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SHORT REPORT

Predictive value of the user seal check in determining half-face respirator fit

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Summary Guidelines issued by the Centers for Disease Control and Prevention and the World Health Organization state that healthcare workers should wear N95 masks or higher-level protection during all contact with suspected cases of severe acute respiratory syndrome. Before use, the manufacturer recommends performing a user seal check to ensure that the mask is fitted correctly. This study aimed to test the ability of the user seal check to detect poorly fitting masks. This study is a retrospective review of a mask-fitting programme carried out in the intensive care unit of the Prince of Wales Hospital in Hong Kong. In this programme, all staff were tested with two types of N95 mask and one type of N100 mask. The results of the documented user seal check were then compared with the formal fit-test results from a PortaCount. Using a PortaCount reading of 100 as the criterion for a correctly fitted mask, the user seal check wrongly indicated that the mask fitted on 18–31% of occasions, and wrongly indicated that it did not fit on 21–40% of occasions. These data indicate that the user seal check should not be used as a surrogate fit test. Its usefulness as a pre-use test must also be questioned.

Introduction

Hong Kong Department of Health figures show that 22% of the cases of severe acute respiratory syndrome (SARS) in Hong Kong occurred in healthcare workers (http://www.info.gov.hk/dh/diseases/ap/eng/infected.htm). The Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO) currently recommend the use of N95 masks or higher-level protection to prevent the transmission of SARS to

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staff in these areas (http://www.cdc.gov/ncidod/sars/infectioncontrol.htm and http://www.who.int/csr/sars/infectioncontrol/en/).

In unfitted masks, the average penetration by ambient aerosol was found to be 33%, compared with 4% in fitted masks.[1] Due to the unreliability of an unfitted respirator, the National Institute for Occupational Safety and Health (NIOSH) has made fit testing of N95 respirators mandatory for tuberculosis prevention.[2] Both the CDC and the WHO recommend that fit testing should be carried out prior to use of N95 masks for SARS prevention. In the context of a SARS epidemic, however, fit testing a sufficient number of staff may cause logistic difficulties.

Prior to use of a respirator, the manufacturers recommend that the user should carry out a user seal or fit check to exclude gross leaks. It has been suggested that this check might be used as a surrogate for formal fit testing. We carried out this study to determine the false-positive and false-negative rates of a user seal check in determining the fit of disposable N95 and N100 respirators.

The NIOSH standards do not apply in Europe. In a healthcare setting, masks meeting the FFP2 standard are similar to N95 masks, and FFP3 masks are similar to masks meeting the N100 standard.

Methods

This was a retrospective analysis of data collected during an occupational safety programme for SARS and tuberculosis prevention for nurses working in the intensive care unit (ICU) of the Prince of Wales Hospital in Hong Kong.

All nurses were fit tested using a PortaCount Plus (TSI Incorporated, St Paul, Minnesota, USA) according to the protocol described in the US regulation, 29 CFR 1910.134.[3] The PortaCount measures the number of ambient dust particles inside and outside the respirator, and calculates a fit factor that is a ratio of the two measurements. The machine runs in two modes; the N99/N100 mode and the N95 mode. In the N99/N100 mode, the device counts all particles sized between 0.02 and 1 μm diameter. In the N95 mode, only particles with a diameter of 0.04 μm are counted. One N100 mask (8233) and two N95 masks (1860s and 9210) (3M, St Paul, Minnesota, USA) were tested. Prior to carrying out each fit test, the nurse was asked to perform a user seal check, and to state whether or not she could detect a leak. The mask was considered to have passed the user seal check if no leak was detected.

Following the manufacturer's recommendation, the two N95 masks were tested using the N95 mode, and the N100 mask was tested using the N99/N100 mode.

All staff were already familiar with the 1860s and 8233 masks, as they had used them during the epidemic. Most staff had not used the 9210 mask previously. Prior to testing all of the masks, the staff were instructed in their use.

One modification was made to the PortaCount. The re-usable tubing supplied by the manufacturer was replaced with 150 cm of disposable PVC tubing of the same internal diameter to minimize any risk of cross-infection. As this tubing was longer than the tubing usually used in the N95 mode, the ambient purge time in this mode was increased to 15 s to compensate for the additional length. This time was found in separate testing to be 5 standard deviations greater than the average time required to purge this length of tubing.

To ensure an adequate ambient particle count throughout the testing, the 8026 Particle Generator (TSI Incorporated, St Paul, Minnesota, USA) was used to generate saline particles throughout the testing procedures.

The accuracy of the user seal check was scored against the quantitative fit test. Following the NIOSH guidelines, a fit factor of 100 on this test was used as the pass mark for each of the respirators.

The number of staff fitting each mask and the difference between the number of males and females were compared using the Chi-squared test (EPI-INFO v6, CDC). A P value <0.05 was considered to be significant.

Results

All nurses were of Chinese descent. The 1860s (N95) mask was tested in 82 female nurses and two male nurses, the 9210 (N95) mask in 81 females and 12 males, and the 8233 (N100) mask in 79 females and 12 males.

The user seal check was correct on 71–75% of occasions. Detailed results are shown in Table I. Fit factors for masks that had been incorrectly passed were 19–87 for the 1860s (N95) mask, 7.8–92 for the 9210 (N95) mask, and 12–91 for the 8233 (N100) mask. The user seal check was no more accurate in men compared with women; 50% vs 76% for the 1860s (N95) mask, 66% vs 74% for the 9210 (N95) mask, and 75% vs 70% for the 8233 (N100) mask (no significant differences). The 50% failure rate with the 1860s mask in men appears high; however, only two men were tested on this mask.