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Sensitivity and specificity of the user-seal-check in determining the fit of N95 respirators

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SUMMARY

N95 respirators are recommended by the World Health Organization (WHO) and the Centers for Disease Control and Prevention (CDC) to prevent the inhalation of droplets which may transmit respiratory pathogens. The reliability of N95 respirators in preventing transmission depends on their fit to the wearer. Quantitative fit testing (QNFT) is the gold standard used to determine this fit objectively. The manufacturers of the respirators also recommend performing a self-reported user-seal-check to detect for leakage. This study aims to investigate the capability of the user-seal-check in determining the fit of N95 respirators by investigating the sensitivity and specificity of the user-seal-check compared with QNFT. A prospective and cross-sectional research design was used. A total of 204 local Chinese undergraduate nursing students were recruited to test two commonly used respirator models (3M 1860S and 3M 1862). The results of the user-seal-check were compared with the results of the gold standard QNFT using the Condensation Nucleus Counter Fit Tester System. The sensitivity and specificity of the user-seal-check results obtained with the respirators were calculated. The results indicated low sensitivity, accuracy and predictive value of the user-seal-check in determining the fit of the N95 respirators. The user-seal-check was not found to be reliable as a substitute for QNFT. The results also suggested that the user-seal-check may be unreliable for detecting gross leakage. We recommend that QNFT is used to determine the fit of N95 respirators.

Introduction

Worldwide outbreaks of infectious respiratory diseases such as severe acute respiratory syndrome (SARS), avian influenza A, and the H1N1 influenza pandemic, have brought about greater awareness of respiratory protection for healthcare workers.[1–4]

The World Health Organization (WHO) and the Centers for Disease Control and Prevention (CDC) have recommended the use of N95 respirators to prevent the spread of airborne infectious diseases.[5,6] However, the reliability of the N95 respirator to prevent such transmission depends on its fit to the wearer.[7] In ill-fitting respirators, the average penetration by an ambient aerosol has been found to be 33% compared with 4% in well-fitting respirators.[7] Such penetration may be caused by the gap between the respirator and the wearer's face, which is termed leakage. This gap may allow leakage of airborne contaminants into the wearer's breathing zone, leading to ineffective protection. Because of this potentially ineffective protection, the National Institute for Occupational Safety and Health (NIOSH) made fit-testing of N95 respirators compulsory for tuberculosis prevention before 2003. Both the CDC and the WHO recommended that fit testing should be carried out prior to the use of N95 respirators for SARS prevention.[5,6] Fit testing is now a mandatory measure for frontline staff working in infected areas in Hong Kong. During an epidemic of an airborne transmitted disease, there may be logistic difficulties in performing fit testing for all clinical staff.

According to the protocol from the United States Occupational Safety and Health Administration (OSHA), both quantitative fit testing (QNFT) and qualitative fit testing (QLFT) are the recognised methods to determine whether a respirator fits a wearer or not. Nowadays, QNFT rather than QLFT serves as the gold standard in determining the fit.[6–8] QNFT is an assessment of the adequacy of fit by numerically measuring the amount of leakage into the respirator.[8] Using an electronic device, the ratio of specific particles in the air inside and outside the breathing zone when wearing the respirator is measured and this ratio directly reflects the quantity of leakage. By

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contrast, the QLFT is a pass/fail fit test to assess the adequacy of fit that relies on the individual's response to a test agent such as isoamyl acetate or irritant smoke near the wearer's nose while wearing the respirator.[8] QLFT only measures the presence of leakage or not. QLFT may include bias such as differences in the wearer's sense of smell or uneven and immeasurable concentration of the test agents in the air.[9,10] QNFT is thought to be the more reliable method for fit testing, as reported in worldwide guidelines and research literature.[11–13]

N95 respirator manufacturers recommend that the wearer should carry out a user-seal-check. This is a standardised test performed by the wearer to detect gross leakage in a respirator. As suggested by some guidelines, no further QNFT is needed for a given respirator if leakage is detected by the user-seal-check.[8,14,15] Furthermore, it has been suggested that a user-seal-check may be used as a substitute for QNFT if QNFT is not yet available. A previous retrospective study reported that the user-seal-check failed because its false-positive and false-negative rates in determining the fit of N95 respirators were too high.[11] There were limitations to this study including the retrospective design, differences in the number of each given models being tested, staff being able to select the respirator for testing and no standardised procedures for donning the respirators. Variations in the donning technique may have affected the reliability of the reported results because the technique of donning has been shown to correlate with leakage.[16,17] These limitations restrict the reliability of the findings. Therefore, this topic warrants further investigation with a prospective study design.

Methods

Design and participants

A descriptive, prospective, and cross-sectional research design was employed in this study. A sample of 204 local Chinese undergraduate nursing students was invited to participate. All the students were in year 2 with 18 weeks of clinical experience.

Setting

In order to minimise variation in the environment such as the concentration of suspended particles and dusts, all tests in this study were conducted in an assigned air-conditioned room with temperature set at 23 °C and humidity at about 75%.

Data collection

The demographic data of the participants (age and sex), the results of the user-seal-check, and the results of the QNFT with two given respirators were recorded in a data sheet. A standardised N95 respirator wearing protocol and guidelines for performing the user-seal-check (i.e. visual fit check, pressure–tightness test or negative/positive pressure check) were presented to the participants at the beginning of the study.[7,15]

Conducting a user-seal-check

To conduct a user-seal-check, the wearer visually checks whether there is a gap between his/her face and the respirator. Then, the wearer forcefully inhales and exhales several times. The respirator should collapse slightly upon inhaling and expand upon exhaling. The wearer should not feel any air leakage between his/her face and the respirator. If any leakage is found, this is the sign of poor facial fit and a positive result of user-seal-check for the detection of leakage.

Conducting QNFT

The fit of the N95 respirator to the wearer was measured using a QNFT device. This was a PortaCount respirator fit tester system (Model Pro+ 8038, TSI Incorporated, St Paul, MN, USA). This system is based on a miniature, continuous-flow condensation nucleus counter (CNC) which is technology recognised by the OSHA to count air particles ranging from 0.02 to 1.00 μm in diameter.[18] The use of the QNFT device followed the manufacturer's guidelines and the protocol described by the OSHA.[8,19] Once the wearer has donned the respirator and QNFT system in accordance with the manufacturer's guidelines, the wearer performs eight exercises as recommended by the system. Figure 1 shows the fit tester system, tubing connection and respirator. The eight exercises included normal breathing, deep breathing, side-to-side head movement, up-and-down head movement, talking (a standard set of passage was provided for reading),

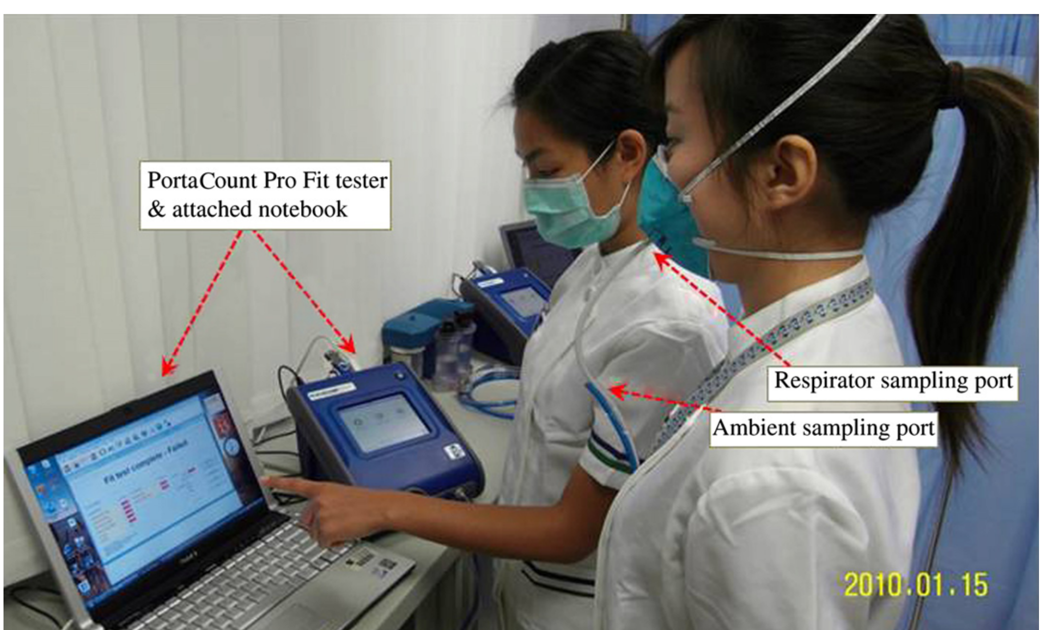

Figure 1. The fit tester system, tubing connection and respirator.