Inhalation Exposure and Respiratory Protection of Home Healthcare Workers Administering Aerosolized Medications (Simulation Study)

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ABSTRACT

There is little information regarding aerosol exposure from using medical nebulizers and the factors affecting the risk of exposure, especially for treatments performed in a patient's home environment. Home healthcare workers (HHWs) are a rapidly growing work population often exposed to aerosol hazards. Thus, we designed a simulated environment to measure the aerosol inhalation exposure of an HHW administering pressure-nebulized medications. We determined the relative contributions of different factors to aerosol reduction, namely, the room air exchange rate, proximity to the patient, and patient breathing rate, in an exposure chamber simulating a patient's bedroom. Additionally, the performance of respiratory protective devices worn by an HHW, a surgical mask and N95 filtering facepiece respirator (FFR), was evaluated using NaCl as a well-established surrogate. The particle concentration in the breathing zone of an unprotected worker ranged from 7,118 to 284,600 cm^{-3}. The proximity to the aerosol source affected the aerosol concentration, but the influence of this factor diminished when the distance increased beyond 24 inches. For an unprotected HHW, ventilation was the most effective way to reduce exposure to nebulizer-produced medical aerosols. An increase in the air exchange rate from 0 to 5 h^{-1} significantly reduced the exposure; however, a further increase (to 17 h^{-1}) produced only a small reduction in the particle concentration. Therefore, no evidence suggests that patient homes require extremely efficient ventilation to mitigate HHWs' exposure to nebulizer-produced medications. Increasing the patient's breathing flow rate reduced the aerosol inhalation exposure; however, this factor cannot be controlled, which weakens its practical viability. Wearing respiratory protection devices was found to be the most efficient way to reduce aerosol exposure (within the set of tested variables). As expected, an N95 FFR with a proper seal was about 20-fold more efficient than a surgical mask.

Keywords: Aerosol exposure; Medical nebulizer; Respiratory protection; Home healthcare.

INTRODUCTION

Healthcare professionals working in hospitals can come into close contact with numerous types of occupational hazards such as exposure to reproductive hazards (Lawson *et al.*, 2012) as well as infectious agents and blood borne pathogens (Veccio *et al.*, 2003). Exposure of healthcare workers to medications, especially when performing treatments involving aerosolized drugs, has the potential for significant reactions, including, but not limited to bronchospasm, allergy, and anaphylaxis (Nicklas, 1990;

Riordan and Smaldone, 1992; Bone and Amundson, 1993; Jayaraman and Brar, 2016). Home healthcare workers (HHWs) providing their services in patients' homes do not have the benefit of working in a controlled environment such as a hospital setting. Hospital rooms typically have a high air exchange rate (AER); e.g., surgical suites are often operated at about 20 air exchanges per hour (ASHRAE, 2017). Additionally, hospital rooms are frequently cleaned. In contrast, residential settings typically have relatively low exchange rate or no ventilation at all. Besides the healthcare related exposures, HHWs can also be exposed to household hazards (Sherman *et al.*, 2008; Agbonifo *et al.*, 2017).

One exposure source of the HHWs is the medications that are administered using medical nebulizers, which aerosolize medication intended for patient inhalation, e.g., for asthma and COPD treatment (Campbell, 1999). Some of the most common pressure-nebulized medications are

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ipratropium bromide, budesonide (Elmashae *et al.*, 2018), and albuterol sulfate (Kerwin *et al.*, 2016; Elmashae *et al.*, 2018).

Medical nebulizers are not built to provide a tight fit to a patient under treatment. The facial mask connected to a nebulizer does not have a perfect seal on the patient's face and there is a visible cloud around the patient during treatments. Therefore, an HHW can receive secondhand exposure while administering medication with a nebulizer. Secondhand exposure to inhaled bronchodilators by a healthcare professional has been associated with an increased health risk (Ari *et al.*, 2016). Although home healthcare is one of the fastest growing healthcare fields in the United States (Gershon *et al.*, 2008), very few agencies adequately address occupational aerosol exposure of HHWs and provide respiratory protection training and fit testing to minimize the inhalation exposure of their employees in patient homes (Gershon *et al.*, 2010). It is not uncommon for HHWs to enter a home with no respiratory protection at all. The authors found no guidelines or recommendations from the Occupational Safety and Health Administration (OSHA) or the National Institute for Occupational Safety and Health (NIOSH) that would adequately address the HHWs' exposure to pressure-nebulized medications or require respiratory protection in patients' homes.

There is insufficient information regarding the aerosols that escape from the mask of a medical nebulizer into the patient's room and breathing space of a healthcare worker. The factors affecting the concentration of these particles in a home environment are not characterized. In a pilot laboratory study conducted by our group with a jet-nebulizer, inhalation exposures to the above-listed medications were evaluated (Elmashae *et al.*, 2018). This study was performed in a small chamber simulating a two-dimensional configuration with two manikins, which mimicked a patient and an HHW facing each other. It was concluded that the total aerosol mass concentration in the breathing zone of an HHW could vary from 2.29 to 10.2 $\mu g\ m^{-3}$. Conducting the testing under controlled laboratory conditions, this rather simplistic simulation effort could not fully address the environmental conditions affecting the HHW's exposure in a typical home. Another pilot investigation, which was focused on the evaluation of respiratory protective devices used in a home healthcare environment, was carried out under field conditions and involved multiple tasks; however, this effort was not specifically focused on the nebulizer treatments and did not consider variables such as AER (Elmashae *et al.*, 2017).

The present study built on the foundation created by the recent pilot laboratory testing of Elmashae *et al.* (2018) aims at developing the next level simulation setting to measure the aerosol exposure of an HHW affected by different environmental factors, and to determine the relative contributions of these factors on the aerosol exposure reduction in a room-size chamber. The performance of different respiratory protective devices typically worn by an HHW was also evaluated.

MATERIALS AND METHODS

Experimental Design

This simulation study was performed in an exposure chamber (24.3 m^3) as presented in Fig. 1. The chamber was equipped with a closed-loop ventilation and air filtration system under three different AERs: 0 (calm air), 5 h^{-1}, and 17 h^{-1}. The calm air represents a home with turned off or non-functioning ventilation, which serves as the worst case scenario from the exposure standpoint. Air exchange rate of 5 h^{-1} is believed to be a reasonable estimate of a highly efficient residential home ventilation (based on our review of multiple surveys, e.g., those quoted in Reichman *et al.*, 2017). The highest tested rate of 17 h^{-1} represents the high-air-exchange hospital settings; the AERs listed in the ASHRAE/ANSI/ASHE standard for ventilation of healthcare facilities ranges from 15 h^{-1} in procedure rooms to 20 h^{-1} in operating rooms (ASHRAE, 2017). The latter was utilized to compare aerosol exposure levels for an HHW administering a pressure-nebulized medication in a patient's home and a hospital room.

A breathing manikin simulating a patient was placed approximately in the center of the test chamber with a nebulizer mask positioned on the manikin's face using a standardized procedure. A breathing simulator (BRSS, Koken Ltd., Tokyo, Japan) was connected to the manikin via plastic tubing. A HEPA filter was placed between the manikin and breathing simulator. The filter prevented particles inhaled by the manikin from being exhaled and "double-counted" in the breathing zone. The tests were conducted at two breathing conditions of a patient represented by the mean inspiratory flow (MIF) rates of 15 and 30 L min^{-1}. The MIF was varied by changing the breathing frequency (from 0.25 to 0.5 Hz) with a tidal volume being kept the same (1 L). The tested MIF values are representative of respiratory rates typically seen in adults and children (Lindh *et al.*, 2009; Barrett *et al.*, 2012; Rodriguez-Molinero *et al.*, 2013).

The test variables are presented in Table 1 below. In addition to the AER and MIF, we varied the proximity of an HHW to the aerosol source (nebulizer), and the level of respiratory protection.

The study protocol was designed so that any exposure to potentially hazardous aerosolized drugs would be avoided. A sodium chloride (NaCl) aerosol was used as a surrogate of nebulized medications commonly administered by HHWs based on the findings reported in our earlier study (Elmashae *et al.*, 2018). Particles were aerosolized by a PARI LC Sprint reusable nebulizer (Model 023F35, PARI Respiratory Equipment Inc., Midlothian, VA, USA) charged with a 0.9% NaCl solution. The nebulizer was connected to an adult PARI mask. A Vios PRO compressor ran at 10 L min^{-1} for a minimum of 10–12 min to reach concentration plateau in the chamber before data collection started for the tests conducted at AER = 5 and 17 h^{-1}. When testing at no air exchange, it took longer, 15–20 minutes to reach the intended plateau. Typically, nebulizer treatment sessions last between 5 and 10 min, but some may take up to 20 min.
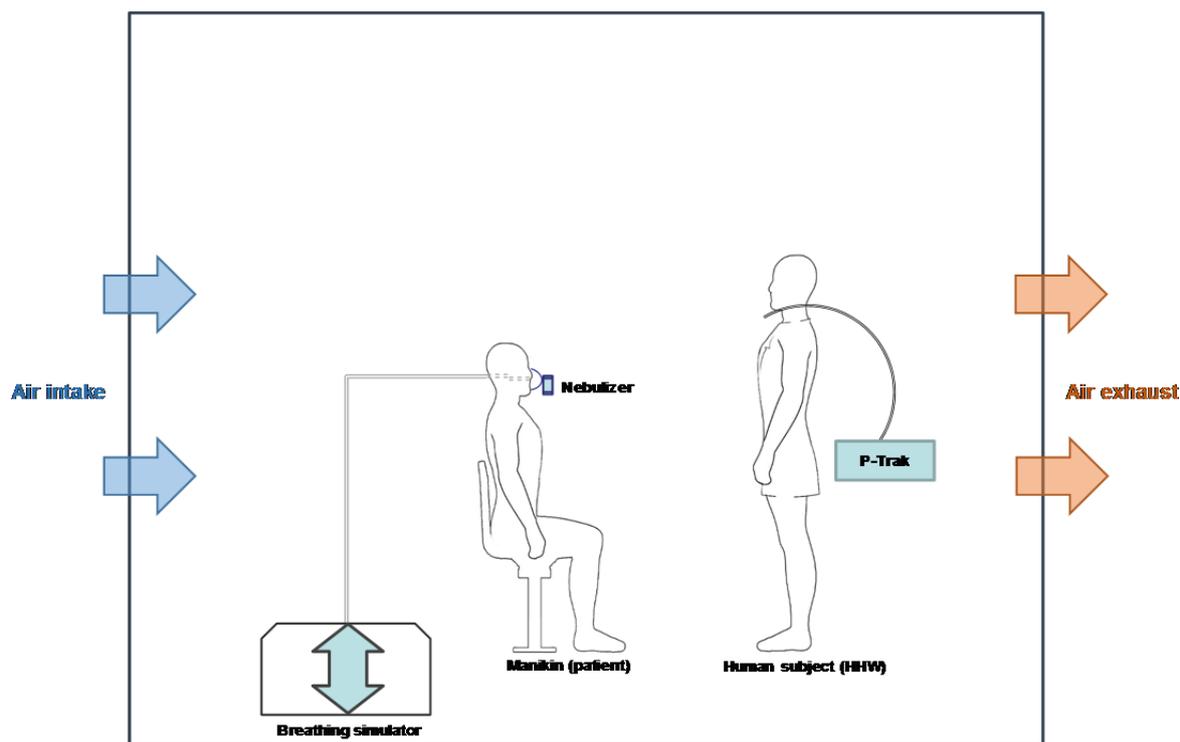
Fig. 1. Schematic diagram of the experimental set-up in the exposure chamber.

A study subject representing an HHW administered the nebulizer treatment to the manikin while standing at different distances from the latter (measured from nose to nose). The four levels of proximity (Table 1) were chosen to represent a working range, including close interaction (6 inches), a typical operational proximity (90°-bent elbow) (12 inches), manipulation of the nebulizer with a stretched-out arm (24 inches), and no manipulation with the nebulizer (the HHW standing 48 inches away).

The air exchange system for the chamber, which included multiple intakes and exhausts (schematically shown as arrows in Fig. 1), was configured so that the HHW-representing subject stood downstream from the patient-representing manikin. This configuration allowed simulating the worst-case scenario when the aerosol particle transport due to the air exchange enhanced the concentration in the breathing zone of the HHW. The linear air velocity through the chamber, however, was too low (< 1 cm s^{-1}) to anticipate a sizable flow direction effect on the HHW's aerosol exposure.

The three respiratory protection conditions for the subject included wearing no mask/respirator (an unprotected HHW), wearing a surgical mask (Surgine II, model 4260, Ethicon, Inc., Arlington, TX, USA), and wearing an N95 facepiece filtering respirator (FFR) (3M, model 1860S, Maplewood, MN, USA). The N95 FFR was fit tested prior to wearing with the fit factor passing the OSHA-established threshold of 100 (OSHA, 1999). Two P-Trak condensation particle counters (Model 8525, TSI Inc., Shoreview, MN, USA) were operated in parallel to measure the particle concentration inside (C_{in}) and outside (C_{out}) the mask/respirator when worn. Before testing, the instruments were calibrated against

each other. Each trial ran for 5 minutes with three replicates for each study condition. For both types of protection devices, the measured C_{out} represented the exposure of an unprotected worker. As C_{out} was measured—simultaneously with C_{in}—for both respiratory protection devices (three times for each), the total number of replicates for the unprotected HHW was six.

The study protocol was approved by the University of Cincinnati Institutional Review Board (IRB). The informed consent was signed prior to study. After passing a questionnaire-based medical examination, the human subject was cleared to wear an N95 FFR.

Data Analysis

The particle concentration values measuring the HHW's breathing zone (with and without mask/respirator) using the P-Trak in 6-second time increments were analyzed. The minimum and maximum concentrations across all tested conditions were identified and recorded. The time-weighted average (TWA) values of the aerosol concentration were calculated for each condition over a 5-min runtime (fifty 6-second increments). The arithmetic mean and standard deviation were calculated for all replicates.

The Simulated Workplace Protection Factor (SWPF) for both the surgical mask and N95 FFR was determined as a ratio of time-weighted averages of C_{out} and C_{in} as follows:

$$SWPF_{TWA} = \frac{\int_0^t C_{out}(t)\,dt}{\int_0^t C_{in}(t)\,dt} \tag{1}$$

Table 1. A layout of the variables examined in this study.[A]

Variable	Levels
Air Exchange Rate (AER)	0, 5, 17 h^{-1}
Distance	6, 12, 24, 48 inches
Mean Inspiratory Flow (MIF)	15, 30 L min^{-1}
Protection Condition[B]	Unprotected, Surgical Mask, N95 FFR

[A] The number of replicates varied if the HHW subject was unprotected (6 replicates) vs. protected (3 for surgical mask and 3 for N95 FFR).
[B] The tests involving respiratory protective devices were operated only at a MIF = 15 L min^{-1}.

The SWPF data were analyzed and found lognormally distributed. The minimum and maximum SWPF values across all tested conditions were identified and recorded. For each set of conditions (AER, distance, and protective device), the geometric mean (GM) and geometric standard deviation (GSD) were calculated from three 5-min runs.

A mixed effect model was used to compare the variables in this study. This model allowed for the variables to have fixed effects within the same parameters, granting the ability to compare AER, distance, and MIF with their different units. The model was fit to the data obtained for exposure level (represented by the aerosol concentration) and for the SWPF. Accordingly, the effects of the studied factors, such as AER, distance, and MIF were examined. If any factor was found statistically significant, a multiple comparison method (Tukey's contrast test) was performed to look for the differences among multi-levels of each factor and identify the trend in reduction. A p-value of < 0.05 was considered to be statistically significant. Statistical analysis was performed in R-Studio (version 1.1.447, The R Foundation, New Zealand).

RESULTS AND DISCUSSION

Unprotected HHW

The particle concentration values measured in 6-second increments in the breathing zone of an unprotected subject across the entire set of conditions ranged from 7,118 cm^{-3} to 284,600 cm^{-3}. The concentrations found in this investigation were generally in excess of those measured in the field (Elmashae *et al.*, 2017) (the upper limit was about 5-fold greater) suggesting that this simulation study represents a conservative case. Fig. 2 presents the measurement results. Increase in each of the factors (AER, distance, and MIF) led to the decrease in aerosol exposure. As expected, the aerosol concentration was highest at AER = 0 and when the HHW was in the closest proximity to the nebulizer outlet. The concentration decrease was less pronounced (with respect to distance) when the AER was 5 or 17 h^{-1}, compared to AER = 0. The highest level of data variation was found for the 6-inch distance because the particle dispersion via the manikin exhalation introduced variability that was much more evident within closer proximity.

The effect of AER, distance, and MIF on the inhalation aerosol exposure of an HHW was significant (p < 0.001), as shown in Table 2. The mixed effect model revealed that the AER in the chamber was the most significant factor reducing the particle concentration. AER was 5-fold more effective than the proximity, and 4-fold more effective than MIF. In fact, with the introduction of fixed AER, such as 5 or 17 h^{-1}, the distance and MIF were no longer significant (p > 0.05). In addition, an increase of AER from 5 to 17 h^{-1} did not provide the same substantial reduction as seen when AER increased from 0 to 5 h^{-1}. This suggests that an introduction of air exchange as little as 5 h^{-1} could significantly reduce the aerosol exposure of an HHW in a home environment, and it may not be necessary to establish an AER as high as the one used in hospital operating rooms (e.g., 17 h^{-1}) to effectively decrease the inhalation exposure risk. Fig. 3 demonstrates the concentration reduction as AER is increased.

Based on Tukey's contrast test, proximity to the source had the most substantial effect on the particle concentration in the HHW's breathing zone only when there was no air exchange. The particle concentration decrease with the distance was significant (p < 0.001) but appeared less pronounced as the distance increased beyond 24 inches. Therefore, the benefit of distance from the source of the nebulizer-aerosolized medication diminishes because of the air dilution factor. When the chamber was ventilated (AER = 5 and 17 h^{-1}), the overall concentration in the environment was approximately one-tenth the level measured with no ventilation, and the distance did not appear to affect the concentration as much (Fig. 2). However, the concentration decreased significantly whenever the distance increased with two exceptions: (1) between 6 and 12 inches (AER = 5 h^{-1}, MIF = 15 L min^{-1}); and (2) between 12 and 24 inches (AER = 17 h^{-1}, MIF = 30 L min^{-1}). The estimated effect of distance on particle concentration in a ventilated environment was much lower than that with no ventilation. Therefore, in a well-ventilated room, increasing the distance to the patient may not be an effective way to substantially reduce the exposure level. It is acknowledged that this also depends upon how the ventilation system is configured.

These findings are generally consistent with our pilot study (Elmashae *et al.*, 2018) that utilized a more simplistic approach for assessing the aerosol particle concentrations during nebulizer use at distances of 6, 12, and 21 inches from the source involving two manikins and no air exchange factor.

Similar to distance, the patient's MIF significantly reduced particle concentration (p < 0.001) as was shown by the comparison of the data obtained at 15 and 30 L min^{-1}, but only had a substantial effect when there was no ventilation present. However, this finding can be at least partially attributed to the experimental design, and not
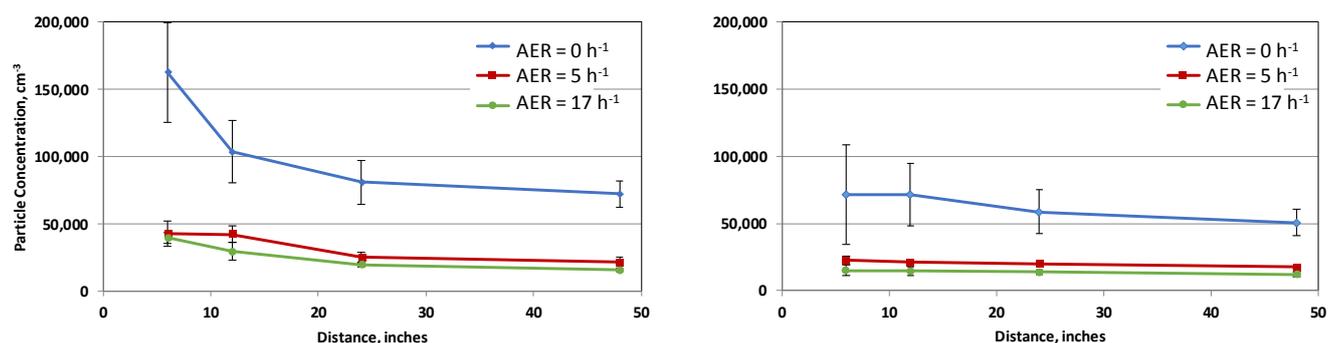
Fig. 2. The effect of the HHW's proximity to the patient-manikin (distance) and of the AER on the aerosol particle concentration in the HHW's breathing zone at manikin's MIF of 15 L min^{-1} (A) and 30 L min^{-1} (B). Each data point represents an arithmetic mean and standard deviation of six measurements.

Table 2. Statistical results of the Mixed Effect Model involving the Air Exchange Rate (AER), Distance, Mean Inspiratory Flow (MIF) rate and their interactions.

Environmental Factors	Estimated Effect Value	Std. Error	Degrees of Freedom	t-value	p-value
Intercept	12.786709	0.06811332	8675	187.72701	0.0000
AER	−0.208143	0.01371614	8675	−15.17502	0.0000
DISTANCE	−0.037332	0.00134901	8675	−27.67400	0.0000
MIF	−0.052838	0.00133073	8675	−39.70609	0.0000
AER:DISTANCE	0.000983	0.00062669	8675	1.56883	0.1167
AER:MIF	0.000032	0.00069705	8675	0.04645	0.9630
DISTANCE:MIF	0.000918	0.00006275	8675	14.62228	0.0000
AER:DISTANCE:MIF	0.000005	0.00002895	8675	0.17399	0.8619
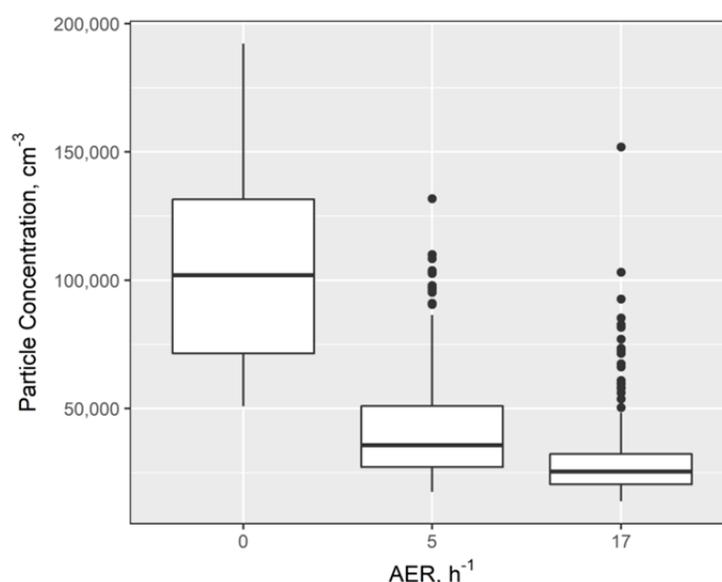
Fig. 3. The effect of AER on the aerosol particle concentration while the subject stood at 12 inches and manikin's MIF was 15 L min^{-1}. The increase of the AER from 0 to 5 h^{-1} decreased the particle concentration most significantly.

necessarily to the effect of MIF per se. As a HEPA filter was placed between the breathing simulator and the manikin's breathing line, more particles were naturally drawn onto the filter at 30 L min^{-1} compared to 15 L min^{-1}, thus decreasing the overall aerosol concentration in the environment. Additionally, increase in MIF improves the air mixing around the manikin and enhances the evaporation of the nebulizer-generated droplets. We visually observed a dense cloud at MIF = 15 L min^{-1} around the nebulizer mask, which essentially disappeared (or got diluted) once the flow rate was increased to 30 L min^{-1}. This likely affected the aerosol concentration in the room and, consequently, the particle concentration that we measured in the breathing zone of the healthcare worker. An increase

in MIF during a fixed ventilation rate was statistically significant, but the estimated effect was of much lower magnitude compared to the effect of ventilation.

Protected HHW

When the subject was wearing the surgical mask, the particle concentrations measured in 6-second increments inside the mask across the entire set of conditions ranged from 58 to 128,400 cm^{-3}, and the values of $SWPF_{TWA}$ varied from GM = 2.58 (GSD = 1.23) to GM = 6.55 (GSD = 1.16) (Fig. 4). Thus, the surgical mask provided low respiratory protection, which is consistent with findings of numerous studies (Chen and Willeke, 1992; Rengasamy *et al.*, 2004; Grinshpun *et al.*, 2009; Booth *et al.*, 2013; He *et al.*, 2013; Gao *et al.*, 2016; Grinshpun *et al.*, 2016; Elmashae *et al.*, 2017). It should be noted that a surgical mask was never intended to be an effective respiratory protective device for the wearer, but was designed to reduce exposure of others to the wearer-released particles. There was no consistent significant trend in which the AER and distance affected the SWPF of the surgical mask.

The particle concentrations inside the N95 FFR obtained in 6-second increments ranged from 32 to 7,324 cm^{-3}, and the $SWPF_{TWA}$ varied from GM = 62.1 (GSD = 1.21) to GM = 101.6 (GSD = 1.13) (Fig. 4). No significant effect of either distance or AER was identified ($p > 0.05$). An HHW wearing an N95 FFR will be significantly ($p < 0.001$) better protected than an individual wearing a surgical mask (Fig. 4). The respiratory protection improvement was on average around 20-fold.

The SWPFs of the surgical mask tested in the present simulation study were comparable to workplace protection factors obtained in the field investigation of Elmashae *et al.* (2017) that was conducted in a real home healthcare environment with different working tasks including a nebulizer treatment; the SWPFs of the tested N95 FFR were somewhat higher than the field measured values. The

difference may be attributed to various reasons, e.g., the fact that the subject in our study was less active than the actual workers performing multiple tasks in a home; consequently, less intense body movement helped maintain the respirator fit resulting in higher measured SWPF.

Among all factors affecting the aerosol exposure of an HHW tested in this investigation, wearing an N95 FFR was the most effective means for exposure reduction.

CONCLUSIONS

This simulation study suggests that for an unprotected HHW administering nebulizer-aerosolized medications, some form of ventilation (air exchange) is the most effective way of reducing aerosol exposure. This ventilation does not have to be as effective as in a hospital room; an AER of 5 h^{-1} could be sufficient to significantly reduce the exposure risk. Proximity to the aerosol source matters, but its effect diminishes once the distance increases beyond 24 inches.

The SWPF offered by a surgical mask was significantly lower than that of the N95 FFR, as expected. Among all the factors affecting the aerosol exposure of an HHW that were tested in this investigation, wearing an N95 was the most effective way to reduce exposure. Therefore, an HHW should consider wearing an N95 FFR during home visits to decrease the risk of exposure to nebulized medications. We fall short, however, of claiming that N95-grade FFRs adequately protect an HHW from these hazards or identifying a specific level of respiratory protection that must be achieved. This is because no permissible exposure limits have been established for most of the medications delivered by medical nebulizers. We note that other types of control (e.g., source control) may be as effective as or even more effective than respiratory protection—for instance, a better-designed nebulizer delivery system that reduces fugitive aerosol exposure may help minimize the
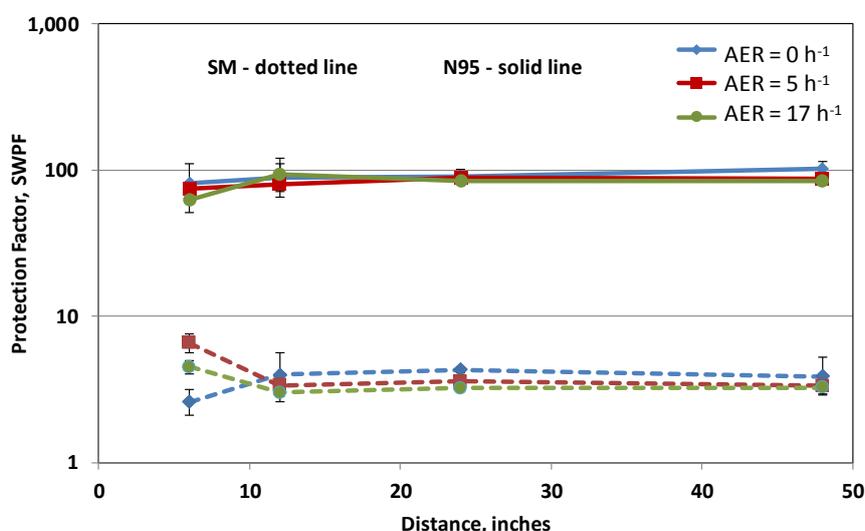
Fig. 4. SWPFs of the surgical mask (SM) and the N95 FFR determined at different HHW's proximities to the aerosol source and different air exchange conditions. The patient-manikin's MIF was 15 L min^{-1}. Each data point represents an arithmetic mean and standard deviation of three measurements.

release of aerosol into the environment and thus reduce healthcare workers' exposure to medications—but these alternatives were not examined in our study.

It is acknowledged that while the present study considerably expanded the scope of our earlier investigation (Elmashae *et al.*, 2018), it is still a simulation study and, as such, has limitations. Future investigations should be conducted in homes to improve the assessment of HHWs' exposure to aerosolized medications delivered by different nebulizers as well as to other aerosol hazards, which, in turn, will help us to better understand the potential role of respiratory protective devices in controlling the aerosol exposure of these workers.

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