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Performance of Two Respiratory Protective Devices Used by Home-Attending Health-Care Workers (A Pilot Study)

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Abstract

Objectives: This pilot study aimed at determining the Workplace Protection Factor (WPF) for respiratory protective devices widely used by health-care workers to reduce exposure to potentially hazardous aerosols when attending patients in their homes. Two devices were tested, an N95 filtering facepiece respirator (FFR) and a surgical mask (SM).

Methods: Three home-attending health-care workers were recruited, medically cleared and fit tested. At the workplace, the aerosol concentrations outside (C_{out}) and inside (C_{in}) of the tested respiratory protective device worn by a subject were measured using two simultaneously operating P-Trak condensation particle counters within the particle size range of approximately 20–1,000 nm. Real-time and integrated (time-weighted average, TWA) values of WPF = C_{out}/C_{in} were determined.

Results: This pilot study demonstrated that the WPF of the tested N95 FFR consistently exceeded that of the SM. The $WPF_{TWA(C)}$ values calculated for the entire test time (based on the TWA aerosol concentration values) ranged from 29 to 40 and 2 to 9, respectively. In all cases, the N95 FFR provided protection above the Occupational Safety and Health Administration's (OSHA) assigned protection factor of 10, whereas the SM often offered little or essentially no protection against the measured sub-micrometer aerosol particles. For both devices, the protection level was found to depend on activity. For example, the $WPF_{TWA(C)}$ for one subject wearing the N95 FFR was 56 during normal activity but fell almost 70% during tracheal suctioning. It is explicable considering that different procedures implemented by health-care workers in homes generate particles of different sizes and require different body movements; both factors are anticipated to affect the WPF.

Conclusions: Wearing an N95-certified respirator helps significantly reduce the aerosol inhalation exposure of home-attending health-care workers. An SM offers much lower protection. The WPF depends on several factors, including, but not limited to, the health-care worker's activity and/or body movements; the WPF varies from one worker to another.

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Keywords

Health-care workers; Respiratory protection; N95 respirator; Surgical mask

INTRODUCTION

Home health-care is one of the most rapidly expanding industries in the United States due to the aging population and rapidly rising hospital costs. A 38% growth is expected between 2014 and 2024.[1] Home-attending health-care workers are employed in homes of elderly individuals, persons with disabilities, or with other chronic health conditions. Activities include assistance with bathing, dressing, and housekeeping, as well as administering medication and performing various medical procedures, e.g., wound care.

While on duty, home-attending health-care workers are potentially exposed to a wide range of hazardous aerosols and, therefore, may be at health risk. In contrast to hospital settings, patients' homes may lack appropriate sanitary conditions and have poor or no ventilation. Home health-care workers have little control over their work environment, which substantially varies from one patient's home to another. Unlike other workplaces, engineering and administrative controls cannot be easily implemented here leaving respiratory protection devices (RPDs) the only feasible option to reduce the workers' inhalation exposure to airborne particles.[2] It is not uncommon for a home-attending health-care worker to enter a patient's home unprotected. Others wear surgical masks (SMs) and in some cases, NIOSH-certified N95 facepiece filtering respirators (FFRs), which remains the most prevalent RPD in health-care.[3] While these devices are widely used, no information is available about their protection level against aerosols during home health-care activities. Studies examining the protection offered by N95 FFRs and SMs have been mostly conducted in laboratory settings[4], with few attempting to evaluate their efficiency in simulated health-care settings.[5–7] Existing guidelines and recommendations for protecting health-care workers do not extend to those attending patients in their homes.

This pilot study was carried out to assess the protection provided by one N95 FFR and one SM, which are widely used by health-care workers. The aerosol concentrations inside (C_{in}) and outside (C_{out}) of each of the tested devices were measured on wearers attending patients in homes. The Workplace Protection Factor (WPF) was determined as C_{out}/ C_{in}.

MATERIALS AND METHODS

Health-care Environment

The pilot study was conducted in a home that was being visited by three different health-care professionals. The measurements were performed in the patient care room (11 ft. x 12 ft. x 9 ft.), which also housed medical equipment such as a nebulizer, laptop ventilator, air compressor and suction machine.

Human Subjects Recruitment, Training, and Pre-testing

Home-attending health-care professionals were recruited for this study by distributing recruitment flyers among the Cincinnati area home health providers. Three nurses (all female) from the Children's Hospital Medical Center were selected as the study subjects. Each subject signed a written consent form.

Prior to the tests, the subjects were medically cleared for wearing RPDs based on the OSHA respirator medical clearance questionnaire, which was reviewed by a physician. Also before the workplace evaluation, the participating workers were fit tested with the N95 FFR selected for the study (SM is not subjected to fit testing). Consistent with the US OSHA protocol 29 CFR1910.134[(7)], a PortaCount (Model 8020, TSI, Inc., Shoreview, MN) was used for the fit testing. A particle generator (Model 8026, TSI Inc.) was used to provide an ambient aerosol concentration sufficient to perform the fit testing (at least 1000 particles/cm^3).

Smokers among the selected subjects were asked to refrain from smoking for at least 30 minutes before the test; all subjects were asked to abstain from eating, chewing gum, and drinking, except for water, for at least 15 minutes before testing. Subjects were evaluated to ensure that there was no facial hair or signs of moisture on their facial surface. A demonstration session on respirator/mask donning was conducted for each subject. A user seal check was performed immediately prior to testing with an N95 FFR in accordance with manufacturer's instructions.

The study protocol was approved by the University of Cincinnati Institutional Review Board (IRB) as part of a larger research effort.

Tested RPDs

As there are no specific N95 FFR or SM models recommended by OSHA or NIOSH to be used by home-attending health-care workers, we selected disposable devices, which are widely utilized in hospital settings. These included a Model 1860 N95 FFR (3M Company, St. Paul, MN) and a Model 1818 SM (by 3M Company).

Testing Subjects Wearing RPDs during Home Visits

At the beginning of a home visit, each subject wearing an RPD was equipped with a setup that consisted of two simultaneously operating P-Trak condensation particle counters (Model 8525, TSI Inc.) measuring the total aerosol concentrations outside of the RPD in the breathing zone (C_{out} – breathing zone sampling line) and inside the RPD (C_{in} – in-respirator sampling line). The two particle counters were connected to the sampling probes via identical Tygon tubes (6 ft. long) and placed on a wheeled cart. According to the manufacturer, the P-Trak's operational particle size range is 20 nm to approximately 1,000 nm. The concentration data were recorded in 5-second intervals. Each subject was tested on two different days: wearing the N95 FFR on one day and SM on another day (both times for approximately 40 min).

The real-time WPF_t was calculated as a ratio of C_{out} to C_{in} measured for every 5-second interval. The per-subject time-weighted averages were calculated for the entire test time as

well as for specific activities, such as the nebulizer treatment, tracheal suctioning, and normal activity (e.g. typing a note, giving food or monitoring the patient). There were two ways for defining the integrated WPF:

- based on the ratio of time-weighted averaged concentration values:

$$\mathrm{WPF_{TWA(C)}} = \frac{\int_0^t C_{out}(t)dt}{\int_0^t C_{in}(t)dt}$$

and

- based on the integration of WPF over the corresponding time interval:

$$\mathrm{WPF_{TWA}} = \frac{1}{t}\int_0^t WPF(t)dt$$

The first one is a measure of the overall aerosol exposure reduction provided by an RPD worn by a worker. The second one reflects the changes in a real-time measured WPS occurring every 5 s. The latter definition assumes an instant response of the inside aerosol concentration to the changes in the outside one so that $C_{in}(t)$ immediately follows $C_{out}(t)$. Since there is a lag between the two concentrations, WPF_{TWA} has a limited utilization while the concentration-based $WPF_{TWA(C)}$ seems more representative if the temporal variability of C_{out} is high.

Data Analysis

The data analysis was performed using SPSS v.22.0 (IBM Corp., Armonk, NY). The WPF_t, $WPF_{TWA(C)}$ and WPF_{TWA} were calculated for each subject and device (N95 FFR and SM) evaluated in this study. A paired t-test analysis was performed to examine the difference in $WPF_{TWA(C)}$ between the N95 FFR and SM.

Between-subject variability of the three health-care workers wearing N95 FFR and SM in WPF_t, was investigated with a two-way ANOVA followed by pairwise comparisons using Scheffe post-hoc analysis. The normality of data distribution was confirmed before appropriate statistical analyses were applied. A p-value of <0.05 represented a significant difference.

RESULTS AND DISCUSSION

The total particle concentration measured in the breathing zone during the six experiments (3 subjects with two RPDs each) ranged from 145 to 56,840 cm^{-3}. The total concentration inside the N95 respirator ranged from 5 to 7,224 cm^{-3} while the concentration inside the SM ranged from 108 to 13,035 cm^{-3}. As an example, Figure 1 presents the real-time measured C_{out} and C_{in} for the tested N95 FFR as well as WPF_t obtained for Subject 1. The data shown in the figure reveal that WPF_t changes within an activity as well as from one activity to

another for the $WPF_{TWA(C)}$. The former was observed even when the aerosol concentration in the breathing zone was nearly constant for a specific activity. This observation is consistent with the findings of the simulation study of Hauge *et al.*.[6] Head or body movements, such as bending at the waist and moving the head up and down, have been identified as factors affecting the simulated WPF.[7] In general, head and body movement may affect the RPD's fit, and thus, the WPF given that the faceseal leakage often represents the main penetration pathway for particles to enter into an RPD.[7,9] The between-activity variation of the $WPF_{TWA(C)}$ value was considerable. For example, switching from the normal activity to the tracheal suctioning procedure resulted in a decrease of the activity-specific $WPF_{TWA(C)}$ from 56 to 19 for Subject 1. In addition to variations associated with the head and the body movement of a health-care worker, the change in $WPF_{TWA(C)}$ from one activity to another may be attributed to the fact that different activities generate aerosols with different particle size distributions, which impacts the particle penetration both through the filter and the faceseal leakage.

Figure 2 presents the $WPF_{TWA(C)}$ values calculated over the entire test for each of the three RPD-wearing health-care workers exposed to aerosols during home visits. These shift-integrated $WPF_{TWA(C)}$ ranged from 29 to 40 for the N95 FFR and from 2 to 9 for SM. In all cases, it was above the OSHA's assigned protection factor of 10 for N95 FFR. The data revealed that the N95 FFR provided an order of magnitude higher protection for home-attending health-care workers as compared to the SM. A paired t-test showed that the difference was significant ($p < 0.01$). The data suggests that SMs perform very poorly. This is in line with the findings of previous studies, which concluded that the WPF of N95 FFRs consistently exceeded that of tested SMs.[5,9]

When comparing the two approaches for calculating the time-average value of WPF, we found that the concentration-based approach [yielding $WPF_{TWA(C)}$] was more conservative than the other one; in all cases, $WPF_{TWA(C)}$ was lower than (or approximately equal to) WPF_{TWA}. Like $WPF_{TWA(C)}$, the WPF_{TWA} values exceeded the OSHA's assigned protection factor of 10 for all subjects wearing N95 FFR. Furthermore, WPF_{TWA} exceeded 10 for Subject 1 wearing SM.

Between-subject differences analyzed jointly for the N95 FFR and SM based on the WPF_t data were found significant ($p<0.001$). The pairwise comparison pointed to a single similarity: for Subjects 1 versus 3 wearing N95 FFR. The between-subject differences are believed to be dependent on facial characteristics of the subject as well as their head and body movements while providing health care to patients. It is acknowledged that the above conclusions are preliminary because this pilot study does not have sufficient power to generate credible quantitative information about between-subject variability of the WPF_t.

LIMITATIONS

This pilot study was limited to only one N95 FFR and one SM; consequently, the data collected may not be fully representative of all RPD models currently available on the market. This pilot study tested only three subjects and one home. A follow-up investigation may include a broader list of RPDs, a greater number of subjects featuring a variety of facial

dimensions, as well as more activities performed by home-attending health-care workers. Additionally, it would be useful to examine different home environments.

CONCLUSIONS

This is the first study that investigated the performance of RPDs of health-care workers during home visits. Based on the pilot data on WPF, it is concluded that wearing an N95 respirator significantly improves the respiratory protection of home health-care workers as compared to an SM. The $WPF_{TWA(C)}$ of the N95 FFR wearers averaged over the entire test time was above the OSHA's assigned protection factor of 10, whereas the SM often provided little or essentially no protection against the measured sub-micrometer aerosol particles. At the same time, these shift-averaged $WPF_{TWA(C)}$ values were below the passing fit test level of 100 for both devices. The protection level seems to depend on the activity and body movements and vary from one individual to another.

Acknowledgments

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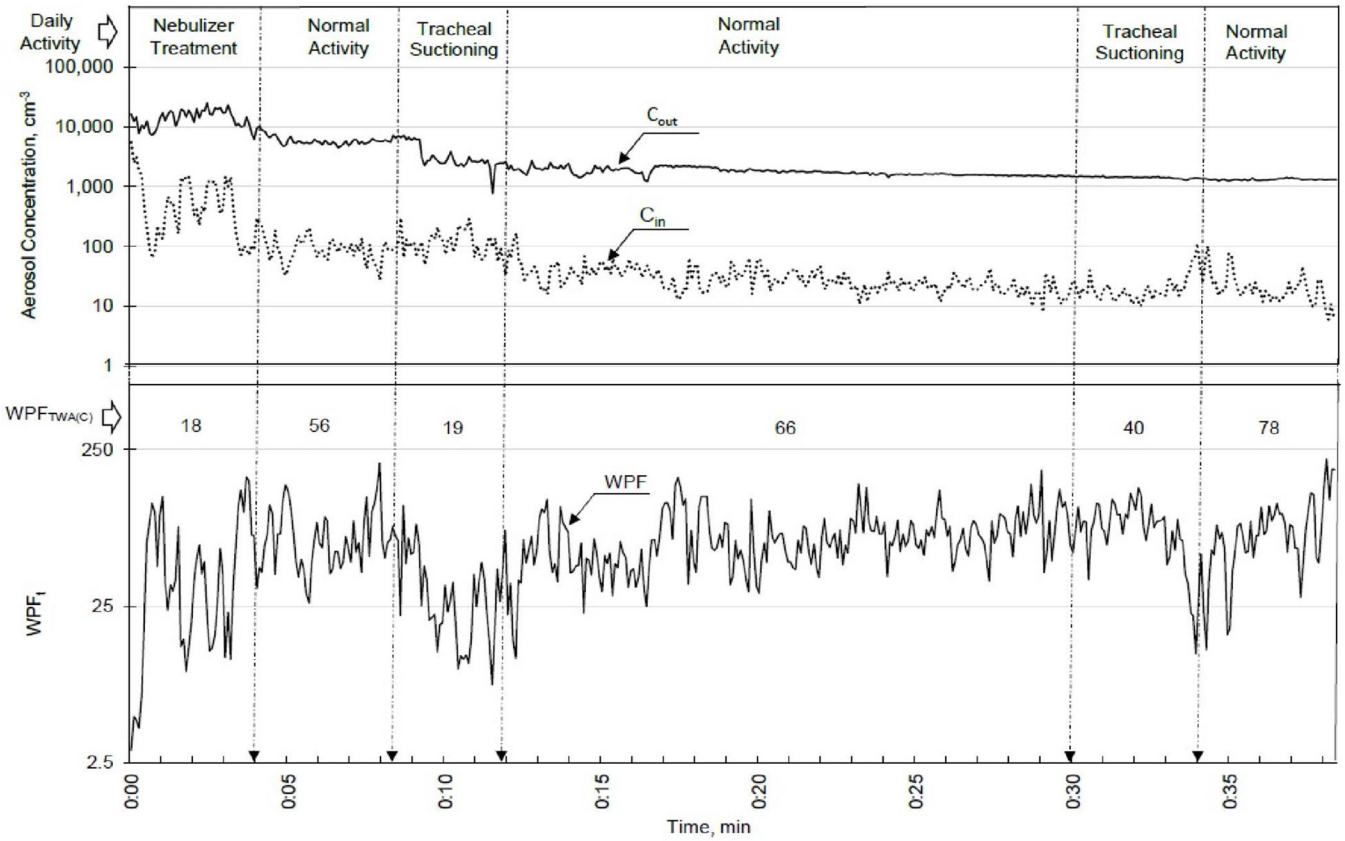

FIGURE 1.

The real-time particle concentrations (in the breathing zone, C_{out}, and inside the N95 FFR, C_{in}) and a real-time WPF measured for Subject 1. The WPF values integrated per activity are also listed.

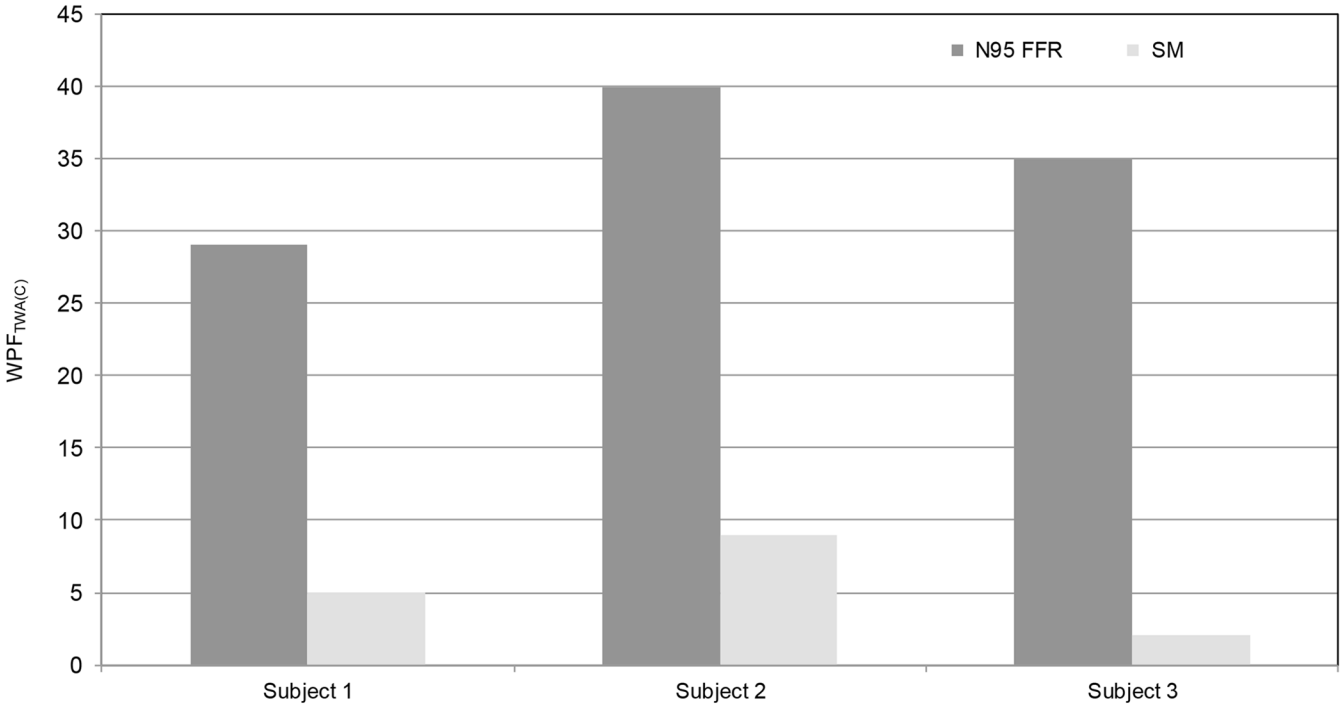

FIGURE 2.

The $WPF_{TWA(C)}$ values time-weighted averaged over the entire test time for three RPD-wearing subjects. Each bar represents a single day measurement.