group 4 was the sole group selected from acute care. This group was included to determine whether frequent use of respiratory protection influences the ability of a user to maintain a good respirator fit.

Table II summarizes the comparative analyses employed for assessing each study objective.

Participants in each of the four groups underwent the same education/training and fit-testing procedures in Year 1. Participants went through this process individually to ensure that there was no influence from their peers during the session. Components of the education/training and fit-test sections are described in detail in the following sections.

2.4. Initial Information Collection

At the initial fit-test session, a variety of information was collected as outlined in Table III. Staff members who indicated a respiratory condition that would preclude their use of a respirator were not fit-tested and excluded from the study.

2.5. Standardized Respirator Education Video

To ensure consistency of education / training between participants and groups each year and between years, a standardized video was presented as the education component. The education video was approximately 7 minutes in duration and contained the following elements:

- What is an N95 FFR? (including a basic description of how particulate filters operate, what the "N" and the "95" represent, intended use, and limitations)
- When is an N95 FFR required? (including discussion of common airborne infectious hazards)
- Demonstration of a User Seal Check
- Demonstration of Donning and Doffing an N95 FFR (including re-use limitations)
- What is Fit-Testing?

2.6. Education Checklist

Following the video segment, the researcher assessed the participants understanding of the material using a standardized checklist (see Appendix F). If there were any misunderstandings or deficiencies in the knowledge related to the education demonstrated by the participant, the researcher reviewed the topic(s) with the participant.

2.7. Selection of N95 Respirator and Donning/Doffing Training

Two models of N95 FFRs were included in this study: 1) 3M 1860 model, and 2) 3M 1870 model. The 3M 1860 model comes in two sizes: 1) regular (3M 1860), and 2) small (3M 1860S). These N95 FFRs were studied because they are the most common models currently utilized within healthcare in BC and across North America.[21] These particular models are designed specifically

for healthcare and both Fraser Health and Vancouver Coastal Health have had very good fit-test passing rates on these three models (collectively >90%).

One of the three aforementioned N95 FFR models was provided to the participant based on professional judgment of the researcher, a qualified fit-tester. The researcher demonstrated the proper donning and doffing technique for the selected model to the participant while the participant practiced in parallel. If the selected respirator felt comfortable on the user's face and the researcher believed that the situated N95 FFR model fits well, then the process proceeded to the next step. This follows the method currently in place at Fraser Health, which typically results in a 50:50 division between respirator models 3M 1860 and 3M 1870.

2.8. User Seal Check

The researcher had the participant doff the aforementioned selected N95 FFR model. Prior to having the subject re-don the N95 FFR, the researcher placed a probe inside the N95 FFR as required for the Portacount QNFT (see following section). The end of the probe was capped to ensure there was no leakage through the probe into the respirator. Placing the probe in the N95 FFR at this stage allowed for the progression of the fit-tests from either the QLFT to the QNFT or vice versa without disturbing or removing the N95 FFR between tests. This ensured that the results obtained from the QLFT can be correlated to those obtained from the QNFT since the tests will be comparing the same respirator donning. The participant was then asked to don the respirator, without any assistance, and subsequently perform a user seal check.

The user seal check was completed as per the manufacturer's instructions and included the following steps: (1) both hands were placed completely over the N95 FFR, (2) inhale and exhale sharply being careful not to disturb the position of the respirator, and (3) if air leaks around

nose, readjust the nosepiece; if air leaks at the respirator edges, work the straps back along the sides of the head.[41]

Based on the user seal check, the subject was asked whether he/she felt that a good facial seal was obtained. If the subject felt that a good seal was obtained, the researcher documented it as a "pass" and proceeded to the QLFT or QNFT. If the participant did not feel that a good seal was obtained, the participant re-donned. If after re-donning with the same N95 FFR model the participant still did not feel a good seal was obtained, a different N95 FFR model was attempted as per the previously described procedures.

2.9. Fit-Testing

All male participants were required to be clean shaven where the respirator came in contact with the face. Male participants were informed on the need to be clean shaven whenever an N95 FFR is worn.

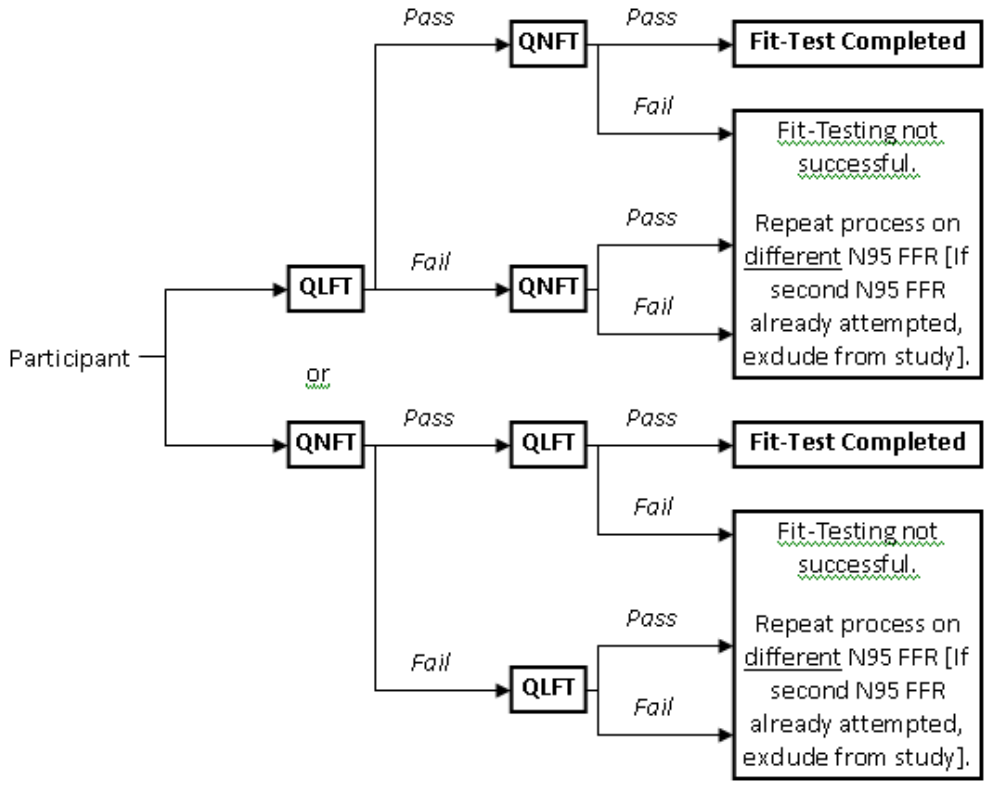
A QLFT was conducted using the 3M FT-30 Qualitative Fit Test Apparatus (Bitrex). A TSI PORTACOUNT® Plus Respirator Fit Tester Model 8020 with a TSI N95-Companion Model 8095 (Portacount) was utilized to conduct the QNFT. Both QLFT and QNFT were conducted in accordance with the requirements outlined in CSA Z94.4-02.

The order of the testing was alternated between the two fit-test methods to ensure that one method did not affect the outcome of the other. Regardless of whether the subject passed or failed the initial fit-test method, the participant proceeded immediately to the alternate fit-test method. Although this is not a common practice, this process allowed for a comparison of the pass and fail rates between these two methods as outlined in Objective #3.

Figure 1 depicts a flowchart of the fit-testing process for the first year for all participants. Only participants who passed on both the QLFT and the QNFT methods for a particular respirator

model were considered a pass and eligible for the remainder of the study. If there was a failure on either the QLFT or the QNFT for a particular model of respirator, the process was repeated using one of the other N95 FFR models. A participant who failed on two N95 FFR models was excluded from further participation in the study. Once a pass was obtained for a particular N95 model on both the QLFT and the QNFT, no other N95 FFR models were fit-tested and the session was completed. The successful N95 FFR model was documented and the participant was notified that, should the need arise, they could only wear that particular model.

Figure 1: Process for completing QLFT and QNFT fit tests



2.10. Respirator Usage Form

Participants were asked to record their N95 FFR usage on a monthly basis using the form found in Appendix E and submit it at their next fit-test session. Every subject was informed of the purpose of the usage form during the fit-test sessions and was asked to track their N95 FFR usage throughout the research project. They were asked in the past year how many months

did they don the mask. Subsequently, they were asked during those months how often did they have to don the mask. This was of particular importance for the acute setting participants and was used to assess study Objective #4 which is to ascertain the effect of regular usage on fit-test failure rates as well as the level of donning skills retained by staff.

2.11. Weight Change and Facial Changes

The CSA standard and WSBC OHSR require that a fit-test be carried out "whenever changes to the user's physical condition could affect the respirator fit." Two changes that could potentially affect the respirator fit are a change in body weight or change in facial structure (e.g. dentures, etc). To account for these potential issues, each participant who was fit-tested was weighed and photographed.

2.12. Subsequent Sessions

In Year 2, the groups each received a different level of follow-up (as outlined in Table I). Groups 1 and 4 received education / training, performed a user seal check, and underwent a fit-test. These sessions were conducted using the same methods outlined in the previous sections with one notable exception – participants received donning and doffing training only on the respirator model in which they passed their fit-tests during Year 1 and performed the user seal check and underwent the fit-tests for that particular model only. If they failed either the QLFT or QNFT, for whatever reason, they were then excluded for the remainder of the study.

Group 2 received education / training only in Year 2. These education / training sessions followed the methodology outlined in the previous section.

Group 3 did not receive any form of follow-up services in Year 2.

In Year 3, all groups were asked to perform a user seal check and underwent a fit-test. Participants did not receive the education as per previous years. Participants were asked to

don the N95 FFR prior to the insertion of the probe. Their ability was assessed and some assistance given where needed. They doffed the N95 FFR, the probe was inserted and they were asked to don the N95 FFR again. Once they felt they had a good seal, they underwent a fit-test; either the QLFT or QNFT first then immediately followed by the alternate method.

2.13. Data Analysis

Two key assumptions were made *a priori* with respect to our results ("raw data"):

1. All of our qualified participants, those who passed both Bitrex and Portacount in Year 1 are "true" passes i.e. no participant passed either method in error.
2. There was no error associated with either the Bitrex or Portacount fit-test methods in subsequent years i.e. no participant failed or passed in error.

However, based on the literature, it is known that there are errors associated with the fit-test methods employed resulting in individuals who pass in error (beta error) as well as individuals who fail in error (alpha error).[18] Coffey et al determined that for filtering facepiece respirators, the Bitrex method has an alpha error of 65% and a beta error of 8% while the Portacount method has an alpha error of 58% and beta error of 6%. We are not aware of any study that has applied the alpha and beta errors established by Coffey et al. nor were any process for application brought forward by Coffey et al. Because of the significance of the alpha and beta errors associated with the fit-testing methods, we felt compelled to account for these errors and therefore incorporated the values proposed by Coffey et al. into our analysis. As such, "adjusted data" will be presented and discussed in addition to the raw data. See Appendix H for an example of the calculations used for "adjusted" data.

It is important to note that Coffey et al.'s calculated alpha and beta errors were determined for 33 different N95 FFR models, not strictly the models utilized in this study.

2.13.1. Analyzing objective #1

Before an overall comparison of the Bitrex (QLFT) and Portacount (QNFT) results can occur, those factors that may influence the outcome of a fit-test need to be evaluated independently. These three factors are: (i) respirator model (i.e. characteristics associated with a particular model may result in different fit-test outcomes between methods), (ii) sequential order of the fit-test method (i.e. Bitrex or Portacount), and (iii) the year in which the fit-test was administered (knowledge of previous fit-test results may affect the outcome of subsequent fit-tests, particularly a qualitative fit-test).

a) To determine the effect of the respirator model on fit-test outcome and the effect of fit-test order, the data from across the three years was combined as it does not need to be evaluated longitudinally (the effect of year on fit-test outcome is assessed separately in Section b).

   Overall percent agreement between the fit-test methods was calculated using the following equation: [Subjects pass:pass + Subjects fail:fail) / total subjects] *100.

   However, this equation does not take into consideration of chance agreements. Kappa (κ) does takes into account agreements that could occur due to chance[42, 43] and can be used to determine the difference between the observed agreement and the expected agreement in fit-test outcomes. Since kappa is a better measure of agreement than simple percentages, kappa calculations, as summarized in Appendix G, were performed.

   Kappa statistic agreement was based on the following scale developed by Landis and Koch: < 0.0 = poor agreement, 0.00 to 0.20 = slight agreement, 0.21 to 0.40 = fair agreement, 0.41 to 0.60 = moderate agreement, 0.61 to 0.80 = substantial agreement, 0.81 to 1.00 = almost perfect agreement.[44]

b) In order to determine the effect of the year when the fit-test was administered on fit-test outcome, it is important to assess the data longitudinally and therefore include only those individuals who were involved from the study's beginning until its completion.

The potential effect of alpha and beta errors was also taken into consideration and adjustments to the raw data were made (see Appendix I for a detailed summary of the steps taken to adjust the data).

2.13.2. Analyzing Objective #2

A comparison of pass rates between Group 1 (education and fit-testing in Year 2) and Group 3 (no intervention in Year 2) in Year 3 was conducted. In order to eliminate any potential effect resulting from participants who were not included in Years 2 and 3, it was necessary to evaluate longitudinally, using only those participants who completed the entire study i.e. 91 participants from Group 1 and 130 participants from Group 3. Adjusted data was calculated as per Appendixes H and I.

2.13.3. Analyzing Objective #3

Fit-test pass rates in Year 3 between Group 1 (education and fit-testing in Year 2), Group 2 (education only in Year 2), and Group 3 (no intervention in Year 2) were compared. The fit-test in Year 3 was administered without any education or donning assistance provided by the fit-tester in order to evaluate the level of donning skills retained by participants in all groups,

2.13.4. Analyzing Objective #4

Fit-test pass rates in Year 3 between Groups 1 (residential group) and 4 (acute care cohort) were compared. Participants in both these groups were provided with the same education and fit-testing at the same intervals throughout the course of the study.

2.13.5. Analyzing Objective #5

Each subject was asked to perform a user seal check and the outcome was documented as either “pass” (good seal) or “fail” (inadequate seal). These reported results were then compared to the subsequent Bitrex and Portacount fit-tests to assess the accuracy of the user seal check in determining a successful fit.

All statistical analysis was performed using STATA (StataCorp LP, College Station, Texas).

3. RESEARCH FINDINGS

A total of 26 healthcare facilities participated in this study. In Year 1, 784 participants were initially assessed. Of these, 674 (86%) were deemed eligible to remain in the study as each subject was able to successfully pass on both the Bitrex and Portacount methods with the same N95 FFR. The remaining 115 subjects were unable to pass both the QLFT and QNFT on one of the available N95 FFRs and were therefore excluded from the study.

The majority of study participants in Groups 1, 2 and 3 were care aides (65%) with the remainder of participants from other various job categories. Table IV presents an overview of the job titles of the participants in Year 3 in Groups 1, 2, and 3. Group 4 was comprised of Emergency Department nurses, paramedics and Respiratory Therapists. The average age of participants was approximately 45 and 90% of all subjects were female.

From Year 1 to Year 3, a total of 327 participants were lost for follow-up (49%) – see Table V. By group, the loss for follow-up was as follows: Group 1, 62 participants lost (41%); Group 2, 65 participants lost (43%); Group 3, 122 participants lost (48%); and Group 4, 78 participants lost (66%).

The degree of loss for follow-up was greater than initially anticipated but several unforeseen incidents, such as the H1N1 pandemic and organizational changes, had a significant impact on

the retention of subjects for the full duration of the study. The main reason for loss, accounting for 50% of the total loss, was due to participants leaving the department / organization. Specific reasons for loss of follow up are detailed in Table VI.

With regards to weight change amongst the subjects, the residential care staff in Year 1 had an average weight of 153.2 lbs which remained consistent at 153.4 lbs in Year 3. Table VII further breaks down the percentage of subjects that had an increase or decrease of 10% of their initial weight within the three-year period of the study. Since the majority of subjects had negligible weight change, this variable had no impact on the outcomes of our study. It should be noted though that not all participants agreed to have their weight taken – approximately 5% did not consent.

3.1. *Objective #1:* Compare the fit-test outcomes between the Bitrex and Portacount methods

3.1.1. Effect of Respirator Model on Fit-Test Outcomes

Assessment of raw data:

Tables VIII a, b, and c summarize the fit-test outcomes of the Bitrex and Portacount methods by N95 FFR model. The overall percent agreement of the two fit-test methods when the results of each of the three N95 FFR models (3M 1860, 1860S, and 1870 models) are assessed separately is 78%, 83%, and 82%, respectively. The κ value for the 3M 1860, 1860S, and 1870 models when assessed separately is: 0.53, 0.54, and 0.61, respectively. These results indicate that there is moderate agreement for 1860 and 1860S and substantial agreement for 1870 (although at the lower end of this scale category) in outcomes between the QNFT and QLFT methods and are not dependent on any of the three N95 FFR models.

Assessment of adjusted data:

The overall percent agreement of the two fit-test methods when the adjusted results of each of the three N95 FFR models (3M 1860, 1860S, and 1870 models) are assessed separately is 73%, 78%, and 74%, respectively (Tables IXa-c). The κ value for the 3M 1860, 1860S, and 1870 models when assessed separately is: 0.14, 0.14, and 0.14, respectively.

These values indicate a slight level of agreement between the two methods but the relative level of agreement between the methods is the same for all three models and therefore the respirator model does not affect agreement of the fit-test outcomes.

3.1.2. Effect of Order of Fit-Test Methods on Fit-Test Outcomes

Assessment of raw data: Tables X a and b summarize the fit-test outcomes of the Bitrex and Portacount methods by the order in which the fit-test method was administered. The overall percent agreement of the two fit-test methods was 80% when Bitrex was the first fit-test method administered and 84% when the Portactount was first. The κ value when Bitrex was first was 0.54 and 0.65 when Portacount was first. The methods have moderate and substantial agreement, respectively, regardless of the order of fit-test method delivery.

Assessment of adjusted data: Adjusted data is shown in Tables XI a and b. For the adjusted data, the overall percent agreement of the two fit-test methods was 76% when Bitrex was the first fit-test method administered and 75% when the Portactount was first. The κ value when Bitrex was first was 0.15 and 0.14 when Portacount was first.

Again, these values indicate an overall slight agreement between the two methods but the relative level of agreement between the methods is very similar irrespective of the order in which the fit-tests were administered and therefore the order of two fit-test methods does not affect agreement of the fit-test outcomes.

3.1.3. Effect of Fit-Test Year on Fit-Test Outcomes

Assessment of raw data: Of the 341 who remained for the entire duration of the study, 46 originally failed on one or both of the fit-test methods in the first year but then successfully completed a fit-test on both fit-test methods on a different N95 FFR. As these original failures are not pertinent to the subjects' follow-up over time (as they continued on using a different model and this effect was assessed in Section 3.1.1), the original failures were excluded from the analysis.

Tables XII a, b, and c summarize the fit-test outcomes of the Bitrex and Portacount methods by the year of the fit-test. In Year 1 there was 100% agreement (In other words, every participant from Year 1 passed both fit-test methods and therefore remained for the duration of the study (longitudinal data); however, this does not mean that there was 100% agreement between the fit-test methods for every participant fit-tested in Year 1. In Year 2, there was 81% agreement and in Year 3 there was 71% agreement. Since there was 100% agreement between the fit-test methods in Year 1 by nature of how we defined subsequent participation, only the κ values for Year 2 and 3 are of importance - the κ values were 0.49 in Year 2 and 0.36 in Year 3. This suggests a moderate agreement in Year 2 and a fair agreement in Year 3. The level of agreement between the two methods decreases over time.

Assessment of adjusted data: Tables XIII a and b summarize the fit-test outcomes of the Bitrex and Portacount methods by the year of the fit-test.

As with the raw data, the adjusted data shows agreement between the two methods changes substantially over time: 100% in Year 1, 87% in Year 2, and 74% in Year 3. Again, only the κ values for Year 2 and 3 are of importance - the κ values were 0.22 in Year 2 (fair agreement) and 0.15 in Year 3 (slight agreement).

3.1.4. Overall Comparison of Fit-Test Outcomes Between the Bitrex and Portacount Methods

The overall percent agreement between the two fit-test methods when using the *raw data* was 82% with a κ value of 0.58 representing a moderate agreement (see Table XIVa). The overall percent agreement between the two fit-test methods when using the *adjusted data* was 84% with a κ value of 0.07 reflective of a slight agreement (see Table XIVb).

This suggests that the overall agreement between the Bitrex and Portacount fit-test methods is slight to moderate.

3.2. *Objective 2:* Determine if there is a significant difference between failure rates associated with annual versus biennial fit-test frequencies for N95 FFRs commonly used in healthcare.

Of 556 participants from residential care who achieved a successful fit on one of the N95 FFR models in Year 1, 91 participants from Group 1 and 130 participants from Group 3 completed the entire study.

Assessment of raw data: Table XV summarizes the longitudinal pass rates (raw data) for the study groups in Year 3 for both the Bitrex and Portacount methods. In Year 3, Group 1 and Group 3 had identical pass rates using the Bitrex method – 56%. The Portacount pass rates were also very similar – 41% for Group 1 and 43% for Group 3. There was no statistically significant difference found between pass or failure rates associated with annual versus biennial fit-test frequencies.

Assessment of adjusted data: Table XVI summarizes the longitudinal pass rates (adjusted data) for Groups 1 and 3 in Year 3 for both the Bitrex and Portacount methods. For the adjusted data in Year 3, Group 1 and Group 3 had identical pass rates using the Bitrex method – 81%. The Portacount pass rates were also very similar – 73% for Group 1 and 75% for Group 3. Like the raw data, there was no statistically significant difference found between pass or failure rates

associated with annual versus biennial fit-test frequencies. However, the overall pass rates are much higher in Year 2 and Year 3 for the adjusted data compared to the raw data.

Similar to the results of Johanson and Morgan, the results of the current study suggest that changing to a fit-test frequency greater than one year does not result in an increase in fit-test failure rates when compared with fit-tests conducted on an annual basis.[29]

3.3. *Objective #3:* Evaluate the level of N95 FFR donning skills retained by staff fit-tested on an annual basis only, biennial basis only, or biennial basis but with an annual education component in between fit-tests.

Assessment of raw data: Table XV presents the longitudinal raw fit-test pass rates for Groups 1 to 3 in the follow-up years of the study. The raw pass rates in Year 3 were very similar between the three groups. Using the Bitrex method, the pass rates were 56% (Group 1), 57% (Group 2), and 56% (Group 3). With respect to the Portacount method, the pass rates were 41% (Group 1), 43% (Group 2), and 43% (Group 3).

Assessment of adjusted data: The adjusted pass rates in Year 3 were also very similar between the three groups, although the overall pass rates were higher than that calculated for the raw data. On the Bitrex method, the pass rates were 81% (Group 1), 82% (Group 2), and 81% (Group 3). On the Portacount method, the pass rates were 73% (Group 1), 75% (Group 2), and 75% (Group 3).

Regardless of the fit-test method, the pass rates were virtually identical between the three groups in Year 3. This illustrates that at that point in time, there was no positive or negative effect from whether the participants had received education, fit-testing, or both in the year prior compared to participants who had not received either intervention for a two-year period.

3.3.1. Potential benefit of education

Although the pass rates in Year 3 were similar between groups, the raw pass rates for Group 1 in Year 2 provide some interesting results. As shown in Table XV, the pass rates for the Bitrex and Portacount methods for Group 1 in Year 3 were 56% and 41% respectively, but in Year 2 the pass rates were 78% and 71%, respectively. In Year 2, the difference in results from year 3 and year 2 for both fit-test methods are statistically significant. Group 1 received education immediately followed by fit-testing, whereas in Year 3, only a fit-test was administered. The results seem to indicate that there is an immediate positive effect of education on the fit-test outcome. However, at some point following that over the course of a year, this effect diminishes as illustrated by the similar pass rates between the three groups in Year 3.

However, when looking at the adjusted data shown in Table XVI, this effect is much less pronounced. The pass rates for the Bitrex and Portacount methods for Group 1 in Year 3 were 81% and 73% respectively, but in Year 2 the pass rates were 88% and 85%, respectively.

3.4. *Objective #4:* Determine the effect of regular usage on fit-test failure rates as well as on the level of donning skills retained by staff using N95 FFRs.

Only one fax copy of the N95 FFR usage form was received from Residential Care subjects in Year 1 and no faxes were received in Year 2. This is likely due to the fact that N95 FFRs are not typically used in Residential Care.

N95 FFR usage information was obtained from the acute care job categories (Group 4) as shown in Table XVII. Registered Respiratory Therapists (RRT) were the highest users of N95 FFRs, with a median average use of 144 times per year, as they are routinely engaged in high-risk aerosol generating procedures such as intubations.

Assessment of raw data: Table XV presents the raw pass rates for the various groups over time. In Year 3, the pass rate among Group 4 participants was 81% and 72% (Bitrex and Portacount,

respectively) compared to Group 1 participants with pass rates of 56% and 41% (Bitrex and Portacount, respectively). Interestingly, the pass rates for Group 4 were lower than Group 1 in Year 2 but higher in Year 3.

Assessment of adjusted data: Table XVI presents the adjusted pass rates. In Year 3, the pass rate among Group 4 participants was 91% and 85% (Bitrex and Portacount, respectively) compared to Group 1 participants with pass rates of 81% and 73% (Bitrex and Portacount, respectively).

The data suggest that regular usage results in a higher fit-test pass rate over time.

3.5. *Objective #5:* Evaluate the applicability of a user seal check as a surrogate for a fit-test in determining an adequate fit on an N95 FFR.

Note that excerpts in this section have been published in the Journal of Occupational and Environmental Hygiene.[45]

Of the 784 health care workers enrolled in the study, 647 (83%) were naive users of respiratory protection (NB: these values differ from those reported in previous sections as we examined this objective based on data from our Year 1 participants only); that is, those workers who were not previously fit-tested because they were assigned to departments or facilities where use of respirators was not required (i.e. Residential Care). These were participants in Groups 1-3. The remaining 137 participants (17%) were experienced users of respirators, either from emergency or respiratory therapy departments i.e. Group 4. Experienced users were defined as those health care workers who require the use of a respirator at least once a month.

Only four (0.62%) of the 647 naive subjects identified an inadequate seal after their user seal check. Of these four subjects, two went on to pass both the Bitrex and Portacount fit-tests; the other two failed both the Bitrex and Portacount fit-tests. Of the remaining 99.4% of naive subjects (n = 643) who indicated that they had an adequate facial seal prior to fit-testing, 158

(25%) failed the subsequent Portacount fit-test and 92 (14%) failed the Bitrex fit-test (Table XVIII). All 137 experienced users indicated that they had an adequate seal after performing the user seal check; however, 41 (30%) failed the subsequent quantitative fit-test, and 30 (22%) failed the qualitative fit-test.

Of the 784 subjects in this study population, nearly all (780; 99.5%) indicated that they felt they had an appropriate face seal after completing the user seal check. However, the subsequent respirator fit-test results (with failure rates as high as 30%) demonstrate that, in a large majority of the cases, the user seal check was not able to identify a poorly fitting respirator as defined by a fit-test. Using a similar quantitative fit-test method, Derrick et al. found that in 19-31% of occasions, the user seal check incorrectly indicated a properly fitting N95-FFR. [8] These results are comparable to our findings where the user seal check incorrectly indicated a proper fit in 25-30% of occasions, based on naïve and experienced users, respectively. The findings of the current study support those by Derrick et al. who similarly concluded that the user seal check should not be used as a surrogate fit-test for N95-FFR's. Moreover, the current study expands on Derrick et al's findings by including a 'naïve' cohort of respirator users and enrolling a heterogeneous population of subjects, such that the conclusions reached by Derrick and colleagues can now be more confidently generalized.

The user seal check is inherently different from a fit-test in that the latter is a dynamic process involving a series of exercises used to mimic "real world" usage, while a user seal check is a relatively static procedure. When conducting a user seal check on a filtering facepiece respirator, the wearer's hands are placed over the facepiece. This must be done carefully to avoid disturbing the position of the respirator on the face. However the effect of placing one's hands on top of the respirator may result in an alteration of the fit by the application of direct

pressure on the facepiece by the user's hand. The fit may also be altered if only a limited area of the filtering facepiece material is covered as this can result in non-uniform air flow through the remainder or uncovered part of the facepiece material. In addition, noticing a subtle pressure differential with a filtering facepiece device can be quite difficult. Furthermore, the user seal check is subjective, relying on the individual worker to assess whether the respirator has properly sealed to their face; a procedure that both experienced and naïve users failed to achieve at an appropriate rate in the current study.

3.6. Conclusion

Based on the objectives of the study, the results of this project illustrate the following:

1. The overall agreement found between the two Bitrex and Portacount fit-test methods is slight to moderate.
2. There is no significant difference between pass or failure rates associated with annual versus biennial fit-test frequencies for N95 FFRs commonly used in healthcare.
3. N95 FFR donning skills did not differ significantly between staff fit-tested on an annual basis only, biennial basis only, or biennial basis but with an annual education component in between fit-tests in Year 3. There does seem to be an immediate positive effect of education on the fit-test outcome; however, at some point following that over the course of a year, this effect disappears.
4. Regular usage of N95 FFRs reduces fit-test failure rates and increases the level of donning skills retained by staff using N95 FFRs over time.
5. The user seal check is not an appropriate surrogate for a fit-test in determining an adequate fit on an N95 FFR.

3.7. Strengths

Several strengths of the study need be mentioned. Although we had anticipated a larger study sample overall, in Year 3, we still had an average of 100 participants per follow-up group from the residential care facilities. In addition, the subjects were randomly-assigned to the one of the three follow-up groups and were unaware of the type of intervention they were to receive in subsequent years of the study. This eliminated any selection bias issues. Furthermore, we were able to perform longitudinal analyses and follow subjects for the full duration of the study (from the beginning to Year 3). This allows for more robust analysis of the fit-test pass rates.

This was a multi-centre study and therefore the results are representative of non-respirator users for various residential care settings. We also evaluated the effect of weight change and the N95 FFRs models used in the study on the fit-test pass rates and found a negligible effect. In addition, we randomized the sequence of fit-testing (some subjects received a QLFT first; others received the QNFT first) and there appeared to be no effects on the resulting fit-test rates.

3.8. Limitations

Limitations associated with this study need to be addressed. This study only used three N95 FFRs models. There are numerous other N95 FFRs models available and the results found in this study may not be applicable to these other commercially-available N95 FFRs.

The study design is not reflective of actual practice because in real life, if an individual was able to pass on one of the fit-tests, they would be considered eligible to wear a respirator. However, as our study required a subject to pass both fit-test methods sequentially, this may be a potential bias as this reduces our pool of potential subjects (since they have to pass both fit-test methods to be part of the study).

Our study participants were primarily women, which is reflective of the healthcare workforce. However, N95 FFRs are used by men and in other industries and the fit-test rates found in this study may not be representative of the rates for male N95 FFR users and/or for respirator users in other industries.

Regarding study participants there is a possibility of volunteer basis based on the recruitment methods employed. Unfortunately, there is not much that can be done to prevent this bias as our recruitment method had to comply with those of the relevant ethics boards.

The resulting sample size for the acute care cohort (Group 4) is small relative to the three other study groups. In addition, the acute care cohort consisted primarily of Registered Respiratory Therapists (RRTs) whose tasks and responsibilities may not be representative of all "regular users" of N95 FFRs in healthcare.

Our findings suggest that education / training as well as regular usage positively impacts the ability to achieve a successful fit-test. However our study design does not allow us to determine the influence of these two factors individually and, therefore, cannot state with confidence the contribution each factor makes in passing a fit-test.

3.9. Conflict of Interests

Even though two members of the research team are affiliated with the participating health authorities, there are no conflicts of interest to declare as all statements made in this report were agreed upon unanimously.

4. IMPLICATIONS FOR FUTURE RESEARCH ON OCCUPATIONAL HEALTH

- Assess other methods to identify a poorly fitting respirator at time of use (e.g. rather than the user seal check, use of a mirror).
- Examine the impact of regular use on fit-test pass rates for a larger study population.
- Determine the optimal frequency of training / education for knowledge retention among infrequent users as well regular users of N95 FFRs in healthcare.
- Determine optimal method of education delivery (e.g. online, video, poster)
- Examine respiratory protection program elements in other industries as well as other types of respirators besides N95 FFRs.
- Incorporate multiple donning approach in future methodology.
- Compare agreement between different methods using elastomeric respirators.

5. POLICY AND PREVENTION

a) Identification of policy and prevention implications arising from the research

Based on the results of this study, the following policy and prevention implications have been identified:

i) the user seal check should not be considered a surrogate for fit-testing. If workers were to rely solely on the user seal check without being appropriately fit-tested, there is the potential they would not be adequately protected. There should be no change to the regulation whereby the user seal check is employed as a surrogate for fit-testing.

ii) a fit-testing frequency of two-years results in no difference in fit-test outcomes from a fit-test frequency of one-year. With respect to a policy related to the frequency of fit-testing, the

results show that the fit-test outcomes are equivalent between annual and biennial fit-test frequencies.

iii) respiratory protection education / training appears to play a role in the ability to achieve a successful fit-test. No policy statements can be made at this time as there is insufficient evidence regarding the importance of education/training and its relationship to fit-test outcomes.

b) identification of relevant user groups for the research results

Relevant user groups for research results include, but are not limited to, health authorities, healthcare unions, occupational health and safety professionals, infection control experts, and occupational health and safety policy makers.

c) description of any policy-related interactions undertaken by the Applicant

No policy-related interactions have been undertaken at the time of writing of this report.

6. DISSEMINATION/KNOWLEDGE TRANSFER

We submitted a paper related to study objective #5 entitled "Healthcare Workers and Respiratory Protection: Is the User Seal Check a Surrogate for Respirator Fit-Testing?" to the Journal of Occupational and Environmental Hygiene.[45] It was published in the May 2011 issue (DOI: 10.1080/15459624.2011.566016).

The results were presented to the BC Health Authorities Occupational Health and Safety Directors on June 16 and the BC Health Authorities Occupational Health and Safety Managers Meeting on June 2. We are planning on presenting our results to the following groups in the near future: The Healthcare Safety Professionals Association of BC, the American Industrial Hygiene BC-Yukon local section, and the Workplace Health departments at Fraser Health and

Vancouver Coastal Health. Presentation at professional conferences may also take place but the final decision will be determined on a consensus basis by members of the research team.

Once this report has been vetted by the WorkSafeBC Research Secretariat, copies will be disseminated to the Health Employers Association of BC (HEABC), the British Columbia Nurses' Union (BCNU), the Hospital Employees' Union (HEU) and the Health Sciences Association of BC (HSA), the Provincial Infection Control Network (PICNet), and the BC Centre for Disease Control (BCCDC).

At this time, we anticipate writing articles for peer-review journals related to study objectives 1, 2 and 4. Likely journals for consideration include the *Journal of Occupational and Environmental Hygiene* (official journal of the American Industrial Hygiene Association and the American Conference of Governmental Industrial Hygienists) and the *American Journal of Infection Control*. Both journals are published monthly with a worldwide distribution.

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Cartier House Care Center
Delta View Campus of Care
Dr Stuart Pavilion
Eagle Ridge Manor
Evergreen House
Fellburn Care Centre
Hawthorne
Heritage Village
Hollyrood Manor
Langley Lodge
Kinsmen Retirement Center
Kiwanis Care
Maplewood House
Minoru Residence
MSA Extended Care (Worthington and Cottage)
MSA Manor
Northcrest Care Centre
Peace Arch Hospital Emergency Department
Royal Columbian Hospital Emergency Department
Royal Columbian Hospital Respiratory Therapy
Simpson Manor A
Vancouver General Hospital Respiratory Therapy
Willingdon Park Hospital

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APPENDIX A

Annual Fraser Health N95 FFR Fit-Test Expenses

Item	Time per Session (hours)	Sessions per Year	Time per Year (hours)
Train-the-Trainer Fit-Test Sessions			
Trainers (2)	4	8	64
Attendees (~8)	4	8	256
Standing Fit-Test Sessions			
Fit-Testers (2)	8	126	2016
Additional Scheduled Fit-Test Sessions			
Fit-Tester	Variable	Variable	~300
Trained Fit-Tester Sessions			
Trained Fit-Tester	Variable	Variable	~300
Staff Time for Fit-Testing	25 minutes	4000	1667
		TOTAL	**4603**

Average wage is ~$40/hour (factoring in benefits) for a total annual cost of $184,120 to Fraser Health.

Note that this is equivalent to the annual cost for Vancouver Coastal Health.

APPENDIX B

Participant Consent Form

fraserhealth
Better health. Best in health care.
300 – 10334 152A Street
Surrey, BC
V3R 7P8
Tel: 604-587-4600

Vancouver CoastalHealth
Promoting wellness. Excelling in care.
10th Fl, 601 West Broadway
Vancouver, BC
V5Z 4C2
Tel: 604-875-4250

SUBJECT INFORMATION AND CONSENT FORM

TITLE OF STUDY: ***Strengthening N95 Filtering Facepiece Respirator Protection Programs by Evaluating the Contribution of Each of the Program Elements***

Co-Principal Investigator:
Quinn Danyluk, MSc CIH
Occupational Hygienist
Fraser Health
Workplace Health
604-520-4435

Co-Principal Investigator:
Chun-Yip Hon, MSc(A) CRSP CIH
Occupational Hygienist/OHS Advisor
Vancouver Coastal Health
Worksafe & Wellness
604-822-9757

SPONSOR: WorkSafeBC Research Secretariat

INTRODUCTION:
N95 filtering facepiece respirators (N95 FFR) are commonly used in acute care facilities because of the potential high risk of transmission of respiratory organisms during many procedures that occur in this setting. Because these procedures are not normally performed in residential care facilities, N95 FFRs are not usually required. In order to ensure N95 FFRs are effective, respirator fit-testing is required but how frequently this testing is required is unclear. You are being invited to participate in this research study because we require a group of healthcare staff that do not normally wear N95 FFRs. The goal is to determine if fit-test frequency, amount of respirator education/training and respirator usage affects fit-testing results.

YOUR PARTICIPATION IS VOLUNTARY:
Your participation is entirely voluntary, so it is up to you to decide whether or not to take part in this study. Before you decide, it is important for you to understand what the research involves. This consent form will tell you about the study, why the research is being done, what you will undergo during the study and the possible benefits, risks and discomforts.

If you wish to participate, you will be asked to sign this form. If you do decide to take part in this study, you are still free to withdraw at any time and without giving any reasons for your decision. If you do not wish to participate, you do not have to provide any reason for your decision not to participate.

Please take time to read the following information carefully before you decide.

WHO IS CONDUCTING THE STUDY?
The two co-principal investigators are occupational hygienists – one for Fraser Health, the other for Vancouver Coastal Health. Both are responsible for overseeing the respiratory protection programs of their respective health authorities. The study is being funded by the WorkSafeBC Research Secretariat, which provides funding for scientific studies aimed at improving workplace health and safety issues that are relevant to BC.

BACKGROUND:
Respirator fit-testing must be performed to ensure that the selected respirator provides an effective seal and therefore adequate protection for the user. However, there has been considerable disagreement as to an acceptable frequency for conducting repeat fit-tests, the effect of respirator education/training on knowledge retention, and the influence of usage rates on fit-test results.

WHAT IS THE PURPOSE OF THE STUDY?
There are five objectives of this study. They are to:

1. Determine if there is a significant difference between failure rates associated with annual versus biennial fit-test frequencies for N95 FFRs. The purpose of which is to evaluate the feasibility and level of protection offered by a two-year fit-test frequency.
2. Evaluate the level of N95 FFR donning and doffing skills retained by staff fit-tested on an annual basis only, biennial basis only, or biennial basis but with an annual education component in between fit-tests. The purpose of which is to ascertain the effect of education on knowledge retention and to establish an appropriate refresher training schedule.
3. Assess the fit-test failure rates (both alpha and beta) between the Bitrex™ qualitative method and the PORTACOUNT® quantitative method for N95 FFRs. The purpose of which is to determine which fit-test method results in the fewest number of errors on the respirator models that are used in BC healthcare.
4. Determine the effect of regular usage on fit-test failure rates as well as on the level of donning and doffing skills retained by staff using N95 FFRs. The purpose of which is to determine if regular usage influences the knowledge and skill retention of a respirator user.
5. Ascertain the accuracy of the user seal check compared with a fit-test as a means to predict the level of fit obtained when using N95 FFRs. The purpose of which is to establish the suitability of the user seal check as a surrogate for fit-testing for the respirators used in BC healthcare.

WHO CAN PARTICIPATE IN THE STUDY?
Participation in the study is completely voluntary and all results are confidential. No one other than members of the research team will have access to personal information. Reports will include group information only; it will not be possible to identify individuals from any report.

WHO SHOULD NOT PARTICIPATE IN THE STUDY?
Individuals with pre-existing medical conditions such as COPD, emphysema, and shortness of breath will not be considered for this study, as these conditions are contraindicated for respirator usage.

WHAT DOES THE STUDY INVOLVE?
Overview of the Study
All subjects will be provided with respirator education and training session and a fit-test in Year 1. They will then be divided into five groups according to their subsequent involvement and will be classified as follows:

STUDY GROUPS						
		Year 1		Year 2		Year 3
Group	Setting Selected From	Education/ Training	Fit-Test	Education/ Training	Fit-Test	Fit-Test
1	Extended Care	✓	✓	✓	✓	✓
2	Extended Care	✓	✓	✓		✓
3	Extended Care	✓	✓			✓
4	Extended Care	✓	✓	✓[A]		✓
5	Acute Care	✓	✓	✓	✓	✓

[A] *education/training on an unrelated topic*

Staff members from Extended Care will be randomly assigned into Groups 1, 2, 3, and 4. For Groups 1 and 5, compare fit-test results between Year 1 and Year 2 AND Year 2 and Year 3. Also, we will compare results between Group 1 and Group 5. For Groups 2, 3 and 4, compare fit-test results between Year 1 and Year 3.

If You Decide to Join This Study

- You will be asked to complete: 1) subject information and consent form, 2) a respirator user screening form, 3) a respirator usage questionnaire, and 4) a fit-test form.
- Your weight will be obtained from a scale and pictures of your face will be taken.
- You will be given respirator education/training by watching a video and, subsequently, review an education checklist provided by a research member.
- You will don at least one of the N95 FFR models (1870, 1860 and 1860S) and perform a user seal check to establish a subjectively determined fit.
- Once you have deemed that you achieved a fit, you will undergo a qualitative fit-test using Bitrex®.
- Immediately afterwards, you will undergo a quantitative fit-test using the PortaCount®.

Depending on which group you have been assigned to, you will repeat some or all of the above steps in subsequent years of the study.

TIME REQUIREMENTS

For all groups, the time required per person in Year 1 is approximately 45 minutes. In Year 2, participants in Groups 1 and 5 will need to set aside 45 minutes while those in Groups 2 and 4 will need to allot approximately 15 minutes. In Year 3, the time required per person in all study groups is approximately 20 minutes.

WHAT ARE MY RESPONSIBILITIES?

You should not eat, drink (except water), smoke or chew gum at least 15 minutes prior to your respirator fit-testing appointment. If you are male, you are asked to be clean-shaven at the time of your fit-testing appointment.

WHAT ARE THE POSSIBLE HARMS AND SIDE EFFECTS OF PARTICIPATING?

- If you have never worn a respirator before, you may experience feelings of anxiety, as there is a slight resistance to breathing when wearing a respirator.

- If you do not know if you are claustrophobic, you may experience certain symptoms of claustrophobia while wearing the hood assembly during the fit-testing.
- The fit-test agent, Bitrex®, is extremely bitter. A small percentage of individuals exposed to Bitrex® may experience side effects such as mild irritation to the nose and throat.
- After undergoing a respirator fit-test, some individuals may feel light-headed and have flushed cheeks.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

Although you may not currently require the use of an N95 FFR as part of your normal working day, emergency preparedness plans are leaning towards the use of N95 FFR during a pandemic. By participating in this study, you will have the opportunity to understand how an N95 functions, how to properly don and doff an N95 FFR as well as be fit-tested on an N95 FFR model. Thus, you will have some of the requisite knowledge and skills to protect yourself in case of a pandemic.

CONTACT:

If you have any questions before or during participation, you can contact the following individual *based on your employer*: Fraser Health – Quinn Danyluk at 604-520-4435 or Vancouver Coastal Health – Chun-Yip Hon at 604-822-9757

If you have any concerns about your rights as a research subject and/or your experiences while participating in this study, contact the Research Subject Information Line in the University of British Columbia Office of Research Services at 604-822-8598.

CONSENT TO PARTICIPATE:

I have read and understood the subject information and consent form. I have also had the opportunity to ask questions and have had satisfactory responses to my questions.

My signature below indicates that I have received a copy of this consent form for my own records and indicates that I consent to participate in this study.

Printed name of subject: _____

Signature of subject: _____

Date: _____

Printed name of witness: _____

Signature of witness: _____

Date: _____

APPENDIX C

Respirator Fit-Test Form

fraserhealth

Respirator Fit-Test Record

BACKGROUND INFORMATION (to be completed by staff member)

Site: _____ **Department:** _____

Date: _____

Employee Name (PRINT CLEARLY): _____

Job Title: _____ **Employee Number:** _____

Status: ❑ Full-time ❑ Part-time ❑ Casual ❑ N/A

Do you work at any other sites or departments?: ❑Yes ❑ No *If "Yes", complete the following*

Other Sites: _____

Other Departments: _____

STAFF HEALTH CONDITIONS (to be completed by staff member)

1. Some conditions can affect your ability to safely use a respirator. Do you have any of the following conditions that may affect respirator use? (Check "Yes" or "No" ONLY. Do not specify) *Chronic bronchitis Difficulty breathing Emphysema Other diagnosed lung disease*	❑Yes ❑No
2. Do you have other conditions that may affect respirator use? e.g. facial rash	❑Yes ❑No
3. Have you had previous difficulties using a respirator?	❑Yes ❑No
4. Do you have any concerns about your ability to use a respirator safely?	❑Yes ❑No
5. Have you had an adverse reaction to Bitrex during a previous fit-test?	❑Yes ❑No
6. Do you have any concerns about wearing the fit-test hood (claustrophobia)?	❑Yes ❑No

Answering "Yes" to any of the above questions indicates further assessment

FIT-TEST

	Model	BITREX Sensitivity Test (Number of Squeezes) 10	20	30	Not Sensitive	BITREX Fit-Test Pass	Fail	PORTACOUNT Pass	Fail	Overall Fit Factor	Comments
N95	3M 1860S	❑	❑	❑	❑	❑	❑	❑	❑		
N95	3M 1860	❑	❑	❑	❑	❑	❑	❑	❑		
N95	3M 1870	❑	❑	❑	❑	❑	❑	❑	❑		

Was there any adverse reaction to BITREX?: ❑ Yes ❑ No ❑ N/A

Employee Signature _____

Fit-Tester (Print Name CLEARLY) _____

workplace health

SEE REVERSE FOR COMMENTS

APPENDIX D

Medical Assessment Form

Information to Physicians Regarding Completion of the Respirator User Screening Record Forms

Introduction

The use of a negative pressure respirator increases the resistance to inspiration and adds to the dead space volume[1-3]. Individuals with certain lung diseases, may be restricted in their use of respirators. Even so, Martyny et al (2002) note:

"*The increased work of breathing imposed by a respirator may influence the ability to tolerate its use especially by a person with asthma or emphysema. Nonetheless, most people with lung disease can use a respirator during activity at moderate work loads. Underlying lung disease is not necessarily a contradiction to respirator use.*"

Assessment

There are two forms attached:

1. Respirator Fit-Test From
This form was completed by the staff member and the occupational health and safety department as part of the initial assessment. It contains information on the type, duration, frequency, and intended use of the respirator. Review this form. This form must be returned by the staff member to the Fraser Health facility Safety Consultant.

2. Medical Determination Regarding Respirator Use
This form will be returned by the staff member to the Fraser Health facility Occupational Nurse and/or Occupational Health Physician. Please complete this form. This form will be treated as confidential.

Additional Information

For your reference a copy of the *Martyny et al* article has been provided.

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3. Muhm J.M. (1999) Medical Surveillance for Respirator Users *Journal of Occupational and Environmental Medicine* 41(11): 989-994

To be completed by physician.
CONFIDENTIAL INFORMATION

MEDICAL ASSESSMENT	
Assessment Date:	

Determination	**REASONING (this section is required to be completed)**
❑ **Class 1: NO Restrictions on Respirator Use**	
❑ **Class 2: Some Specific Restrictions Apply**	Has the patient seen a specialist? ❑ Yes ❑ No *If "Yes", please include relevant information.*
❑ **Class 3: Respirator Use is NOT Permitted**	Has the patient seen a specialist? ❑ Yes ❑ No *If "Yes", please include relevant information.*

Additional Comments:	

Name of Physician:		**Physician Signature:**	

Upon completion of this form, please return to Fraser Health staff member for return to his/her appropriate Workplace Health Occupational Health Nurse

Review Article

Current Concepts

Respiratory Protection

John Martyny, Ph.D., Craig S. Glazer, M.D., and Lee S. Newman, M.D.

THE use of anthrax as a biologic weapon in 2001 and concern about the health effects of exposure to particles and gases at the World Trade Center site (discussed by Prezant et al.[1] elsewhere in this issue) have raised awareness of personal respiratory-protection devices — colloquially referred to as "dust masks" or "gas masks." For decades, many people have used respirators on the job or around the home. Federal regulations mandate the use of respirators in a variety of occupational settings if the levels of toxins in the air cannot be effectively controlled. Clinicians need to be aware of their patients' occupational exposures to airborne toxins[2,3] (Table 1) and should be familiar with the common forms of respiratory protection as well as the benefits and limitations of respirator use. No respirator is fully protective.[4] In fact, respirators are a relatively inefficient form of protection.[1] Respirators should be relied on only as a secondary means of protection from airborne toxic materials. Whenever possible, it is better to reduce airborne contamination by using exhaust ventilation, enclosing the process that produces the exposure, adapting work practices to reduce airborne dust and fumes, or replacing toxic materials with safer alternatives.

TYPES OF RESPIRATORY PROTECTION

Respirators are used to protect against a wide variety of airborne toxins, including chemicals, biologic materials, radiation, toxic dusts, and metal fumes (Table 1), and to supply air in situations of low oxygen, such as those encountered by firefighters.[4-9] Few respirators can protect simultaneously against airborne particulates, gases, and vapors. Many different types of respirators are available (Table 2). When clinicians counsel patients to use a respirator, they must know how to select the correct respirator.

Table 1. Examples of Toxic Compounds Commonly Necessitating the Use of Respiratory Protection.

Gases*	Vapors†	Particulates‡
Ammonia	Benzene	Asbestos
Carbon monoxide	Carbon tetrachloride	Beryllium
Chlorine	Mercury	Biologic agents (e.g., *Bacillus anthracis*, *Mycobacterium tuberculosis*, hantavirus)
Ethylene oxide	Nitric acid	
Formaldehyde	Pesticides	
Hydrogen cyanide	Styrene	Cadmium
Hydrogen sulfide	Sulfuric acid	Coal dust
Nitrogen oxides	Toluene	Latex
Sulfur oxides	Trichloroethylene	Radiation (alpha and beta)
		Silica

*A gas is a formless fluid that completely occupies the space of an enclosure at standard atmospheric pressure and temperature.

†A vapor is the gaseous phase of a material that is a liquid or solid at standard atmospheric pressure and temperature.

‡Particulates are particles of microscopic size dispersed in a gaseous medium. They may be a dust (particles 0.1 to 0.50 μm in diameter), a fume (an aerosol formed by volatilization of molten metal), or a mist (an aerosol of suspended liquid droplets).

Respirators can be divided into two types: air-supplying and air-purifying. Depending on the type, they may fit tightly or loosely.[4] In environments where oxygen levels are low, the types and levels of chemicals are unknown, or the conditions are immediately dangerous to life or health, the highest degree of protection is required.[5,10,11] In these situations, the only acceptable type of respiratory protection is a positive-pressure, self-contained breathing apparatus (referred to as an SCBA).[5] This is an air-supplying, tight-fitting type of respirator. Exposure to many forms of dust, on the other hand, may require the use of only a half-face disposable respirator. Some type of respirator is available for use against most potential exposures. The choice of respirator and filter is determined by the expected types and levels of contaminants, the characteristics of the job, and to some extent, individual characteristics, such as the user's facial features and medical fitness to use respiratory protection.[4,5,10-12]

Air-supplying respirators offer the highest degree of protection[5,13] (Fig. 1A). These respirators provide a breathing atmosphere for the wearer and can thus protect against most exposures. They are normally worn by members of hazardous-material ("hazmat")

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TABLE 2. CHARACTERISTICS OF SPECIFIC TYPES OF RESPIRATORS.

CATEGORY AND TYPE OF RESPIRATOR	NIOSH PROTECTION FACTOR*	USE FOR UNKNOWN EXPOSURES AND CONCENTRATIONS	SPECIFIC CARTRIDGES NEEDED	REQUIRED MAINTENANCE LEVEL	INTERFERENCE WITH EYEGLASSES	CAN BE WORN BY PERSONS WITH FACIAL HAIR
Air-supplying						
Positive-pressure, self-contained breathing apparatus	10,000	Yes	No	High	Yes	No
Supplied air (air line)	10–2000†	No‡	No	High	Yes	Yes§
Air-purifying						
Tight-fitting, powered	50	No	Yes	High	Yes	No
Loose-fitting, powered	25	No	Yes	High	No	Yes
Full-face cartridge	50	No	Yes	Moderate	Yes	No
Half-face cartridge	10	No	Yes	Moderate	Maybe	No
Half-face disposable	10	No	No	Low	Maybe	No

The National Institute for Occupational Safety and Health (NIOSH) assigns a numerical, theoretical protection factor to each type of respirator. A respirator with a protection factor of 10, for example, should reduce the concentration of particles or gases inside the respirator to at least 1/10 of the outside concentration.

†The value depends on the type of mask used (e.g., half-face or full-face).

‡The device cannot be used unless a supplemental escape-bottle self-contained breathing apparatus is provided.

§Only a loose-fitting device can be used.

teams and emergency-response crews when dangerous or unknown exposures are likely.[5-7,9] This high degree of protection comes at a cost. A self-contained breathing apparatus is heavy, and its use is limited to less than 30 minutes.[5,7,9] The combination of a sealed protective suit, the extra weight of the tank, high temperatures, and high workload can exact a heavy toll on the wearer's endurance.

Air-purifying respirators are light and easier to use than air-supplying types,[6,7,9] but they afford less protection (Fig. 1B). Air-purifying respirators are the most commonly used and consequently misused type. A variety of filter cartridges can be attached to the inlets of tight-fitting, air-purifying respirators. They may filter particles, or they may contain a medium that absorbs gases and vapors. Although some combination filters can protect against more than one type of hazard, there is no single filter that will work for all exposures under all conditions.

One of the most common errors is the use of the wrong filter. Thus, it is important to establish the potential types and levels of toxins to which the wearer will be exposed in order to ensure that the respirator will provide adequate protection.[6,10,11] Industrial hygienists are usually responsible for selecting the appropriate respirator for a given work environment. It is important for the wearer to know the circumstances in which a given respirator will provide adequate protection.[4,10,11] For example, a filter designed to protect against very small particles and fibers, such as asbestos, may offer no protection against chlorine and other toxic gases. Improper use can result in injury to or the death of the wearer.[14] Even when the filter is the right one, a person using an air-purifying respirator needs to be able to determine when the respirator is no longer working. For this reason, air-purifying respirators should be used only when the hazardous substance has warning properties (such as being an irritant or having a distinctive smell) that will let the wearer know the respirator is failing.[6] For example, when workers can smell or taste solvents, they can assume the respirator is no longer functioning effectively.

Although many air-purifying respirators operate under negative pressure, with the wearer drawing air into the mask through the filter, powered air-purifying respirators are available that blow air into the mask. Although they are more expensive, powered air-purifying respirators eliminate the problems of heat buildup, dead-space ventilation, and airflow resistance. Loose-fitting powered air-purifying respirators can be worn by people with facial hair, are tolerated for longer periods, are more comfortable, and may result in better compliance with respirator use.

Disposable respirators (Fig. 1C) are far more comfortable than the other types of respirators and interfere less with speech. Disposable respirators can be used for a wide variety of exposures, especially airborne particles. They are frequently used by health care workers who may be exposed to mycobacteria or other biologic aerosols.[8,15] The primary limitation of the half-face disposable respirator is the fit.[15] Because of leakage, these and other loose-fitting respirators may not provide the protection necessary for situations involving high levels of exposure, such as those encoun-

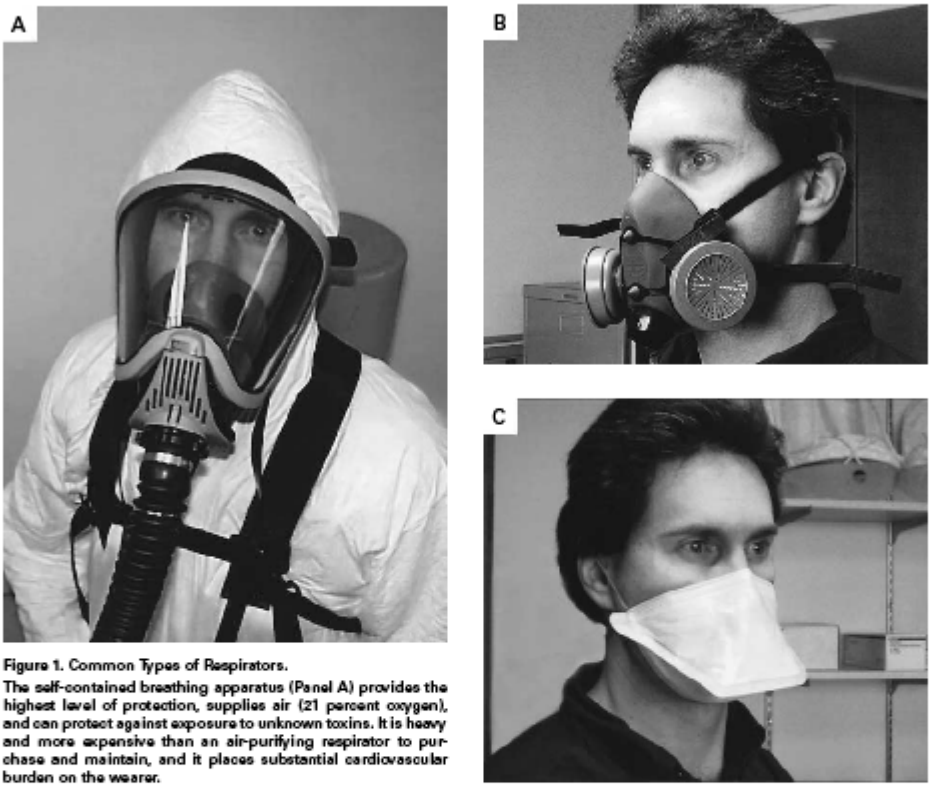

Figure 1. Common Types of Respirators.

The self-contained breathing apparatus (Panel A) provides the highest level of protection, supplies air (21 percent oxygen), and can protect against exposure to unknown toxins. It is heavy and more expensive than an air-purifying respirator to purchase and maintain, and it places substantial cardiovascular burden on the wearer.

The half-face air-purifying respirator (Panel B) has replaceable cartridges that can provide protection from many gases, vapors, and particulates. There is no single cartridge that provides universal protection. This type of respirator does not provide eye protection, and the cartridges must be selected appropriately and replaced frequently.

Half-face disposable respirators (Panel C) are inexpensive and light in weight. They may protect against particles but not against gases or vapors. The efficacy of this type of mask is limited by the difficulty of obtaining an adequate seal against the face.

tered by New York City firefighters during the first week after the collapse of the World Trade Center.[1]

Disposable respirators are manufactured and labeled according to their ability to resist degradation from oil-based liquid aerosols and their efficiency in filtration. The most commonly recommended respirator in the health care setting is the N95: "N" means "not oil-proof," and "95" means that it is at least 95 percent efficient at filtering particles with a median diameter of greater than 0.3 μm. Higher numbers indicate greater filtering efficiency. The N99 respirator, previously called a high-efficiency particulate air-filter respirator, is capable of filtering 99.97 percent of these airborne particulates. A powered air-purifying respirator with a high-efficiency particulate air filter is recommended for use by health care workers during

cough induction and other aerosol-generating procedures in patients with tuberculosis.[15,16]

SELECTION AND USE OF RESPIRATORS

Respirators should be chosen for the protection they provide, not for comfort, although compliance suffers when respirators are uncomfortable. Respirators of all types are unpleasant to wear, especially for an extended period. Noncompliance is one of the major limitations of respirators.[17] Unfortunately, few data are available on the reasons for noncompliance with respirator use. Several studies evaluating the factors associated with a worker's decision whether to use a respirator found that comfort and the ability to talk and see were important.[17-19]

To ensure that the best respirator is chosen, that it is maintained properly, that the workers are trained in how to use it, and that the workers are medically fit to use it, a written respiratory-protection policy should be implemented by the employer.[4-6,8,10,11] This type of program is mandated by the Occupational Safety and Health Administration (OSHA) and should be established even if a workplace is not covered by OSHA regulations.[10] The worker should be fitted with a respirator approved by the National Institute for Occupational Safety and Health that will provide the best protection while allowing the worker to perform necessary tasks.

The choice of respirator and filter can be made with the use of various algorithms available in the literature[4,11] or selection guides provided by the manufacturers. Much, if not all, of the required information can be found on manufacturers' Web sites. These algorithms consider factors such as the type of exposure, job tasks, and oxygen level. The clinician's roles are to identify the need for respiratory protection, assess whether the worker is medically able to use the respirator, and then to refer the worker to qualified sources (see Supplementary Appendix 1 with the text of this article at http://www.nejm.org). Most physicians should not try to select the specific respirator that a patient should use at home or at work unless they have special expertise in occupational health.

After the type of respirator is selected, the user should undergo either qualitative fit-testing (which measures the wearer's ability to detect an irritant or flavorant in an aerosol) or quantitative fit-testing (which measures the number of particles inside, as compared with outside, the respirator) by specially trained technicians to determine which size and brand of respirator fits best. Because most respirators were initially designed for average-sized men, women and persons with unusual facial features may require different respirators.[12] In addition, men with beards or large moustaches will not obtain an adequate fit with any respirator designed to seal against the face.[10] Someone who buys a respirator off the shelf cannot be sure it will provide protection unless it has been properly fit-tested.

Every year people die after donning air-purifying respirators and then entering confined, oxygen-deficient spaces. During the 1991 Gulf War, respirators were distributed to thousands of Israeli civilians. Suffocation from improper mask use was cited as the most direct cause of death in 13 of them.[14] Users must be informed of the limitations of the respirators that they have been assigned as well as when to use them, how to put them on, how to clean and maintain them, how to inspect them for damage, and how to change filters if necessary.[4,6,10,11,20] Simply storing the respirator in the wrong place may negate its usefulness. If a charcoal filter cartridge is left in an area containing solvents, the adsorption capability of the filter will be consumed, even if it is not being worn. For example, home hobbyists may expose filter cartridges to solvents in basements and garages and then wonder why they taste and smell fumes through the mask.

PHYSIOLOGICAL EFFECTS OF RESPIRATORS

Respirators can affect the respiratory, cardiovascular, and musculoskeletal systems. In addition, respirators may compromise vision, communication, and certain motor skills. The tight-fitting, air-purifying type of respirator can substantially increase the work of breathing by increasing the resistance to both inspiratory and expiratory airflow and by increasing dead-space ventilation. The increase in inspiratory resistance is the dominant physiological effect.[21-23] It increases inspiratory time, decreases peak inspiratory flow at moderate workloads, and decreases minute ventilation at high workloads.[24,25] A recent study demonstrated that maximal tolerable workloads decreased in a linear fashion with increasing inspiratory resistance.[24] Increasing the dead space also decreases maximal tolerable workloads in a linear fashion and decreases wearer comfort. However, increasing the dead space does not substantially alter breathing patterns or induce hypoventilation.[26] Tight-fitting, air-purifying respirators do not have substantial cardiovascular effects.[27,28]

A self-contained breathing apparatus significantly increases the heart rate and cardiac work because of its weight.[29] In addition, those using these types of respirators are usually required to wear additional layers of protective clothing that may be heavy and impermeable and may affect temperature regulation. Most respirators can cause small elevations in blood pressure at high work rates.[30]

DETERMINING WHETHER A PERSON CAN USE A RESPIRATOR SAFELY

After performing a basic medical assessment, the clinician is responsible for deciding whether a worker can

safely use a respirator. Ideally, the clinician should know the type and weight of the respirator, the duration and frequency of respirator use, the physical effort required by the job, whether protective clothing or other equipment will be worn, and whether extremes of temperature and humidity may be encountered[10] (Table 3).

Some workers with cardiovascular disease may be unable to perform jobs involving, for example, strenuous work, heat-induced stress, oxygen-deficient or toxic environments, or the use of a self-contained breathing apparatus.[31] If there is uncertainty about a worker's cardiovascular fitness, it may be helpful to administer an exercise test while the worker is wearing the respirator or to allow the person to use the respirator at work on a trial basis, with follow-up assessment.[27,32-34]

The increased work of breathing imposed by a respirator may influence the ability to tolerate its use, especially by a person with asthma or emphysema. Nonetheless, most people with lung disease can use a respirator during activity at moderate workloads.[25,28,35,36] Underlying lung disease is not necessarily a contraindication to respirator use. As Johnson and colleagues showed, anxiety can decrease the maximal tolerable workload to an even greater extent than does the increased work of breathing created by a respirator.[37] A history of inability to tolerate the closed-in sensation of a tight-fitting respirator is a common indicator that a person will have difficulty using the respirator.[38]

Other medical issues must be considered when the environment is immediately dangerous to life or health, so that even brief removal of the respirator could be hazardous. People with chronic productive cough, emesis, or illnesses that may result in loss of consciousness, such as poorly controlled diabetes mellitus or epilepsy, are at potentially greater risk than are people without such conditions in such environments. Other conditions may also prevent workers from tolerating certain types of respirators. For example, the components of the mask touching the face may cause contact dermatitis in some people. Musculoskeletal conditions that produce back pain could prevent the use of a self-contained breathing apparatus.

OSHA requires that "a physician or licensed health-care professional . . . medically evaluate employees to determine under what conditions they can safely wear respirators."[10] Those who perform these evaluations should be sensitive to the implications that certification decisions have for employment and job reassignment. Some workers will lose their jobs if they cannot be medically cleared to use a respirator. OSHA requires the administration of a medical questionnaire or an initial medical evaluation that obtains the same information. Some of the key information required is outlined in Table 3. Other testing is left to the discretion of the health care professional. No specific guidelines regarding clearance are provided. The American Thoracic Society endorses the use of questionnaires,[32] and one recent study confirmed the sensitivity of this approach.[39]

TABLE 3. INFORMATION NEEDED TO DETERMINE FITNESS OF A PERSON TO USE A RESPIRATOR.*

Type and anticipated use of respirator
Frequency and duration of use
Level of physical activity during use
Use of protective clothing or other equipment
Physical stresses in the work environment (e.g., temperature and humidity)
Type and level of exposure to toxic substances during respirator use
Previous experience in using a respirator
Previous difficulty in using a respirator (e.g., eye irritation, rash, anxiety, weakness, and fatigue)
Health factors that may affect fitness to use a respirator†
Smoking status
Conditions that could affect safety in dangerous environments (e.g., seizures, diabetes, claustrophobia, and anosmia)
Pulmonary disorders (e.g., chronic obstructive pulmonary disease, severe asthma, and interstitial lung disease)
Cardiovascular disorders (e.g., atherosclerosis and arrhythmias)
Dermatologic disorders (e.g., facial scarring, latex hypersensitivity, and pseudofolliculitis barbae requiring beard growth that impairs fit)
Visual acuity and need for eyeglasses‡
Musculoskeletal conditions (especially back injury and back pain) and fitness (e.g., range of motion, ability to climb, and ability to lift more than 25 lb [11 kg])‡

*Adapted from Occupational Safety and Health Administration standard 29 CFR Part 1910.134.[10]

†Medical conditions do not necessarily disqualify workers from respirator use.

‡This information must be obtained from a person who expects to use a full-face respirator or self-contained breathing apparatus.

The physical examination and further medical testing are performed at the discretion of the physician. Examinations are recommended if specific symptoms are elicited on the questionnaire. Spirometry or exercise testing may be helpful for anyone with symptoms consistent with the presence of cardiopulmonary disease.[32] Regular follow-up after certification, with repeated medical clearance and repeated assessment of the fit of the respirator, is recommended[32] and in some circumstances required[10] by federal regulations. Recommended criteria for certification have been proposed.[27,32,34] Most experts agree that a person who is medically qualified to perform a job without a respirator will usually be able to perform the same job safely with a respirator.[27,32-34,40] Therefore, it is not surprising that more than 95 percent of workers referred for medical clearance to wear a respirator do not have substantial contraindications.[38,39]

When evaluating a worker for the use of a respirator, the clinician should be cognizant of the need for

TABLE 4. RECOMMENDATIONS FOR THE RESPIRATOR USER.

Consider your environment
Know the hazards that you will encounter and when to use a respirator.
If workers around you are required to wear respirators, you should probably also wear one.
Never wear an air-purifying respirator in conditions of low oxygen levels or during exposure to highly toxic substances.
If you are choosing your own respirator for home use, read the directions and understand its limitations.
If you can taste, smell, or feel the toxin, the respirator is not protective.
Wear respirators correctly
If an employer requires the use of a respirator, make certain that a written respiratory-protection program complying with the requirements of the Occupational Safety and Health Administration is in place.
Test the fit of your respirator to determine whether it is the appropriate size and model.*
When you put your respirator on, test both the inhalation and the exhalation valves.
Do not alter the respirator in any way (e.g., do not mix brands of cartridges and do not use petroleum jelly or cotton along the edge of the mask).
Remember that eyeglasses, eyebrow piercings, beards, or other objects that break the seal of the respirator will substantially lower its protection factor.
Do not remove or loosen your respirator when you are working in a contaminated atmosphere.
Maintain the equipment
Store respirators and cartridges in clean, protected environments.
Change respirator cartridges regularly.

*Supplementary Appendix 1 (available with the full text of this article at http://www.nejm.org) lists organizations that can conduct or arrange for fit-testing.

confidentiality. The health care provider is required to inform both the employer and employee in writing whether the employee is able to use a respirator, whether there are any limitations on its use, and whether further medical evaluation is recommended. Because of patient confidentiality, the employer should not be provided with the specific medical reasons for the decision.

When there are no other practical and immediate means of protection against airborne hazards, respirators can save lives, but only if there has been appropriate attention to respirator selection, training on respirator use (Table 4), and medical evaluation. Even in the best of circumstances, the respirator only adds a margin of safety and cannot guarantee complete protection. It is, at best, a secondary preventive measure. Efforts by workers, industry, labor, and government to control environmental and occupational hazards must continue to be the primary preventive strategy.

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POSTING PRESENTATIONS AT MEDICAL MEETINGS ON THE INTERNET

Posting an audio recording of an oral presentation at a medical meeting on the Internet, with selected slides from the presentation, will not be considered prior publication. This will allow students and physicians who are unable to attend the meeting to hear the presentation and view the slides. If there are any questions about this policy, authors should feel free to call the *Journal*'s Editorial Offices.

APPENDIX E

N95 FFR Usage Questionnaire

N95 FILTERING FACEPIECE RESPIRATOR USAGE QUESTIONNAIRE

Thank you for agreeing to participate in the research entitled "**Strengthening N95 Filtering Facepiece Respirator Protection Programs by Evaluating the Contribution of Each of the Program Elements**". The purpose of this document is to ask you to record the frequency with which you use an N95 respirator on a monthly basis. This relates only to those instances when you use the N95 filtering facepiece respirator (N95 FFR) to protect yourself from airborne hazards and does not include usage by patient or their families. If you have any questions about this form, please contact one of the study's Co-Principal Investigators. If you work for Fraser Health, call Quinn Danyluk at 604-412-6105; if you work for Vancouver Coastal Health, call Chun-Yip Hon at 604-822-9757.

Name: _____

Staff ID Number: _____

Primary Department: _____

Do you work in other departments? If yes, please list: _____

_____

Do you work in other health authorities? If yes, please list: _____

Status: F/T P/T Casual

YEAR 1	**MONTH #**											
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
N95 FFR usage per month												

After Year 1, please fax document to 604.431.2896 and retain for duration of project

YEAR 2	**MONTH #**											
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
N95 FFR usage per month												

After Year 2, please fax document to 604.431.2896 and provide original to research team member at your final fit-testing session related to the project.

For research team only: Assigned Study Group 1 2 3 4

APPENDIX F

N95 FFR Education Checklist

N95 FILTERING FACEPIECE RESPIRATOR FIT-TEST SESSION EDUCATION CHECKLIST

Question	Correct Answer	Answer Correct?		Follow-up Answer Correct?	
		Yes	No	Yes	No
The difference between an N95 filtering facepiece respirator (N95 FFR) and a surgical mask is that a FFR is designed & certified to protect the wearer from certain contaminants in the atmosphere, whereas a surgical mask is designed to protect the patient from the wearer	True	❑	❑	❑	❑
An N95 FFR will provide protection against gas or vapour hazard.	False (*It won't*)	❑	❑	❑	❑
Some N95 FFR models are better than others in terms of protective ability of the material.	False (*There is no difference in protection*)	❑	❑	❑	❑
Types of situations that would require an N95 FFR include Airborne Isolation Precautions and protection against particulates including bacteria and viruses.	True	❑	❑	❑	❑
An N95 FFR can be used more than once.	False. (*An N95 FFR must be used only once, then disposed of*)	❑	❑	❑	❑
N95 FFRs are latex-free.	True	❑	❑	❑	❑
A fit test is a test to ensure that an N95 FFR provides an adequate facial seal with the face.	True	❑	❑	❑	❑
A fit test is required to be performed at least once a week.	False (*Annually*)	❑	❑	❑	❑

APPENDIX G

Process for Calculating kappa

The data is summarized in a table as follows:

	Pass Portacount	Fail Portacount
Pass Bitrex	A	B
Fail Bitrex	C	D

The observed proportion of concordant fit-tests (P_o) is calculated as follows:

$$P_o = \frac{A + D}{A + B + C + D}$$

The expected proportion of concordant fit-tests (P_e) is calculated as follows:

$$P_e = \frac{(A + B)(A + C) + (C + D)(B + D)}{(A + B + C + D)^2}$$

κ is calculated as follows:

$$\kappa = \frac{(P_o - P_e)}{(1 - P_e)}$$

APPENDIX H

Sample calculation illustrating adjustment of data to account for fit-test method error

Using the 3M 1860 raw data as an example (as shown in Table VIIa), the following is the fit-test outcomes found:

	Pass Portacount	Fail Portacount
Pass Bitrex	126	48
Fail Bitrex	8	70

n=252

According to the results of Coffey et al[18], this data should be adjusted to account for errors associated with both the Bitrex or Portacount fit-test methods i.e. participants who failed or passed in error.

To begin with, let's consider adjusting for the beta error rates suggested by Coffey et al (8% for Bitrex and 6% for the Portacount). First, let us adjust the raw data for the Bitrex beta error. The "Pass Bitrex" row needs to be adjusted. Of the 126 individuals that passed Bitrex and Portacount, 10 individuals (i.e. 126 x 8%) should have failed Bitrex (still in the "Pass Portacount" column). Of the 48 individuals who passed Bitrex and failed Portacount, 4 should have failed Bitrex (still in the "Fail Portacount" column). After adjusting for the Bitrex beta error, the results would look like the following:

	Pass Portacount	Fail Portacount
Pass Bitrex	116	44
Fail Bitrex	18	74

n=252

A similar adjustment can be made to account for the Portacount beta error of 6%. Of the 116 individuals that passed Portacount and Bitrex, 7 individuals should have failed Portacount (still in the "Pass Bitrex" column). Of the 18 individuals who passed Portacount and failed Bitrex, 1

should have failed Portacount (still in the "Fail Bitrex" column). After adjusting for the Portacount beta error the results would look like the following:

	Pass Portacount	Fail Portacount
Pass Bitrex	109	51
Fail Bitrex	17	75

n=252

The net change for each of the outcomes can be calculated. Comparing the original data to the adjusted data, the following are the net changes for each outcome:

	Pass Portacount	Fail Portacount
Pass Bitrex	-17	+3
Fail Bitrex	+9	+5

We can now adjust the data to account for the alpha errors determined by Coffey et al (65% for Bitrex and 58% for the Portacount. We would want to start with the raw data in determining the adjustments required rather than using the adjustments for the beta error we just made. Starting with the raw data:

	Pass Portacount	Fail Portacount
Pass Bitrex	126	48
Fail Bitrex	8	70

n=252

To begin with, let's consider adjusting for the alpha error rates suggested by Coffey et al (65% for Bitrex and 58% for the Portacount). First, let us adjust the raw data for the Bitrex alpha error. The "Fail Bitrex" row needs to be adjusted. Of the 8 individuals that failed Bitrex and Portacount, 5 individuals should have passed Bitrex (still in the "Pass Portacount" column). Of the 70 individuals who failed Bitrex and failed Portacount, 46 should have passed Bitrex (still in

the “Fail Portacount” column). After adjusting for the Bitrex alpha error, the results would look like the following:

	Pass Portacount	Fail Portacount
Pass Bitrex	131	94
Fail Bitrex	3	24

n=252

A similar adjustment can be made to account for the Portacount alpha error of 58%. Of the 24 individuals that failed Portacount and Bitrex, 14 individuals should have failed Portacount (still in the “Fail Bitrex” row). Of the 94 individuals who failed Portacount and passed Bitrex, 55 should have passed Portacount (still in the “Pass Bitrex” row). After adjusting for the Portacount alpa error the results would look like the following:

	Pass Portacount	Fail Portacount
Pass Bitrex	186	39
Fail Bitrex	17	10

n=252

The net change for each of the outcomes can be calculated. Comparing the original data to the adjusted data, the following are the net changes for each outcome:

	Pass Portacount	Fail Portacount
Pass Bitrex	+60	-9
Fail Bitrex	+9	-60

We can now add the alpha and beta net adjustments together to get a total adjustment required:

	Pass Portacount	Fail Portacount
Pass Bitrex	-17 +60	+3 -9
Fail Bitrex	+9 +9	+5 -60

The total adjustment, combining the alpha and beta error, results in:

	Pass Portacount	Fail Portacount
Pass Bitrex	+43	-6
Fail Bitrex	+18	-55

Going back to the raw data and making these adjustments:

	Pass Portacount	Fail Portacount
Pass Bitrex	126 +43	48 -6
Fail Bitrex	8 +18	70 -55

n=252

Results in the following for the 3M 1860 model.

	Pass Portacount	Fail Portacount
Pass Bitrex	169	42
Fail Bitrex	26	15

n=252

APPENDIX I

Calculations for adjusting fit-test year data to account for fit-test method error

In Year 1, as previously stated, we made the assumption that there was no error associated with either the Bitrex or Portacount fit-test methods and no participant who passed both of these methods in Year 1 (and was subsequently enrolled in the study) actually passed in error. There were 341 participants who remained until Year 3 and if we were to look at the Year 1 results for these individuals, they all passed on both the Portacount and Bitrex methods.

	Pass Portacount	Fail Portacount
Pass Bitrex	341	0
Fail Bitrex	0	0

n=341

However, from the values determined by Coffey et al, the beta error (chance of passing a fit-test in error) for the Bitrex method is 8% and for the Portacount method is 6%. If these values are true, of this cohort from Year 1, adjusting the data to identify those who should have in fact failed one or both of the fit-test methods results in the following breakdown:

	Pass Portacount	Fail Portacount
Pass Bitrex	295	19
Fail Bitrex	25	2

n=341

Another way to look at this is that there were participants who may have passed in error. In subsequent fit-tests (e.g. in Year 3), these individuals are more likely to be "correctly" identified through the fit-test process and move in to the "fail" category. This is not a reflection of any change in fitting characteristic or ability but simply the result of chance.

Those individuals identified as fails in Year 1 should be removed from the process since they shouldn't have made it through from Year 1 (i.e. they passed in error). In Year 3, our raw data was as follows:

	Pass Portacount	Fail Portacount
Pass Bitrex	127	72-19
Fail Bitrex	27-25	115-2

n=341

Removing those identified as fails in our adjusted data results in the following:

	Pass Portacount	Fail Portacount
Pass Bitrex	127	53
Fail Bitrex	2	113

n=295

At this point, we need to consider the alpha error (we can ignore the beta error since we have already adjusted for those who would have failed in error from the Year 1 data). Let us first consider the alpha errors (chance of failing in error) which Coffey et al determined to be 65% and 58% for the Bitrex and Portacount methods, respectively. Adjusting the data accordingly results in the following:

	Pass Portacount	Fail Portacount
Pass Bitrex	201	53
Fail Bitrex	24	17

n=295

The overall agreement between the two methods is now 74% ((201+17)/(295)).

The data from Year 2 can be adjusted in a similar manner and yields the following, with an 87% agreement between the two methods:

	Pass Portacount	Fail Portacount
Pass Bitrex	94	10
Fail Bitrex	5	3

n=112

The adjusted data therefore shows agreement between the two methods changing substantially over time as well: 100% in Year 1, 87% in Year 2, and 74% in Year 3. (compare with the raw data here)

TABLES

Table I: Participant Study Groups						
		Year 1		Year 2		Year 3
Group	Setting Selected From	Education/ Training	Fit-Test	Education/ Training	Fit-Test	Fit-Test
1	Residential Care	✓	✓	✓	✓	✓
2	Residential Care	✓	✓	✓		✓
3	Residential Care	✓	✓			✓
4	Acute Care	✓	✓	✓	✓	✓

Table II: Summary of Comparative Analyses Used to Assess Stated Objective	
Objective	**Description of comparison**
1	Compare the outcomes between the qualitative (i.e. Bitrex) and quantitative (i.e. Portacount) fit-testing methods.
2	Determine if there is a significant difference between failure rates associated with annual versus biennial fit-test frequencies for N95 FFRs commonly used in healthcare. (Compare fit-test pass rates in Year 3 between Group 1 and 3).
3	Evaluate the level of N95 FFR donning skills retained by staff that are fit-tested on an annual basis only, biennial basis only, or biennial basis but with an annual education component in between fit-tests. (Compare fit-test pass rates in Year 3 between Group 1, 2, and 3 (with Group 1 serving as the control)).
4	Determine the effect of regular usage on fit-test failure rates as well as on the level of donning and doffing skills retained by staff using N95 FFRs. (Compare fit-test pass rates in Year 3 between Group 1 and 4).
5	Evaluate the applicability of a user seal check as a surrogate for a fit-test in determining an adequate fit on an N95 FFR.

Table III: Information and Documentation Collected	
Item	**Description**
Respirator User Health Screening	Used to ascertain if there are any medical complications which could affect the user's ability to wear a respirator. This was developed as per requirements in the CSA Standard as well as in consultation with a Fraser Health Occupational Physician. See Appendix C.
Medical Assessment Form	To be completed if the participant requires physician assessment based on the Respirator User Health Screening (above). See Appendix D.
Respirator Fit-Test Form	Collects the required fit-test information to be documented as per the CSA Standard. See Appendix C.
N95 FFR Usage Questionnaire	Utilized to determine frequency of N95 usage by a subject for the duration of the study. See Appendix E.
Weight and Photo of Participant's Face	Changes in weight can affect respirator fit. In order to ensure that failures on subsequent fit-tests are not the result of changes in weight, the participant's weight will be collected during each fit-test session. Also, two orthogonal view photos of the participant's face will be taken at the time of each fit-test. These photos will be reviewed by the research team only if there are future fit-test failures during the study which cannot be accounted for.

Table IV: Job Titles of Participants in each of the three study groups in Year 3

Job Title	Study Group			End of Study Total (Year 3)
	1	2	3	
Accountant	0	1	0	1
Assisted Living Manager	0	0	2	2
Care Aide	63	50	88	201
Director of Care	0	1	5	6
Housekeeping	4	2	1	7
Housekeeping Supervisor	1	0	0	1
LPN	12	14	14	40
Music Therapist	0	0	1	1
Recreational Therapist	3	2	1	6
RN Residential Care Coordinator	1	3	2	6
RN	6	10	12	28
RPN	0	0	1	1
Social Worker	0	3	1	4
Unit Clerk	1	0	2	3
			Total	**307**

Table V: Number of Study Participants by year

	Group 1	Group 2	Group 3	Group 4	Total Number of Participants
Year 1	153	151	252	118	674
Year 2	121	124	-	57	302
Year 3	91	86	130	40	347
Total Loss to Follow-up (Year 1 to 3)	62 (41%)	65 (43%)	122 (48%)	78 (66%)	327 (49%)

Table VI: Summary of reasons and numbers of those loss for follow-up						
Reasons	**Acute Care**			**Residential Care**		
	Year 2	*Year3*	*Total*	*Year 2*	*Year 3*	Total
Left Department	17	1	18	65	67	132
Left Department – Retired	1	0	1	0	9	9
Left Department – Student	3	0	3	0	0	0
Not available during follow – up	7	9	16	0	29	29
Casual	9	1	10	0	21	21
Long Term Disability	1	0	1	0	16	16
Leave of Absence (LOA)	6	0	6	0	3	3
Education leave	0	0	0	0	3	3
Maternity leave	1	1	2	0	4	4
Refused – No reason given	3	0	3	2	16	16
Refused – Fit tested by others	10	0	10	0	0	0
Refused – Claims Bitrex made sick	0	0	0	0	4	4
Refused – Pregnant	1	0	1	0	2	2
Refused – Sick	0	0	0	0	1	1
On Sick Leave	3	0	3	0	4	4
Breathing difficulties	0	0	0	0	1	1
Not Clean Shaven	0	4	4	0	0	0
Wrong N95FFR	0	1	1	0	3	3
Total	**61**	**17**	**79**	**67**	**183**	**248**

Table VII: Summary of Weight Change from Year 1 to Year 3

Weight Change from Year 1	**Group 1 n = 87**	**Group 2 n = 83**	**Group 3 n = 123**	**Group 4 n = 37**
< ±10%	78 (90%)	72 (87%)	112 (91%)	32 (86%)
≥+10%	5 (6%)	6 (7%)	6 (5%)	4 (11 %)
≤-10%	4 (4%)	5 (6%)	5 (4%)	1 (3%)

Table VIIIa: Effect of Respirator Model on Fit-Test Outcome – 3M 1860 (Raw Data)

	Pass Portacount	Fail Portacount
Pass Bitrex	126	48
Fail Bitrex	8	70

n=252

Table VIIIb: Effect of Respirator Model on Fit-Test Outcome – 3M 1860S (Raw Data)

	Pass Portacount	Fail Portacount
Pass Bitrex	471	96
Fail Bitrex	23	108

n=698

Table VIIIc: Effect of Respirator Model on Fit-Test Outcome – 3M 1870 (Raw Data)

	Pass Portacount	Fail Portacount
Pass Bitrex	301	88
Fail Bitrex	13	146

n=548

Table IXa: Effect of Respirator Model on Fit-Test Outcome – 3M 1860 (Adjusted Data)

	Pass Portacount	Fail Portacount
Pass Bitrex	169	42
Fail Bitrex	26	15

n=252

Table IXb: Effect of Respirator Model on Fit-Test Outcome – 3M 1860S (Adjusted Data)

	Pass Portacount	Fail Portacount
Pass Bitrex	518	88
Fail Bitrex	64	28

n=698

Table IXc: Effect of Respirator Model on Fit-Test Outcome – 3M 1870 (Adjusted Data)

	Pass Portacount	Fail Portacount
Pass Bitrex	374	87
Fail Bitrex	57	30

n=548

Table Xa: Effect of Fit-Test Method Order on Outcome - Bitrex Followed by Portacount (Raw Data)

	Pass Portacount	Fail Portacount
Pass Bitrex	611	169
Fail Bitrex	28	194

n=1002

Table Xb: Effect of Fit-Test Method Order on Outcome – Portacount Followed by Bitrex (Raw Data)

	Pass Portacount	Fail Portacount
Pass Bitrex	287	62
Fail Bitrex	16	130

n=496

Table XIa: Effect of Fit-Test Method Order on Outcome - Bitrex Followed by Portacount (Adjusted Data)

	Pass Portacount	Fail Portacount
Pass Bitrex	717	144
Fail Bitrex	93	48

n=1002

Table XIb: Effect of Fit-Test Method Order on Outcome – Portacount Followed by Bitrex (Adjusted Data)

	Pass Portacount	Fail Portacount
Pass Bitrex	343	73
Fail Bitrex	53	26

n=495

Table XIIa: Effect of Fit-Test Year on Fit-Test Outcome – Year 1 (Longitudinal Raw Data)

	Pass Portacount	Fail Portacount
Pass Bitrex	341	0
Fail Bitrex	0	0

n=341

Table XIIb: Effect of Fit-Test Year on Fit-Test Outcome – Year 2 (Longitudinal Raw Data)

	Pass Portacount	Fail Portacount
Pass Bitrex	79	17
Fail Bitrex	7	24

n=127

Table XIIc: Effect of Fit-Test Year on Fit-Test Outcome – Year 3 (Longitudinal Raw Data)

	Pass Portacount	Fail Portacount
Pass Bitrex	127	72
Fail Bitrex	27	115

n=341

Table XIIIa: Effect of Fit-Test Year on Fit-Test Outcome – Year 2 (Longitudinal Adjusted Data)

	Pass Portacount	Fail Portacount
Pass Bitrex	94	10
Fail Bitrex	5	3

n=112

Table XIIIb: Effect of Fit-Test Year on Fit-Test Outcome – Year 3 (Longitudinal Adjusted Data)

	Pass Portacount	Fail Portacount
Pass Bitrex	201	53
Fail Bitrex	24	17

n=295

Table XIVa: Overall Comparison of Fit-Test Outcomes by Fit-Test Method (Raw Data)

	Pass Portacount	Fail Portacount
Pass Bitrex	898	232
Fail Bitrex	44	324

n=1,498

Table XIVb: Overall Comparison of Fit-Test Outcomes by Fit-Test Method (Adjusted Data)

	Pass Portacount	Fail Portacount
Pass Bitrex	1244	101
Fail Bitrex	132	21

n=1,498

Table XV: Longitudinal Pass Rates For Each Group (Raw Data)

Group	Fit-Test Method	Year 2	Year 3
Group 1 Education & Fit-Testing in Year 2 n = 91	Pass Bitrex	71 (78%)	50 (56%)
	Pass Portacount	65 (71%)	37 (41%)
Group 2 Education only in Year 2 n = 86	Pass Bitrex	N/A	49 (57%)
	Pass Portacount	N/A	37 (43%)
Group 3 No Intervention in Year 2 n = 130	Pass Bitrex	N/A	72 (56%)
	Pass Portacount	N/A	56 (43%)
Group 4 (Acute Care) Education & Fit-Testing in Year 2 n = 36	Pass Bitrex	25 (69%)	29 (81%)
	Pass Portacount	21 (58%)	26 (72%)

Table XVI: Longitudinal Pass Rates For Each Group (Adjusted Data)

Group	Fit-Test Method	Year 2	Year 3
Group 1 Education & Fit-Testing in Year 2 n=84 (Bitrex); n=86 (Portacount)	Pass Bitrex	73 (88%)	68 (81%)
	Pass Portacount	73 (85%)	63 (73%)
Group 2 Education only in Year 2 n=79 (Bitrex); n=81 (Portacount)	Pass Bitrex	N/A	65 (82%)
	Pass Portacount	N/A	61 (75%)
Group 3 No Intervention in Year 2 n=120 (Bitrex); n=122 (Portacount)	Pass Bitrex	N/A	97 (81%)
	Pass Portacount	N/A	91 (75%)
Group 4 (Acute Care) Education & Fit-Testing in Year 2 n=33 (Bitrex); n=34 (Portacount)	Pass Bitrex	28 (85%)	30 (91%)
	Pass Portacount	28 (82%)	29 (85%)

Table XVII: Median Average Yearly Use of N95 FFRs of Group 4 Subjects (Acute Care)

Job Title	Median Average Yearly Use Year 2	Median Average Yearly Use Year 3
Care Aide	24	Not Available
Emergency Room Attendant	12	3
Licensed Practical Nurse	12	10
Manager	0	Not Available
Registered Nurse	30	10
Respiratory Therapist	144	144
Respiratory Equipment Tech	2	0
Respiratory Operations Coordinator	144	0
Unit Clerk	0	Not Available

Table XVIII: Bitex and Portacount Fit-Test Outcomes (n=780)

Study Group	Fit-Test Method	Fit-Test Outcome	
		Pass	Fail
Naive (n=643)	Portacount	485 (75%)	158(25 %)
	Bitrex	551 (86%)	92 (14%)
Experienced (n=137)	Portacount	96 (70%)	41 (30%)
	Bitrex	107 (78%)	30 (22%)