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Comparison of qualitative and quantitative fit-testing results for three commonly used respirators in the healthcare sector

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ABSTRACT

N95 filtering facepiece respirators are used by healthcare workers when there is a risk of exposure to airborne hazards during aerosol-generating procedures. Respirator fit-testing is required prior to use to ensure that the selected respirator provides an adequate face seal. Two common fit-test methods can be employed: qualitative fit-test (QLFT) or quantitative fit-test (QNFT). Respiratory protection standards deem both fit-tests to be acceptable. However, previous studies have indicated that fit-test results may differ between QLFT and QNFT and that the outcomes may also be influenced by the type of respirator model. The aim of this study was to determine if there is a difference in fit-test outcomes with our suite of respirators, 3M - 1860S, 1860, AND 1870, and whether the model impacts the fit-test results.

Subjects were recruited from residential care facilities. Each participant was assigned a respirator and underwent sequential QLFT and QNFT fit-tests and the results (either pass or fail) were recorded. To ascertain the degree of agreement between the two fit-tests, a Kappa (K) statistic was conducted as per the American National Standards Institute (ANSI) respiratory protection standard. The pass-fail rates were stratified by respirator model and a Kappa statistic was calculated for each to determine effect of model on fit-test outcomes.

We had 619 participants and the aggregate K statistic for all respirators was 0.63 which is below the suggested ANSI threshold of 0.70. There was no statistically significant difference in results when stratified by respirator model.

QNFT and QLFT produced different fit-test outcomes for the three respirator models examined. The disagreement in outcomes between the two fit-test methods with our suite of N95 filtering facepiece respirators was approximately 12%. Our findings may benefit other healthcare organizations that use these three respirators.

KEYWORDS

Healthcare workers; Kappa statistic; N95 filtering facepiece respirator; respirator fit-testing

Introduction

Exposure to airborne pathogens is one of many occupational hazards faced by healthcare workers. To minimize the risk of exposure, the use of an N95 filtering facepiece respirator (FFR) is recommended during aerosol-generating procedures, e.g., intubation and/or caring for a patient with a known or suspected respiratory illness such as tuberculosis or varicella (chickenpox).[1] To ensure that the respirator provides an adequate face seal, the user must undergo a "fit-test."[2] Respirator fit-testing, as well as training (i.e., conditions of use, the respirator limitations, how to don/doff appropriately, etc.), form part of a necessary and important requirement of an effective respiratory protection program.[3–5]

There are two common fit-testing methods available for N95 FFRs: a qualitative fit-test (QLFT) or a quantitative fit-test (QNFT). A QLFT establishes whether the respirator wearer can detect an extremely bitter (Bitrex) or sweet (saccharin) taste while performing a series of simulated work exercises such as talking, turning their head side-to-side, etc. If the wearer can detect the taste agent at any time during these exercises, the respirator

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is not providing an adequate seal. A QNFT measures the ratio of ambient aerosols outside and inside the respirator while the wearer performs the same simulated exercises as for the QLFT. This ratio must exceed a certain threshold value, typically ≥100 for N95 FFRs, in order for the respirator to be deemed a proper fit for the wearer. In North America, the specific procedures for respirator fit-testing can be found in the respiratory protection standard developed by the Canadian Standards Association (CSA),[6] which is often prescribed in Canadian occupational health and safety legislation, or in Appendix A of the Occupational Safety & Health Administration's (OSHA) Standard 1910.134.[7]

It is at the discretion of a workplace as to which fit-testing method shall be used as neither legislation nor health and safety agencies have recommended or specified a standard fit-testing method.[8] Theoretically, the two fit-test methods should produce similar outcomes. In British Columbia's Fraser Health Authority (FHA) alone, approximately 8,000 healthcare workers need to be fit-tested on N95 FFRs annually. Given the large number of workers who require a properly fitting respirator, we wanted to determine if the QLFT and QNFT methods have comparable results with the respirators that we have selected for use within our organization (3M - 1860S, 1860, and 1870). To accurately compare results between the two test methods, we performed sequential fit-tests on each subject without removing the respirator in between tests. In addition, we aimed to ascertain if there was a difference in outcomes based on the respirator model, which has been reported previously using other respirators[9] but has not been established for our suite of N95 FFRs.

Methods

Subject recruitment

Ethics approval for the study was obtained from relevant institutional ethics boards prior to the start of the study. Participants were recruited from 24 residential care facilities located in the Metro Vancouver area of British Columbia, Canada. At the time of the study, workers at these facilities were not required to use N95 FFRs; therefore, any bias (i.e., improved fit-test pass rates) associated with previous experience with fit-testing or wearing a respirator was minimized.[8,10,11]

Group presentations were delivered to participating facilities and, subsequently, workers interested in participating volunteered to be enrolled in the study. Details regarding subject selection and the fit-testing methods used are described in an earlier publication;[12] brief overviews of each are presented below.

Fit-testing methods

Participants were initially educated regarding respirators as per CSA Z94.4-02 "Selection, Use and Care of Respirators."[6] Next, each participant underwent a sensitivity taste test using the 3M FT-30 Qualitative Bitter Fit Test Apparatus (Bitrex) (London, ON). If the participant could detect the taste agent, then the qualified fit-tester would assign a participant to one of three N95 FFR models based on professional judgment (i.e., experience with different facial shapes and sizes): 3M health care particulate respirator and surgical mask 1860S (3M 1860S), 3M health care particulate respirator and surgical mask 1860 (3M 1860), and 3M healthcare particulate respirator and surgical mask 1870 (3M 1870) (London, ON). (Note that participants were pre-screened to be medically fit prior to being fit-tested.) These three respirator models were chosen as they are designed specifically for use in healthcare and all three have a mouldable nosepiece to facilitate obtaining a seal to the face. The participant was then shown how to perform a user seal check, a self-administered test to determine if the respirator is properly sealed to the wearer's face, and then asked to perform one. The user seal check procedure can be found in an online video developed by the manufacturer, 3M (https://www.youtube.com/watch?v = W6__Xv7Dvz8).

If the respirator wearer subjectively deemed that their fit was satisfactory following the user seal check, the participant then underwent both a QLFT using the Bitrex method and a QNFT using the TSI Portacount Plus Respirator Fit Tester Model 8020 with a TSI N95-Companion Model 8095 (Shoreview, MN). The two fit-test methods were performed sequentially without the participant removing the N95 FFR between methods. This served to facilitate the accurate comparison of the QLFT and QNFT results on the same donning of a respirator model.[13] The order of the fit-test method was alternated between participants. (Note that the grimace step required by OSHA in 1910.134 for quantitative fit tests was not performed.)

To perform sequential fit-tests, a Portacount probe was inserted into the facepiece before the N95 FFR was donned. A short piece of tubing was then connected to the probe with a tubing adaptor connected to the other exposed end. When the initial fit-test was a QNFT, the tubing from the Portacount was connected to the adaptor. Following the QNFT and prior to the QLFT, a cap was carefully placed over the adaptor to seal it without altering the face seal. The probe was positioned on the respirator facepiece such that it would not interfere with the fit-testing hood; this was done on an individual basis based on the facial characteristics of each subject. When the initial fit-test was a QLFT, the probe was capped for the test and then removed for the subsequent QNFT using

the Portacount as described above. All fit-tests were performed by the same qualified fit-tester.

If the user detected the bitter test (Bitrex) agent during any of the exercises of the QLFT, the fit-test was unsuccessful. A QNFT was successful if the individual's overall fit factor (ratio of outer aerosols vs. inner aerosols) met or exceeded 100.

Data analysis

The QLFT fail-pass results and the QNFT pass-fail results were tabulated into a 2 × 2 contingency table and the nomenclature for each quadrant was as follows: A — passed both fit-test methods; B — passed the QNFT but failed the QLFT; C — passed the QLFT but failed the QNFT; and D — failed both fit-test methods. A QLFT failed if the user was able to detect the test agent during one of the exercises while wearing an N95 FFR. A QNFT failed if user was unable to achieve an overall fit-factor of at least 100 while wearing an N95 FFR.

To determine the degree of agreement between the two fi-tests, a Kappa (K) statistic was calculated as per ANSI Z188.10.[14] ANSI has recommended that a K value greater than 0.70 suggests agreement between two fit-tests.[14]

To determine the effect of respirator model on fit-test outcomes, 2 × 2 fit-test pass-fail tables were produced for each of the three N95 FFRs. Subsequently, the 95% confidence interval for each K of the three respirator models was calculated and compared to determine if there was any overlap. No overlap in the confidence intervals indicates that there is a statistically significant difference in fit-test outcomes between the N95 FFRs. All statistical analyses were performed using SAS 9.4 (Cary, NC).

Results

Summary statistics

In total, 619 healthcare workers agreed to participate, 90% of whom were female. Five individuals were excluded at screening because they could not achieve a suitable seal following the user seal check (n = 4) or were insensitive to the QLFT bitter taste agent (n = 1). Of the three N95 FFR models employed in this study, 77 participants were fitted with a 3M 1860, 335 were fitted with a 3M 1860S, and 202 were fitted with a 3M 1870.

Fit-test method results—overall

As seen in Table 1, a majority of individuals (n = 459 or 75%) passed both fit-tests. A small but noteworthy group (n = 82 or 13%) failed both types of fit-tests even though a subjective fit was achieved following the user seal check.

Table 1. Table of fit-test results for qualitative fit-test (QLFT) and quantitative fit-test (QNFT) and corresponding Kappa statistic – all N95 FFR models.

	QLFT Pass	QLFT Fail	Kappa statistic
QNFT Pass	459 (74.76%)	4 (0.65%)	0.63
QNFT Fail	69 (11.24%)	82 (13.36%)	

Examining quadrants B and C, 69 individuals (13%) who passed the QLFT failed the corresponding QNFT; conversely, only 4 individuals (0.86%) who passed the QNFT failed the corresponding QLFT. The K was 0.63 and therefore did not meet the ANSI recommended threshold of 0.70.

Fit-test results stratified by N95 FFR model

Table 2 shows the pass-fail fit-test results for both QLFT and QNFT by respirator model. The corresponding K statistic was 0.57 (95% CI 0.39–0.75), 0.64 (95% CI 0.52–0.76), and 0.60 (95% CI 0.47–0.72) for 3M 1860, 3M 1870, and 3M 1860S, respectively. On an individual basis, none of the three K's were greater than 0.70. Furthermore, as the three confidence intervals overlapped, there is no statistically significant difference in K for the three N95 FFR models.

Discussion

Two common fit-test methods, QLFT and QNFT, are employed in our health authority to determine whether a given N95 FFR provides an adequate seal for a user and, in turn, affords protection against aerosol transmissible diseases. Our findings indicate that these two methods, QLFT (Bitrex) and QNFT (Portacount), have disparate fit-test outcomes for our suite of respirators (3M - 1860S, 1860, and 1870). We found that the QNFT was able to find failures that were deemed as a "pass" from the corresponding QLFT. In other words, the QLFT passed a user whom the QNFT method identified as a failure.

For those individuals who passed the QLFT but failed the corresponding QNFT (n = 69), it may be due to

Table 2. Table of fit-test results for qualitative fit-test (QLFT) and quantitative fit-test (QNFT) stratified by N95 FFR model and corresponding Kappa statistic (95% CI).

		QLFT Pass	QLFT Fail	Kappa statistic
3M 1860	QNFT Pass	44 (57.14%)	2 (2.60%)	0.57
	QNFT Fail	13 (16.88%)	18 (23.38%)	(0.39–0.75)
3M 1870	QNFT Pass	137 (67.82%)	1 (0.50%)	0.64
	QNFT Fail	27 (13.37%)	37 (18.32%)	(0.52–0.76)
3M 1860S	QNFT Pass	278 (82.99%)	1 (0.30%)	0.60
	QNFT Fail	29 (8.66%)	27 (8.06%)	(0.47–0.72)

the subjective nature of the test itself as some individuals are insensitive to the QLFT taste agent.[9,15] Although a sensitivity test to the challenge agent (i.e., the ability of an individual to taste the bitter/sweet chemical) is performed prior to fit-testing, this may not adequately ensure the individual can accurately detect the test agent. This is supported by one study which reported that participants could "taste" a placebo solution (neither bitter nor sweet) while undergoing a QLFT.[16]

Our findings suggest that the QNFT is more capable of detecting failures than the QLFT for our suite of N95 FFRs. In fact, when we performed a test sensitivity as per ANSI with QNFT as the reference test, the result was 0.543 (not shown) which is well below the required threshold of 0.950.[7] Although the QNFT was demonstrably better than the QLFT for our three N95 FFR models, it can be subject to error. Coffey et al. found that the TSI Portacount QNFT instrument can mistakenly assign an ill-fitting respirator to a user.[17] It is also possible that a user can fail one of the individual fit-test exercises and still pass the overall QNFT as long as their overall fit-factor exceeds 100.[18] Further, it could be argued that the QNFT is overly protective and fails individuals who should pass. However, this question is beyond the scope of this study and should be addressed in future research.

With respect to the effect of the N95 FFR model on the fit-test results, we reported no statistically significant difference between models. Our results differ from other researchers who reported a difference in fit-test pass rates between various N95 FFRs models using different fit-test methods.[9,17] To our knowledge, we are the first to examine the fit-test pass rates for the 3M 1870. The difference in findings between the current study and those reported by others in the literature may be attributed to study design in that we conducted fit-tests sequentially on the *same* respirator donning to allow for direct comparison between the two fit-test methods. This meant that for our sample size of 614 subjects (a study strength in and of itself), every participant underwent both fit-tests without removing or adjusting their respirator. Other studies have used a smaller cohort with each subject undergoing fit-testing on multiple occasions.[9,17,19] Multiple donnings infers that the user gains experience with subsequent donnings and this may result in improved fit-test pass rates and therefore, bias the findings.[8,10,11] We also had the same individual conduct all the fit-tests to prevent the possibility of inter-individual differences during the fit-testing protocols or while assigning N95 FFRs.

Limitations associated with our study are discussed here. The reported fit-test results are only applicable to those models tested in this study. We are unable to comment about other established fit-test methods such as the QuantiFit (a QNFT) or saccharin test (a QLFT) which may serve as alternatives to the fit-test methods employed in this study. There may be a potential problem of respirator placement on the face or movement of the respirator between the two fit-tests but this is inherent in the study design and addressed by the alternating order of testing.[13] Our study population consisted predominantly of females which is common in the healthcare sector. Fit-test results may differ for males though no statistically significant differences between genders have been reported.[20,21] The TSI Portacount model that was used in this study is no longer commercially available; therefore, the latest model (TSI Portacount Respirator Fit-tester 8038) should be employed in future studies. Similarly, the 3M 1870 respirator model is being phased out and replaced with a new model: 3M Health Care Particulate Respirator and Surgical Mask 1870+. We are unable to address the question about accuracy of fit-test methods and future studies should not only determine accuracy but also identify the reasons for any potential differences between fit-test methods. In turn, this knowledge will lead to improved understanding of the validity of a QNFT and QLFT.

Conclusions

In summary, our findings suggest that, given a choice, the QNFT should be the fit-test used for the suite of respirators examined and that the disagreements between the two fit-test methods were similar across all three N95 FFR models. Although the focus of this study relates to fit-testing, it bears reminding that it is just one element of an effective respirator protection program.[22] Education has also been demonstrated to be an important piece to ensure that workers know when and how to wear a respirator properly.[23,24] We hope that these findings will aid other workplaces, in particular healthcare, with respect to their respiratory protection program.

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