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A manikin-based assessment of loose-fitting powered air-purifying respirator performance at variable flow rates and work rates

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ABSTRACT

Loose-fitting powered air-purifying respirators (PAPRs) are used in healthcare settings, although barriers to routine, everyday usage remain, including usability concerns and potential interference with work activities. Loose-fitting PAPRs are approved by the National Institute for Occupational Safety and Health (NIOSH) and must meet minimum performance requirements, including a minimum airflow requirement of 170 L/min. One course of action to address usability concerns is to allow for the use of PAPRs designed with reduced airflow rates. The primary objective of this study was to assess the effect of PAPR flow rate and user work rate on PAPR performance, using a manikin-based assessment method. PAPR performance was quantified using the "Manikin Fit Factor" (mFF), a ratio of the challenge aerosol concentration to the in-facepiece concentration. Flow rates from 50-215 L/min and low, moderate, and high work rates were tested. Two models of NIOSH Approved loose-fitting facepiece PAPRs were tested, both having an Occupational Safety and Health Administration Assigned Protection Factor (APF) or expected level of protection, of 25. A two-way analysis of variance with an effect size model was run for each PAPR model to analyze the effects of work rate and flow rate on PAPR performance. Flow rate and work rate were found to be significant variables impacting PAPR performance. At low and moderate work rates and flow rates below the NIOSH minimum of 170 L/min, mFF was greater than or equal to 250, which is 10 times the OSHA APF of 25 for loose-fitting facepiece PAPRs. At high work rates and flow rates below 170 L/min, mFF was not greater than or equal to 250. These results suggest that some loose-fitting facepiece PAPRs designed with a flow rate lower than the current NIOSH requirement of 170 L/min may provide respirator users with expected protection at low and moderate work rates. However, when used at high work rates, some loose-fitting facepiece PAPRs designed with lower flow rates may not provide the expected level of protection.

KEYWORDS

Faceseal leakage; healthcare; loose-fitting facepiece; manikin fit factor; PAPR; usability

Introduction

Powered air-purifying respirators (PAPRs) are respiratory protective devices that use a blower motor to pull ambient air through an air-purifying element (particulate filter or chemical cartridge) and then deliver that filtered air into a respiratory inlet covering (RIC). PAPR RICs can be classified into the following categories: tight-fitting facepiece (half or full), loose-fitting facepiece, or loose-fitting hood or helmet. As defined by the Occupational Safety and Health Administration (OSHA), tight-fitting facepieces form a complete seal to the face, loose-fitting facepieces form a partial seal to the face, and a hood completely covers the head

and neck and may also cover portions of the shoulders and torso (OSHA 1998). Depending on the type of RIC, loose-fitting PAPRs are designated an Assigned Protection Factor (APF) of either 25 or 1,000 by OSHA. APF is defined by OSHA as the "workplace level of respiratory protection that a respirator or class of respirators is expected to provide to employees when the employer implements a continuing, effective respiratory protection program" (OSHA 1998). Loose-fitting facepiece and loose-fitting hood PAPRs are both designated an APF of 25; however, loose-fitting hood PAPRs can be designated an APF of 1,000 if the respirator manufacturer provides evidence that the respirator demonstrates performance at a level of

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protection of 1,000 or greater through a workplace or simulated workplace study (OSHA 1998).

Loose-fitting PAPRs are used in the healthcare industry, with 78% and 77% of professional nursing society survey respondents having reported using a PAPR in their facility in the past year in 2014 and 2015, respectively (Wizner et al. 2016). However, PAPR prevalence in health care is below that of N95 filtering facepiece respirators (FFRs), with 94% and 95% of survey respondents having reported using an N95 FFR in their facility in the past year in 2014 and 2015, respectively (Wizner et al. 2016). PAPR use in healthcare has been documented during infectious disease outbreaks and pandemics such as the acute respiratory syndrome (SARS) outbreak in 2003 (Khoo et al. 2005), the H1N1 influenza pandemic in 2009 (Rebmann and Wagner 2009), the 2014 Ebola virus outbreak (Beam et al. 2016), and the current COVID-19 pandemic (Chen et al. 2020; Licina and Silvers 2021). Public health emergencies such as pandemics often create a sudden increased demand for respiratory protection and a subsequent shortage of singleuse FFRs (OSHA 2007). Thus, there is a need for alternative classes of reusable respiratory protection such as PAPRs in healthcare during public health emergencies to mitigate potential FFR shortages.

Despite the demand for PAPRs during emergency response, there are documented barriers to routine PAPR usage in healthcare (Liverman et al. 2014; Hines et al. 2019). Barriers include the challenges of learning how to use and maintain PAPRs, as they require the assembly of multiple parts, battery charging, and filter replacement. Other problems include interference in the work of healthcare professionals due to the heavy, cumbersome, and noisy nature of belt-mounted blower motors and hose attachments. These issues are particularly apparent when comparing the usability of FFRs to PAPRs.

Contrary to these disadvantages of PAPR use in healthcare, advantages of loose-fitting PAPRs as compared to FFRs include reusability, the absence of a fit test requirement, the covering of the face and eyes as a fluid barrier, negligible breathing resistance, allowance of facial hair, and higher APFs of 25 or 1,000 (FFRs have an APF of 10). Additionally, some healthcare workers report a preference for using a PAPR over an N95 FFR during increased threat scenarios as compared to working in normal operations (Hines et al. 2019).

The National Institute for Occupational Safety and Health (NIOSH), which approves respirators in the United States, incorporates the following performance tests for loose-fitting PAPRs with high-efficiency (HE) particulate filters (NIOSH 1995): particulate filtration efficiency, minimum required airflow, silica dust loading, and noise level assessment. Such requirements were established when PAPRs were primarily used in industrial settings such as manufacturing, mining, and construction work. The minimum airflow rate for loose-fitting PAPR approval is 170 L/min, and commercially available PAPRs have been observed to provide airflows of 170-206 L/min (Martin et al. 2006). This performance requirement is in place as a safeguard against a potential source of exposure to airborne contaminants called "over-breathing", or the exceedance of the wearer's inspiratory flow rate to the flow rate of the PAPR (Mackey et al. 2005). In other words, over-breathing occurs when the user inhales air at a higher rate than the PAPR is supplying, resulting in the possibility of unfiltered ambient entering the respirator through the seal with the face. One study observed the average peak inspiratory flow of adults working at light, moderate, and heavy exertions to be 100, 150, and 218 L/min, respectively (Anderson et al. 2006), meaning a minimum flow rate of 170 L/min may protect workers at light and moderate work rates but may leave them exposed to contaminants at heavy work rates. Depending on the health care work environment and the exertion level of health care workers, it is possible that a PAPR design preferred by health care workers for routine usage may differ from one used in general workplace settings. To achieve these potential new PAPR designs, NIOSH approval test requirements would need to be modified and such PAPRs would need to demonstrate that they can achieve their expected level of respiratory protection.

In 2020, NIOSH published an interim final rule to update PAPR performance requirements in 42 CFR Part 84 to accommodate the evolving needs of workers (CDC 2020). Through this interim final rule, NIOSH established a new respirator class, PAPR100, to allow for PAPR designs more suited for healthcare than the previous regulations allowed. This regulatory change had no impact on the existing HE PAPR class, which still exists and is used in general workplace settings. The new PAPR100 requirements replaced the existing silica dust test with either a sodium chloride or dioctyl phthalate filtration efficiency test for series PAPR100-N (not resistant to oil) or series PAPR100-P (strongly resistant to oil), respectively. The HE PAPR silica dust test challenges PAPR systems for 4 hr against a 50-mg/m³ to 60-mg/m³ concentration of silica dust. Thus, for a loose-fitting PAPR with a

required minimum flow rate of 170 L/min, the silica dust loads at least 2,040-2,448 mg of silica dust onto the PAPR filter(s). Unlike the silica dust test, the sodium chloride and dioctyl phthalate filtration tests challenge the PAPR filter at a flow rate of 85 L/min against a total loaded concentration of either 200 mg sodium chloride or 215-415 mg dioctyl phthalate.

By replacing the silica dust test with a sodium chloride or dioctyl phthalate test, the new PAPR-100 classes facilitate the design of PAPRs that provide equivalent protection to the HE PAPR but with potentially smaller batteries, blowers, or filters, through reduced test duration, reduced challenge particle concentration, and reduced challenge airflow rate. The PAPR100 requirements also included a fit assessment and a "low-flow warning device" as a required component, which must alert the user when the PAPR airflow rate falls below 115 L/min for tight-fitting PAPRs or 170 L/min for loose-fitting PAPRs. Thus, the minimum PAPR airflow rate requirement for both tightfitting and loose-fitting PAPRs remained unchanged for the PAPR100 class.

Another potential solution to reduce the weight and noise level of PAPRs may be to create smaller blower motors with lower airflows, potentially improving usability while still providing the expected level of protection. The protection provided by such PAPRs may be acceptable for routine usage when workers are not heavily exerting themselves. For example, health care workers in a Zhu et al. (2019) study performed isolation unit cleaning while having their breathing patterns recorded and were found to have a peak inspiratory flow rates of 107 L/min, placing them in the low to moderate work rate range, with peak inspiratory flows well below the 170 L/min NIOSH minimum for a loose-fitting PAPR.

The primary objective of this study was to determine the effect of two variables on PAPR performance using a manikin-based assessment method: PAPR flow rate and user work rate. It was expected that PAPR performance decreases as work rate increases, as observed by Gao et al. (2016) and Bergman et al. (2017), and that PAPR performance decreases as flow rate decreases, as observed by Matsumura et al. (2019).

Methods

Supplied-air system

An external, filtered, supplied-air system with a controllable airflow rate was developed (Bergman et al. 2019) to replace the PAPR blower motor and filter, which were removed. This was also done for two reasons: (1) to allow for complete control of the flow rate supplied to the PAPR, and (2) to isolate facepiece leakage as the only source of inward leakage (Bergman M et al. 2017). Thus, this study cannot be considered a total PAPR system test, but rather a facepiece leakage test.

PAPR models

Two NIOSH-Approved loose-fitting PAPR models were used in this study and modified to connect to the external supplied-air source with HEPA-filtered air, as described in Bergman et al. (2019): (1) the MaxAir 78SP-36 with disposable cuff (size S/M) (Bio-Medical Devices, Inc., Irvine, CA); and (2) the 3 M Air-Mate with BE-12 face (regular size) (3 M Company, St. Paul, MN). Both models were tested in a loose-fitting facepiece RIC configuration as loose-fitting facepiece PAPRs have a lower APF of 25 compared to the loose-fitting hood or helmet PAPRs, which could potentially be assigned an APF of 1,000. It was thought that the effect of flow rate and work rate on PAPR performance may be more pronounced in loose-fitting facepiece PAPRs due to their design. The MaxAir is a helmet-like design, with the blower motor contained within the helmet beneath the cap and filter. The Air-Mate has an external blower motor and filter connected to the RIC via a flexible hose. All connections from the supplied air source to the PAPR RIC were sealed to ensure there were no sources of leakage. Total inward leakage for loose-fitting PAPRs can be attributed to three possible sources (Bergman et al. 2017): (1) leakage through the gap between the user's face and the RIC (i.e., facepiece leakage); (2) filter penetration; and (3) PAPR components leakage (e.g., hoses, valves, seams). Facepiece leakage was the sole focus of this study, as filter penetration and PAPR components leakage were assumed to be negligible.

Before connecting the PAPR models to the supplied-air system, the flow rates of the commercially available, unmodified PAPRs were quantified. This was done using the setup described in Bergman et al. (2017), by offsetting the positive flow of the PAPR blower motor with a vacuum air pump and bringing the pressure of a container to zero. The two models were tested slightly differently due to the differences in design, with the MaxAir flow being measured from the facepiece and the Air-Mate flow measured from a sealed test chamber. Measured flow rates were set as

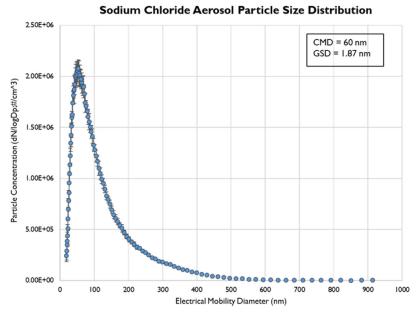


Figure 1. Sodium chloride aerosol particle size distribution (average of five SMPS scans).

maximum values when determining externally supplied airflows for study design.

Aerosol and test chamber

The PAPRs were donned on a medium-sized advanced static headform (Bergman et al. 2014) and placed in an acrylic test chamber, as described in Bergman et al. (2019). The challenge aerosol was 2% w/v sodium chloride (NaCl). The aerosol concentration inside the test chamber and the facepiece were measured simultaneously using two TSI 3022 A condensation particle counters (CPCs). Breathing was simulated using a breathing simulator (model BRSS, Koken Ltd., Japan) that produced a sinusoidal breathing waveform coupled with an external breathing lung with an inflatable bladder.

The chamber concentration was held between 200,000 and 300,000 particles/cm³ during testing. At five randomized points during data collection, a size distribution analysis was run on the challenge aerosol using a scanning mobility particle size spectrometer (SMPS) system (Bergman et al. 2019). Data from the five scans were averaged and resulted in a count median diameter (CMD) of 60 nm with a geometric standard deviation (GSD) of 1.87 nm (Figure 1). An aerosol with a CMD of 60 nm is within the size range typically generated for respirator filter and fit test evaluation.

Experimental design

PAPR airflow rates selected in this study ranged from 50-215 L/min. Six flow rates were selected for each

model-work rate combination; however, flow rates selected for each model-work rate combination varied due to differences in measured operational flow rates (see Methods subsection "PAPR Models") and differences in performance because of work rate. Work rates selected for this study (Table 1) were light, moderate, and heavy, characterized by minute ventilations (V_e) of 25, 48, and 88 L/min, respectively. Each flow rate/work rate combination was replicated five times (n=5). For exact flow rates and work rates assessed for each model; see results Tables S2 and S3 in Supplementary Materials.

Minute ventilation (V_e) is equal to breath frequency multiplied by breath tidal volume (Equation 1). Based on the literature (Anderson et al. 2006), mean peak inspiratory flow () can be estimated from V_e using : V_e ratios of 3.3, 3.2, and 3.1 for light, moderate, and heavy work rates, respectively.

Minute ventilation

$$V_e = f * V_T \tag{1}$$

where

 $V_e = minute \ ventilation$

f = frequency

 V_T = tidal volume

The light work rate represents low-intensity, routine activities, such as checking vital signs, filling IV bags, and walking and pushing a wheelchair (Ainsworth et al. 2011). The moderate work rate would include higher-exertion tasks such as moving a patient or heavy equipment (> 50 lb) between rooms or lightly jogging (Ainsworth et al. 2011). The heavy

Table 1. Work rates and simulated breathing characteristics.

Work Rate	Minute Ventilation (V _e) (L/min)	Frequency (f) (breaths/min)	Tidal Volume (V _T) (L)	Estimated Mean Peak Inspiratory Flow (PIF) (L/min)	PIF : V _e
Light	25	21	0.8	82.5	3.3
Moderate	48	28	1.2	153.6	3.2
High	88	38	2.3	272.8	3.1

Table 2A. Model A two-way ANOVA results.

						Partial Variation Accounted For			
Source	DF	Type III SS	Mean Square	F Value	Pr > F	Partial Eta-Square	Partial Omega-Square	95% Confidence Limits	
flow rate	3	4.71E + 10	1.57E + 10	2.15E + 06	<.0001	1	1	1	
work rate	2	5.63E + 10	2.81E + 10	3.86E + 06	<.0001	1	1	1	
flow rate*work rate	6	4.04E + 10	6.73E + 09	9.24E + 05	<.0001	1	1	1	

Table 2B. Model B two-way ANOVA results.

						Partial Variation Accounted For			
Source	DF	Type III SS	Mean Square	F Value	Pr > F	Partial Eta-Square	Partial Omega-Square	95% Confidence Limits	
flow rate	3	5.10E + 10	1.70E + 10	9.75E + 03	<.0001	0.9984	0.998	0.9968	0.9986
work rate	2	5.07E + 10	2.54E + 10	1.45E + 04	<.0001	0.9984	0.9979	0.9968	0.9986
flow rate*work rate	6	3.78E + 10	6.30E + 09	3.61E + 03	<.0001	0.9978	0.9972	0.9957	0.9981

work rate represents high-exertion tasks such as running upstairs or sprinting (Ainsworth et al. 2011).

Manikin fit factor (mFF)

The experimental output measure (dependent variable) in this study was the Manikin Fit Factor (mFF), which is a measure of respirator performance, specifically facepiece leakage, using a manikin headform.

The mFF is calculated as the ratio of chamber airborne challenge concentration (Cout) to in-facepiece concentration (C_{in}) (Equation (2)). The term mFF is accepted by the American Industrial Hygiene (AIHA®) Respiratory Association Protection Committee (AIHA Respiratory Protection Committee 2022). The mFF values were generated using the mean concentration recorded by each of the two CPCs over 2-min sample times. The data from the upstream and downstream CPCs were logged at a rate of 1 s⁻¹ using Aerosol Instrument Manager software (V.9.0.0.0, TSI Inc.).

Manikin fit factor

$$mFF = \frac{[C_{out}]}{[C_{in}]}$$
 (2)

where

mFF = manikin fit factor

 C_{out} = chamber airborne challenge concentration

 $C_{in} = in$ -facepiece concentration

The facepiece sampling tube was penetrated through the facepiece and placed in the "breathing zone" of the manikin, which is between the nose and the mouth and \sim 2 cm away from the face. The chamber sampling tube was located \sim 2 cm outside the facepiece in line with the manikin's breathing zone.

For each flow rate-work rate combination, five 2min tests were completed in succession, and the outside and inside concentrations were averaged over the course of 2 minutes. The average outside concentration (in particles/cm³) over 2 minutes was divided by the average concentration inside (in particles/cm³) over 2 minutes to yield the mFF value. When reporting results, mFF was capped at 100,000 for two reasons: (1) the false count rate of the CPC instruments; and (2) practicality when considering OSHA APF values.

The model 3022 A CPCs used in this study have a false background particle count of 0.01 particle/cm³, per the manufacturer's user manual. Theoretically, the false background particle count has a negligible effect at higher measured concentrations, but at lower concentrations, the false particle count may represent a larger proportion of the particle count measurement. See Table S1 in Supplementary Materials. With the test chamber concentration maintained at 250,000 particles/cm³, an mFF of 100,000 will have a theoretical false count error of 0.4%. Additionally, 100,000 is more than two orders of magnitude greater than the OSHA APF of 25 for loose-fitting facepiece PAPRs, so reporting values greater than 100,000 lacks practicality when compared to the OSHA APF.

Data analysis

SAS 9.4 (SAS Institute, Cary, NC) was used for data analysis. Before capping the mFF values at 100,000, the Shapiro-Wilk normality test was run on each set of five trials. With a total of 36 sets of tests, 33 did not significantly deviate from normality. For this reason, the arithmetic mean was used to represent the central tendency of the data for results and analyses. A two-way analysis of variance (ANOVA) with an effect size model was run for each PAPR model to determine if the factors of work rate, flow rate, and their interactions were significant factors impacting mFF. The effect size model provided further insight into the main effect and interaction effect contributions to the variance of PAPR performance (mFF).

Results

Mean, standard deviation, and fifth percentile mFF values were calculated for each set of five trials, grouped by model, work rate, and flow rate, and displayed in tabular form (Tables S2 and S3 in supplements). Minimum and maximum mFF among the five trials for each group were also reported. Mean mFFs grouped by model, work rate, and flow rate, with five trials per group, are displayed in graphical representations (Figure 2), with PAPR performance plotted in logscale to illustrate the flow rate and work rate effects. Standard deviations across the five trials for each group are also plotted, though not visible at all points due to the low variability of the data. MFFs for both models responded similarly to changes in work rate and flow rate. Reference lines for an mFF of 250, which is 10 times OSHA APF of 25 for loose-fitting facepiece PAPRs, and a flow rate of 170 L/min, which is the NIOSH minimum flow rate for loose-fitting PAPRs, were overlaid on the plot for reference. Two hundred and fifty, or 10 times the OSHA APF of 25, was used as the "pass level" for the purposes of his study as a safety factor to compensate for potential differences between laboratory measurements and actual protection provided in the workplace and to provide further confidence in the results. Similarly, OSHA designates passing fit factors as 100 and 500 for tight-fitting half facepiece and tight-fitting full facepiece air-purifying respirators, respectively, which is 10 times their APFs of 10 and 50 (OSHA 1998). Thus, although there is no fit test requirement for loose-fitting facepiece PAPRs such as those tested in this study, using 250, or 10 times the OSHA APF of 25, as the passing level for this study aligns with OSHA's methodology for setting the quantitative fit test passing level for other respirator types.

Model A mFFs were greater than or equal to 250 at flow rates as low as 62, 125, and 190 L/min for low,

moderate, and high work rates, respectively. This means that, at low and moderate work rates, PAPR performance was maintained at flow rates below the minimum requirement of 170 L/min. However, there were flow rates at which an mFF greater than or equal to 250 was no longer maintained at both low and moderate work rates. At a high work rate, PAPR performance was not maintained at flow rates below the NIOSH minimum.

Model B mFFs were greater than or equal to 250 at flow rates as low as 75, 125, and 200 L/min for low, moderate, and high work rates, respectively. Thus, at low and moderate work rates, but not high work rates, PAPR performance was maintained at flow rates below the NIOSH minimum, though there were flow rates at which an mFF greater than or equal to 250 was no longer maintained at both low and moderate work rates.

Analysis of variance

A two-way factorial analysis of variance (ANOVA) was run for each PAPR model examining the effect of flow rate, work rate, and their interactions on mFF. See Tables 2A and 2B. Since not every flow rate included in this study was tested with each work rate, the analyses were conducted on only the uniform flow rates that were tested with every work rate to allow for a balanced ANOVA. The model A analysis was conducted on the three work rates (low, moderate, and high) and the following four flow rates, each of which was tested in combination with all three work rates: 50, 100, 150, and 206 L/min. The model B analysis was conducted on the three work rates (low, moderate, and high) and the following four flow rates, each of which was tested in combination with all three work rates: 50, 100, 150, and 215 L/min. The main effect and interaction effect significance was based on $\alpha = 0.05$. Additionally, an effect size measure within each ANOVA model was run. Partial Eta square was calculated to represent the degree of association between the independent variables and their respective interactions, after accounting for the effects of the other variables and interactions, on the variance of the dependent variable mFF. The ANOVA model determined that work rate and flow rate are the main effects significantly impacting mFF. In terms of interaction effects, the analysis found the two-way interaction between flow rate and work rate to also be significant. The effect size measure determined that the effects of flow rate, work rate, and the flow rate-

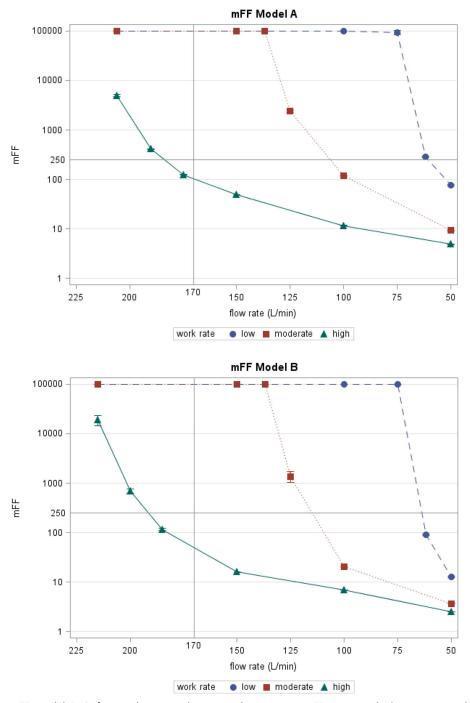


Figure 2. (A) Mean mFF model A. Reference lines are shown on the y-axis at mFF = 250, which is 10 times the OSHA APF of 25 for loose-fitting facepiece PAPRs, and on the x-axis at 170 L/min, which is the NIOSH minimum flow rate for loose-fitting PAPRs. (B) Mean mFF model B. Reference lines are shown on the y-axis at mFF = 250, which is 10 times the OSHA APF for loose-fitting facepiece PAPRs, and on the x-axis at 170 L/min, which is the NIOSH minimum flow rate for loose-fitting PAPRs.

work rate interaction on the variation of mFF were roughly equal.

Discussion

Both analyses determined that work rate, flow rate, and their interactions significantly impact PAPR performance. As expected, as work rate increases, mFF decreases, and as flow rate decreases, mFF decreases.

Gao et al. (2016) and Bergman et al. (2017) found similar associations between work rate and PAPR performance. Both studies donned loose-fitting PAPRs on a static headform and controlled the breathing using a breathing simulator. Gao et al. characterized the breathing rate using mean inspiratory flow (MIF) and found it to significantly affect mFF. Bergman et al. characterized work rate into low, moderate, and high with the same minute ventilation values as in this study and found that work rate significantly affected PAPR performance. Neither of these studies varied the PAPR flow rate within the PAPR model, but both found that increasing the work rate decreases PAPR performance.

Matsumura et al. (2019) found a similar association between flow rate and PAPR performance by varying flow rate from 60-160 L/min using an external laboratory compressed air system, much like in this study. PAPR models were donned on a robotic mannequin that could perform head and arm movements, and inward leakage was measured as a percentage of total chamber concentration. It was found that as the airflow rate decreased, the inward leakage percentage increased. The Matsumura et al. study did not include flow rates greater than the NIOSH minimum of 170 L/min, and the work rates selected were low to moderate, characterized by minute ventilations from 30-40 L/min. As in the present study, Matsumura et al. did not assess the filter penetration of the PAPR filter.

Since routine health care work may be characterized as low to moderate (Zhu et al. 2019), mFFs at these work rates may be indicative of the PAPR performance experienced by health care workers during routine work. The results of the present study suggest that some loose-fitting facepiece PAPRs designed with airflow rates below 170 L/min may maintain their expected protection during common health care activities ranging from walking, talking, checking vital signs, and moving patients in and out of bed (Ainsworth et al. 2011). This is also true when considering the fifth percentile mFF as a safety factor, which provides additional confidence in the results. High work rates, though unlikely to be experienced during routine health care work, are possible during emergencies. Results of this study suggest that some loose-fitting PAPRs designed with airflow rates below 170 L/min may not maintain their expected protection during scenarios in which workers are running upstairs or sprinting down hallways.

Although the impact of the movement aspect of these activities on PAPR performance cannot be assessed using a static, manikin-based method, the effects of breathing tidal volumes and frequencies on the likelihood of over-breathing and subsequent compromise in PAPR performance can be easily controlled and reproduced. These attributes of complete

control and reproducibility of test conditions are the foundation of manikin-based studies.

Limitations

This was a study of PAPR facepiece leakage as opposed to total inward leakage. This is a limitation in that PAPR filter penetration was not assessed. Filter penetration is a critical component of total inward leakage, and filter penetration may be dependent on the PAPR flow rate.

Additionally, the complete PAPR system performance was not tested as an experimental control at varying work rates. Although PAPR operational flows were measured and incorporated into the study design by replicating the operational flow rate using the external supplied-air system, the performance against the sodium chloride challenge aerosol was not assessed using the PAPR blower motor and filter. A direct comparison between PAPR system performance and facepiece leakage with external supplied-air performance would demonstrate that the facepiece leakage measurement output of this study representative of the PAPR system performance. Further studies will examine PAPR total inward leakage with fully configured PAPR systems and varying work rates and flow rates.

Only two PAPR models were assessed in this study, both of which were loose-fitting facepiece PAPRs. Assessing a greater sample size of loose-fitting facepiece PAPRs, as well as other types of RICs such as loose-fitting hoods or helmets or tight-fitting facepieces, would be necessary to draw stronger conclusions about PAPR performance at varying flow rates and work rates and will be completed in future studies. PAPR performance of recently approved PAPR100 respirators at varying flow rates and work rates can also be measured in future studies, as this study was initiated and conducted before the publication of the PAPR100 interim final rule.

This study was conducted on a stationary manikin as opposed to human subjects performing simulated workplace exercises. It is possible that incorporating movement into the mFF measurements would impact PAPR performance due to potential shifting and breakage of the face seal created by certain movements and would be more representative of PAPR performance in workplace settings.

Conclusions

This study determined that PAPR performance is significantly impacted by both flow rate and user work rate, and that performance can be maintained at flow rates below the NIOSH minimum at low and moderate work rates, thereby providing latitude for improvement in usability. This study also suggests that PAPR performance may not be maintained at high work rates with flow rates set below the NIOSH minimum of 170 L/min. However, at all work rates, flow rates at which mFF dropped below 250 were observed.

Future work needs to be done assessing the entire PAPR system at varying flow rates, separating total inward leakage into filter penetration and facepiece leakage as functions of airflow rate. Future work may also involve using other methods to assess PAPR performance at reduced flow rates such as articulated (robotically moving) head forms, human subjects, and computational fluid dynamics (CFD) simulation. Additionally, a larger sample size of PAPR models and a variety of PAPR RIC configurations need to be studied to observe the impact of PAPR design on performance when varying flow rate and work rate.

The initial rationale for this study was the barriers to regular PAPR use in healthcare, with barriers being device complexity and interference in work activities. With this being a manikin-based study, the authors were unable to assess usability. Future work will be completed to assess the effect of the PAPR flow rate on worker usability.

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Conflicting interest

The authors report there are no competing interests to declare.

Disclaimers

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention. The use of trade names is for identification purposes only and does not mean product endorsement by the Centers for Disease Control and Prevention. Mention of any company or product does not constitute an endorsement by the National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention. N95, PAPR100-N, PAPR100-P, HE, and NIOSH Approved are registered certification marks of the U.S. Department of Health and Human Services (HHS).

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Data availability

The data that support the findings of this study are available from the corresponding author upon reasonable

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