Annals of Work Exposures and Health, 2021, 1–13
https://doi.org/10.1093/annweh/wxab069
Original Article

The Chartered Society for Worker Health Protection

OXFORD

Original Article

Physiological Impacts of Surgical Mask Coverage of Elastomeric Half-mask Respirator Exhalation Valves in Healthcare Workers

Eileen Zhuang[1,*], Paul Thurman[2,3], Hegang H. Chen[4], Melissa A. McDiarmid[5] and Stella E. Hines[1,5]

[1]Department of Medicine, Division of Pulmonary and Critical Care Medicine, University of Maryland School of Medicine, 22 S. Greene Street, Baltimore, MD 21201, USA; [2]R Adams Cowley Shock Trauma Center, University of Maryland Medical Center, 22 S. Greene Street, Baltimore, MD 21201, USA; [3]University of Maryland School of Nursing, 655 W. Lombard Street, Baltimore, MD 21201, USA; [4]Department of Epidemiology and Public Health, University of Maryland School of Medicine, 660 W. Redwood Street, Baltimore, MD 21201, USA; [5]Department of Medicine, Division of Occupational and Environmental Medicine, University of Maryland School of Medicine, 11 S. Paca Street, Suite 200, Baltimore, MD 21201, USA

*Author to whom correspondence should be addressed. Tel: +1-410-328-8141; e-mail: ezhuang@som.umaryland.edu

Submitted 19 June 2021; revised 23 July 2021; editorial decision 27 July 2021; revised version accepted 18 August 2021.

Abstract

Objectives: Elastomeric half-mask respirator (EHMR) use in healthcare increased significantly during the COVID-19 pandemic. Concern for potential release of infectious aerosols from EHMR exhalation valves prompted recommendations to cover them with surgical masks (SMs), thereby improving source control. The physiological and subjective effects of wearing a SM over the exhalation valve of an EHMR, however, are unknown.

Methods: Twelve healthy healthcare worker volunteers completed a 30-min series of simulated healthcare-related tasks, including resting, talking, walking, and bending, proning and supinating a weighted manikin, and performing cardiopulmonary resuscitation. This series recurred three times with different mask configurations—SM only, EHMR only, or EHMR with SM covering the exhalation valve. A transcutaneous sensor continuously measured carbon dioxide (tcPCO$_2$), oxygen saturation (SpO$_2$), and heart rate (HR) from each subject. Subjects scored their rates of perceived exertion (RPE) and levels of discomfort after each round. Physiological parameters and subjective scores were analyzed using mixed linear models with a fixed effect for mask type, activity, age, body mass index (BMI), and gender. Analysis also tested for interaction between mask type and activity.

Results: Physiological parameters remained within normal ranges for all mask configurations but varied by task. Statistically significant but small decreases in mean tcPCO$_2$ (37.17 versus 37.88 mmHg, $P < 0.001$) and SpO$_2$ (97.74 versus 97.94%, $P < 0.001$) were associated with wearing EHMR with SM

What's important about this paper

Elastomeric half-mask respirators (EHMRs) have seen increased use during the COVID-19 pandemic, but the concern has been raised that infectious droplets could be transmitted via the exhalation valve. One proposed solution has been to cover the valve with a surgical mask (SM), but the physiological effects of doing so are unknown. We showed that physiological changes associated with wearing a SM over an EHMR while performing healthcare-related tasks such as cardiopulmonary resuscitation are small and clinically insignificant. This suggests that covered EHMRs can be worn safely without adverse physiological effects during healthcare-related tasks. These results are important for healthcare workers, hospital administrators, and other decision makers involved in setting respiratory protection policies in healthcare settings.

over the exhalation valve compared with EHMR alone. Mean HR did not differ between these mask configurations. Wearing SM only was associated with lower RPE and level of discomfort compared with EHMR, but these subjective scores did not differ when comparing EHMR with SM to EHMR only. Age, BMI, and gender had no significant effect on any outcomes.
Conclusions: Wearing a SM over an EHMR did not produce clinically significant changes in $tcPCO_2$, SpO_2, or HR compared with uncovered EHMR during healthcare-related tasks. Covered EHMR use also did not affect perceived exertion or discomfort compared with uncovered EHMR use. Covering the exhalation valve of an EHMR with a SM for source control purposes can be done safely.

Keywords: carbon dioxide; COVID-19; elastomeric respirators; healthcare workers; heart rate; oxygen saturation; PPE

Introduction

The COVID-19 pandemic led to increased use of respiratory protective devices, or respirators, to protect healthcare workers (HCWs) from inhalation of infectious viral aerosols. In the USA, hospitals provide respirators to HCWs in compliance with the Occupational Safety and Health Administration (OSHA) Respiratory Protection Standard (U.S. Department of Labor, 2015). This standard requires that hospitals have comprehensive and effective respiratory protection programs (RPPs) to protect workers from recognized hazards. For many years, hospital RPPs have been part of infection control strategies to limit exposure to diseases such as tuberculosis, measles, or varicella (U.S. Department of Labor, 2015). Most often, hospitals historically used disposable N95 filtering facepiece respirators (N95 FFRs) as a standard tool for HCW respiratory protection (Wizner *et al.*, 2016).

Healthcare facilities have increasingly used elastomeric half-mask respirators (EHMRs) during the COVID-19 pandemic due to shortages in N95 FRs (Hamby, 2020; Fernando *et al.*, 2021). These air-purifying particulate respirators seal tightly to the face with a conformable face mask (Bach, 2017). Unlike single use FFRs, the cartridges on EHMRs can be reused until the filter lifespan is depleted. EHMRs protect wearers to at least the same level as do N95 FFRs, are intended for reuse and can be repeatedly cleaned and disinfected (National Academies of Science Engineering and Medicine, 2019; Barros *et al.*, 2021). Hospitals that incorporated EHMRs into RPPs during this pandemic were less reliant on the unstable N95 FFR supply chain and therefore less likely to leave HCWs vulnerable to inhalational exposure to SARS CoV-2 (Chalikonda *et al.*, 2020; Feinmann, 2020; Hamby, 2020).

Concerns for transmission of SARS CoV-2 in the exhaled breath of asymptomatic infected people prompted universal masking guidelines during the COVID-19 pandemic (Fisher, 2020; Suzanne, 2020). A primary aim of masking was source control, meaning limiting emission of infectious respiratory droplets in exhaled breath. However, one EHMR feature raised some questions about their ability to provide source control, in addition to user protection. Prior to 2020, all EHMRs had exhalation valves. These valves use a one-way filterless membrane over an opening, allowing the wearer's breath to leave the respirator directly, leading to greater user comfort and lower expiratory airflow resistance (Fernando *et al.*, 2021). This feature created a distinction from the traditional un-valved tight-fitting N95 FFRs used in healthcare RPPs, which have no outward leakage. In 2020, however, loose-fitting surgical or procedural masks—not N95 FFRs—had become the standard of care for source control in healthcare settings (National Center for Immunization and Respiratory Diseases (NCIRD), Division of Viral Diseases, Centers for Disease

Control and Prevention, 2020). These masks allow significant amounts of outward leakage (NIOSH, 2020). Compared with these loose-fitting options, the degree to which EHMRs allowed release of exhaled breath was not known.

Questions quickly arose regarding the potential for infectious material to be emitted from the exhaust valve of an EHMR worn by a HCW (Chang *et al.*, 2020; Springer, 2021). This prompted precautionary guidance to cover the exhaust valve of an EHMR. One strategy involved covering the valve with a surgical mask (SM), which aims to limit exhaled breath to at least the same level as that emitted from a traditional SM (NIOSH, 2020). The solution would be practical in hospitals, where SMs are already used and can easily be placed over the front of the EHMR.

Covering the exhalation valve of an EHMR bears potential negative user consequences. Foremost, covering the exhalation valve may increase respirator airflow resistance, carbon dioxide (CO_2), and moisture buildup. This may alter comfort and breathability of the respirator and lead to alterations in physiological endpoints among users, such as CO_2 retention, drop in oxygen saturation (SpO_2), or increases in heart rate (HR). Although physiological impacts from covering the exhaust valve of N95 FFRs have been studied, no studies have evaluated similar impacts with EHMRs (Roberge *et al.*, 2010a,c; Kim *et al.*, 2013). In studies where SMs were placed over N95 FFRs, both with and without exhalation valves, there were no impacts on physiological endpoints assessed following 1 h of treadmill walking, such as SpO_2, HR, or transcutaneous carbon dioxide ($tcPCO_2$), which is a validated surrogate measure for partial pressure of dissolved arterial carbon dioxide (Chang *et al.*, 2020; NIOSH, 2020; Springer, 2021). Respirator scientists hypothesize that the physiological impacts of SM placement over the exhalation valve of an EHMR leads to similar nonsignificant physiological impacts as seen in N95 FFR-based studies.

The objectives of this study were to evaluate physiological parameters and changes incurred by wearing an EHMR covered by a SM during simulated healthcare work tasks likely to be experienced during provision of critical care services. We also aimed to examine the effect of wearing EHMR on users' subjective experiences, including comfort and perceived exertion. We hypothesized that use of an EHMR covered by a SM during healthcare-related task simulations would result in no significant increases in $tcPCO_2$, drops in SpO_2, or increases in HR compared with uncovered EHMRs, but would lead to lower comfort ratings and higher perceived exertion scores.

Methods

Study subjects

We recruited a convenience sample of 12 HCWs for this study, similar in design to prior physiology studies of respirator wearers (Harber *et al.*, 1982, 1984; Louhevaara *et al.*, 1986; Caretti *et al.*, 2006; Roberge *et al.*, 2010a, b, c; Kim *et al.*, 2013). Subjects were recruited from physicians, advanced practice providers, nurses, and respiratory therapists who worked at the study hospital. Eligibility requirements included age over 18 years, completion of medical clearance and fit-testing to wear this study's EHMR, and basic life support certification to perform cardiopulmonary resuscitation (CPR). Exclusion criteria included self-reported untreated respiratory or cardiac disorders, facial hair that would interfere with correct fitting of an EHMR, and self-reported pregnancy. Pregnant workers were excluded due to the known alterations in respiratory physiology incurred at various stages of pregnancy. Participants self-reported their height, weight, and age. The study was approved by the University of Maryland, Baltimore institutional review board, and all subjects provided written informed consent. Participants received payment for their time.

Mask characteristics

During each simulation session, each participant was provided a new SM and a new EHMR according to their assigned size from prior fit-testing. We used Halyard™ Fluidshield® 3 ASTM level 3 ear-loop SMs with attached eye shield, and 3M™ 7500 Series EHMRs with new 3M™ 7093 P100 filters. Subjects placed the SM over the EHMR by securing one ear loop and then pulling the mask over the front of the respirator, extended so that the lower edge fully covered the downward-facing exhalation valve of the EHMR, and then looping over the other ear (Fig. 1). The study team visually inspected each participant's SM over EHMR placement to confirm that the SM covered the exhalation valve.

Physiological monitoring

Subjects' physiological parameters were monitored continuously throughout the simulation protocol using a noninvasive transcutaneous device (SenTec Digital Monitoring System, SenTec Inc., Lincoln, RI). These parameters included $tcPCO_2$, SpO_2, and HR. Monitoring probes were attached to participants' foreheads per manufacturer instructions and secured with clear dressing. An onsite manufacturer representative assisted with setup and calibration. The recorded physiological values were downloaded and exported using

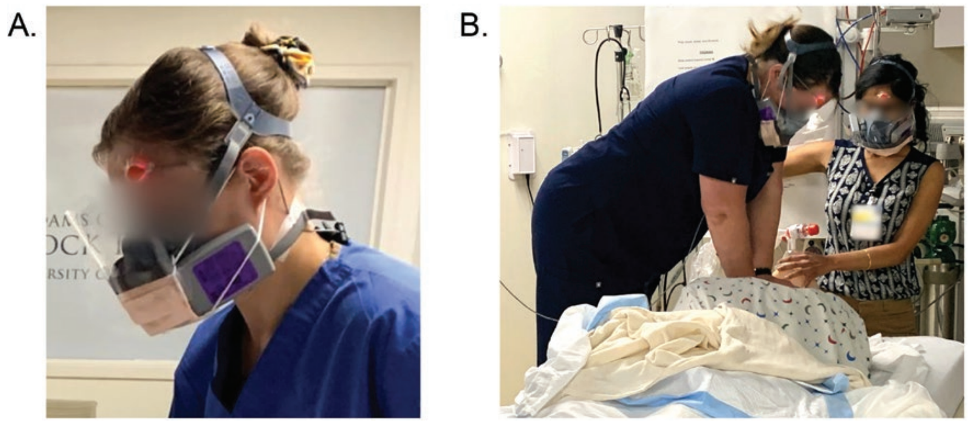

Figure 1. Photos taken during HCW simulation sessions. (A) SM worn over EHMR. (B) HCWs engaged in the CPR sequence tasks of compressions and bagging while wearing EHMR + SM.

manufacturer software (V-Stats, SenTec Inc., Lincoln, RI).

Simulation protocol

A 30-min series of tasks was designed to simulate common healthcare-related activities (Table 1). We held three simulation sessions with four participants in each session. Each group of participants performed this task series a total of three times, each time wearing a different mask configuration—SM only, EHMR only, and EHMR with SM worn over the exhalation valve (EHMR + SM). No tasks occurred with participants completely unmasked due to COVID-19 requirements for universal masking at the time. The order of the mask configurations was randomized for each group. At the beginning of each simulation session, research staff presented verbal and written instructions and demonstrations of the tasks to participants. Each 30-min round occurred continuously, with each time interval and activity announced by research staff. Between rounds, a 15-min rest period allowed physiological parameters to return to baseline, during which time subjective assessments were administered as below.

For the proning and supining tasks, a 100-pound simulation manikin was prepared on a bed in the supine position, with a weighted vest and ankle weights to bring the total weight to approximately 172 pounds to simulate more realistic adult body weight (Fryar *et al.*, 2021). Proning was selected as a task that has seen increased use and attention during the COVID-19 pandemic (Mathews *et al.*, 2021). As it requires manually moving patients who may be heavy, critically ill, intubated, sedated, and unable to participate in transferring, proning is a potentially risky procedure that involves both physical exertion and mental stress. A simplified proning and supining protocol (described below) was created to standardize the process in all groups. Verbal and written instructions were available to participants during the simulation. Two participants were positioned on each side of the bed with the simulation manikin, one at the chest and one at the feet. The group then transferred the manikin from a supine position to a prone position in a coordinated fashion. Then, on each side of the bed, the participants at the head/chest and feet switched positions, to account for potential differences in exertion due to weight distribution of the manikin. Afterwards, the group transferred the manikin from a prone position back to a supine position. The proning and supining process was then repeated once more. Research staff removed chest weights from the weighted vest prior to the next sequence involving CPR and placed a backboard underneath the manikin. Immediately following this 7-min proning and supining task series, participants proceeded to the CPR sequence.

The 16-min CPR sequence was divided into eight 2-min rounds. During each round, each subject performed one of four tasks—providing bag-valve-mask ventilation (bagging) to the manikin, or counting chest compressions aloud chest compressions, resting. These were performed in a predetermined order as shown in Table 1. Chest compressions and bagging were performed in a 30:2 ratio. A laptop with visual feedback regarding the quality and depth of chest compressions was visible to participants, and a metronome set to 100 beats per minute provided audiometric feedback regarding desired speed of compressions. As an example, Fig. 2 shows HCWs engaged in the CPR sequence tasks of compressions, bagging, and resting while wearing EHMR + SM.

Table 1. Thirty-minute HCW task sequence.

Task	Time (min)	Description			
Rest (control)	2	Sit at rest wearing SM only			
Don mask	1	Put on test mask configuration			
Rest (test)	2	Sit at rest wearing test mask configuration			
Read	1	Read the 'Rainbow Passage' aloud			
Walk	1	Walk in place, and every 10 steps, squat to ground and simulate picking up an object			
Prone and supine	7	Prone and supine a 172-pound simulation manikin			
CPR	16	Take turns performing eight 2-min periods of chest compressions on a simulation manikin, resting, bagging, and counting compressions aloud			
			Subject A	Subject B	Subject C	Subject D
		Round 1	Compress	Rest	Bag	Count
		Round 2	Rest	Bag	Count	Compress
		Round 3	Bag	Count	Compress	Rest
		Round 4	Count	Compress	Rest	Bag
		Repeat the above for rounds 5–8				

Subjective assessments

At the beginning of the rest period immediately after each 30-min simulation round, subjects were seated and asked to complete two subjective assessments. To assess rate of perceived exertion (RPE), a standard Borg RPE scoring scale was administered with scores ranging from 6 to 20, where higher scores indicated higher levels of perceived exertion (Borg, 1998). A modified perceived comfort scale was administered, with scores ranging from 1, indicating 'very slightly or not at all uncomfortable', to 5, indicating 'extremely uncomfortable' (Roberge *et al.*, 2010b).

Statistical analysis

Data points for each participant were collected to the second (5820 observations/participant) by the SenTec monitor for the measurements of SpO_2, $tcPCO_2$, and HR. Measures were exported from V-CareNet software (SenTec Inc.) into an Excel file (Microsoft, Inc.), then transferred to SPSS (IBM, Inc.). These data were aggregated using the mean, median, and maximum for each variable to the minute (97 observations/participant) creating a data measurement file. Time points for each participant, activity, and mask configuration were recorded in a research file. The data measurement file was joined to the corresponding time with a 30-s lag in the research file, adding the demographic and activity variables. This lag accounts for the physiological lag between activity and change in peripheral values (Sentec, 2020). A time series variable was created for each participant's measurements so that the baseline time was zero and each activity was an increase by one.

All variables were examined for normality. SpO_2 was transformed using winsorizing because of lack of normality. Missing values were handled using listwise deletion. The joined research and measurement file was utilized to create spaghetti graphs for each participant over the activities and mask configurations to examine the variation between participants and within groups. The mean value and confidence interval for all participants were graphed for each mask configuration over the activities. As each measurement point was from the same person, the assumption of independence was violated. Thus, mixed linear models were used where the correlation between the repeated measurements was captured by including participants as a random variable, to examine the relationship of the mask configuration and activity to each physiological measure. The intraclass correlation coefficient for $tcPCO_2$, SpO_2, and HR was 17, 1, and 32%, respectively, in the null models, indicating that a large proportion of the variance occurred within groups, further justifying the use of mixed

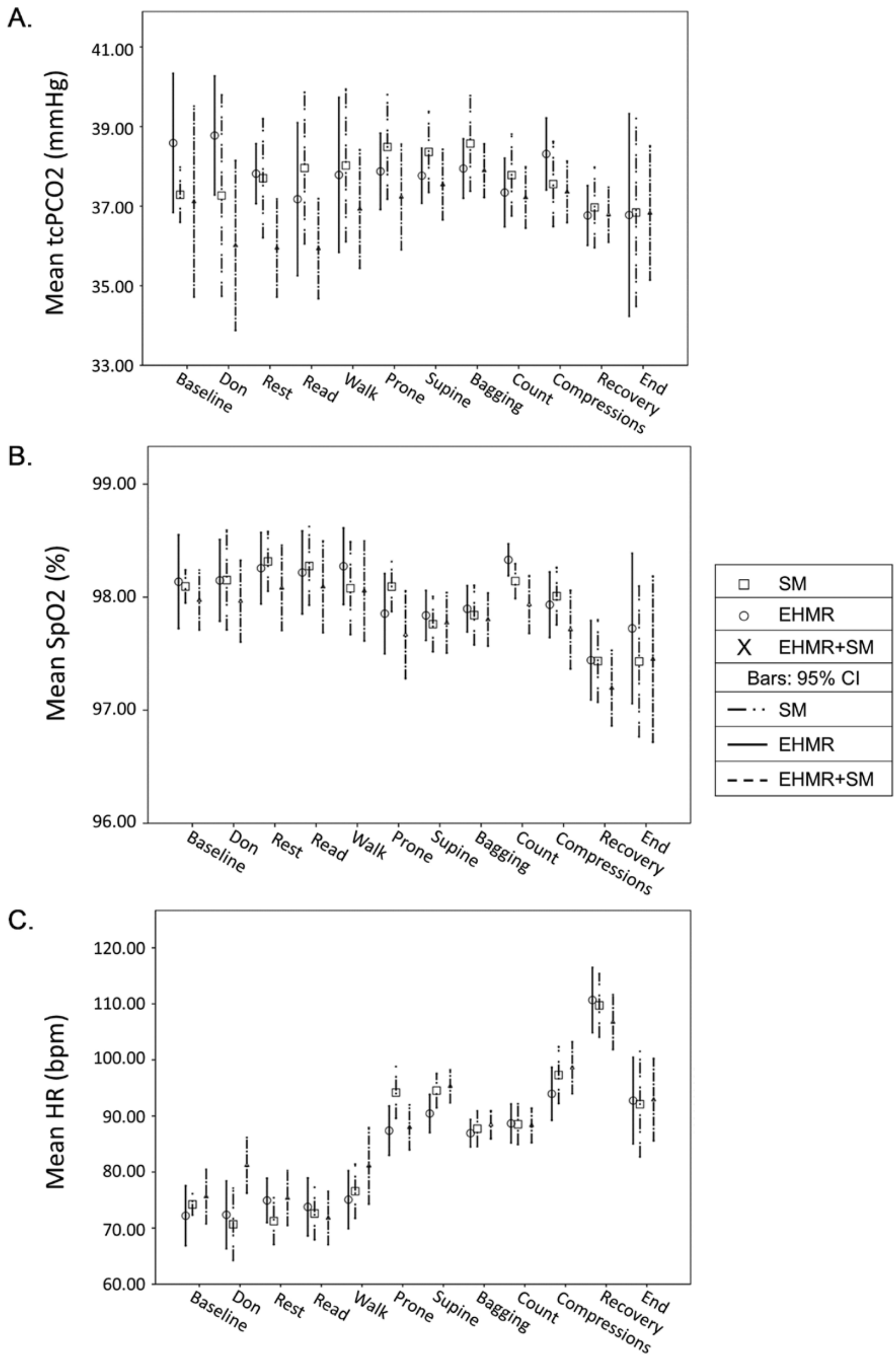

Figure 2. Mean physiological parameters with 95% confidence intervals by mask and activity, shown for (A) $tcPCO_2$, (B) SpO_2, and (C) HR, unadjusted. CI, confidence interval.

models. Bivariate modeling was carried out for mask configuration, activity, gender, and body mass index (BMI). Although some participant characteristics did not reach significance, they were included as control variables. Age and BMI were examined both as continuous and categorical variables. Age was categorized to <35 and ≥35 and BMI was categorized to <25 (indicating normal weight) and ≥25 (indicating overweight or obese). Final models included only mask type, activity, BMI, gender, and age. Comparisons were made between the full models using the mean aggregates for $tcPCO_2$, SpO_2, and HR. Models were examined for interactions between mask configuration, activity, BMI, and age.

Results

Participant characteristics are described in Table 2. Most were under 35 years old, women, and had normal body mass (BMI <25).

Physiological endpoints and tasks

Group mean and standard deviation (SD) values for $tcPCO_2$ for all activities averaged over all mask configurations were 37.51 ± 2.97 mmHg (normal range 35–45 mmHg) (Messina and Patrick, 2020). Mean and SD SpO_2% (normal 95–100%) and HR (beats per minute, normal 50–90 at rest) values were 97.87 ± 0.90 and 89.92 ± 16.73, respectively (Nanchen, 2018; Hafen and Sharma, 2021). Physiological parameters remained in normal ranges but varied per task. For $tcPCO_2$, compared with baseline values (37.38 mmHg), $tcPCO_2$ increased by 0.42 mmHg during chest compressions and fell during the immediate recovery period by 0.47 mmHg. Compared with baseline values (98.09%), SpO_2 fell slightly during supining (−0.3%), chest compressions (−0.21%), recovery (−0.71%), and at the end of the test sequence (−0.55%). HR varied the most with task, rising compared with baseline (74.36) during proning (+15.44), supining (+18.88), bagging (+13.90), counting (+14.03), compressing (+22.09), and recovery (+35.20).

Table 2. Demographic characteristics of HCW participants.

Subject #	Gender	Age (years)	BMI (kg/m²)
1	F	31	21.3
2	F	55	23.5
3	F	25	19.4
4	F	26	19.5
5	M	28	31.2
6	F	38	34.1
7	F	34	17.5
8	F	29	29.0
9	F	43	31.2
10	F	35	24.8
11	F	33	22.0
12	F	33	18.3

Physiological endpoints and mask configuration

Table 3 shows overall mean physiological values for each mask configuration. $tcPCO_2$ and SpO_2 differed for the EHMR + SM compared with uncovered EHMR ($P < 0.001$). These differences, however, were minor, less than 1 mmHg for $tcPCO_2$ and less than 1% for SpO_2, with all values for each mask configuration remaining within the normal physiological range (Table 3). There were no differences in HR between mask configurations. Additionally, physiological outcomes during SM use were not significantly different from uncovered EHMR use. Fig. 2 shows mean and 95% confidence intervals for physiological outcomes during different tasks, averaged by mask configuration. When adjusted for task, testing sequence, age, BMI, or gender, the statistical relationships persisted in comparison of EHMR + SM compared with EHMR, ($P < 0.01$ for $tcPCO_2$, $P < 0.01$ for SpO_2, and $P > 0.05$ for HR). Age, BMI, gender, or CPR task sequence did not significantly affect physiological outcomes associated with mask configuration. There were no significant interactions between mask configuration and activity, for $tcPCO_2$, SpO_2, or HR.

Table 3. Overall mean $tcPCO_2$ level, SpO_2, and HR values observed under different face mask configurations.

	Mean $tcPCO_2$ (SE) (mmHg)	Mean SpO_2 (SE) (%)	Mean HR (SE) (beats per minute)
EHMR (ref)	37.88 (.81)	97.94 (.15)	89.99 (2.49)
SM	37.74 (.81)	97.94 (.15)	88.49 (2.47)
EHMR + SM	37.17 (.81)***	97.74 (.15)***	91.38 (2.48)

SE, standard error.
***Compared with EHMR, $P < 0.001$.

Table 4. Subjective assessments by mask configuration, compared with uncovered EHMR use.

Mask type	Mean (SE)
(A) RPE	
EHMR (ref)	13.08 (0.58)
SM	11.37 (0.58)*
EHMR + SM	13.54 (0.58)
(B) Perceived comfort scores	
EHMR (ref)	2.17 (0.18)
SM	1.25 (0.18)*
EHMR + SM	2.42 (0.18)

SE, standard error. RPE scale, 6 = no exertion at all, to 20 = maximal exertion. Perceived comfort score, 1 = very slightly or not at all uncomfortable, to 5 = extremely uncomfortable.
*$P < 0.05$.

Subjective assessments

HCWs rated perceived exertion during use of EHMR with or without SM similarly, and in the range of 'somewhat hard' per the Borg RPE scale (Table 4) (Borg, 1998). Similarly, HCWs rated perceived comfort similarly for covered and uncovered EHMR and in the range of 'a little uncomfortable' (Roberge *et al.*, 2010b). HCWs perceived lower exertion ('light') and less discomfort ('very slightly or not at all uncomfortable') when wearing SMs compared with EHMRs.

Discussion

We evaluated whether covering an EHMR with a SM leads to adverse alterations in physiological parameters among HCW performing simulated healthcare tasks. We found that when EHMRs are covered with SMs, users have no clinically significant changes in physiological parameters compared with uncovered EHMRs. There were statistically significant differences in $tcPCO_2$ between covered and uncovered EHMRs. Whether the EHMR was covered or uncovered, $tcPCO_2$ values were normal and were slightly lower, not higher, when the EHMR was covered compared with uncovered (37.17 versus 37.88 mmHg). SpO_2 also remained normal, but significantly lower during covered EHMR use compared with uncovered EHMR use (97.74 versus 97.94%). There was no difference in HR between mask configurations, and neither BMI, sex, nor age impacted the relationship between physiological endpoint and mask type. Similarly, participants rated exertion and comfort similarly with covered and uncovered EHMRs. Together, these findings suggest that HCWs can safely wear SMs over the exhalation valve of EHMRs without adverse physiological consequences.

While HR did not differ by mask configuration, highest HR values were measured during the 'recovery' interval immediately following chest compressions. While this may seem counterintuitive, HR averaged over the 2-min 'compressions' interval included baseline values associated with lower intensity tasks that preceded the interval (either 'counting' or 'supine'). The expected physiologic response to exercise includes gradual increase in HR to support the body's need for more oxygen delivery (Hopkins *et al.*, 2021). Thus, a sudden increase in HR isolated to the 'compressions' interval would be unexpected. During recovery, individual fitness levels would affect the speed of HR decline (Fan *et al.*, 2020). Overall, the 'recovery' interval measured in this study likely reflects physiological burden of the highest degree of exercise experienced from the 2-min 'compressions' interval. Importantly, HRs had decreased notably by the time of the post-recovery interval, 'bagging'. Therefore, this pattern shows that work increased during exercise, leading to HR increase, that fell once the HCW rested, back to pre-CPR values. Prior work has shown that cardiac output, a product of HR and cardiac stroke volume, increases minimally due to presence of N95 FFRs or face masks compared with no masks at lower intensity exercise (Wetter *et al.*, 1999). At high intensity exercise, notably, face mask and N95 FFR use does not significantly affect cardiac output (Fikenzer *et al.*, 2020).

Our results share some similar findings with previous studies of EHMRs. Several studies have examined physiological outcomes during EHMR use, although none specifically evaluated the impact of covering the exhalation valve. Studies examining outcomes among people wearing EHMRs have shown normal $tcPCO_2$, SpO_2, and HR, without significant differences compared with people wearing N95 FFRs (Bansal *et al.*, 2009; Roberge *et al.*, 2010b). Harber, however, found a significant increase in HR of EHMR users compared with N95 FFR users among a mixed population of people with and without respiratory disease, but did not study $tcPCO_2$ or SpO_2 (Harber *et al.*, 2010). Unknown, however, is whether covering the EHMR exhalation valve alters these physiological responses.

Other investigators have studied the impact of covering N95 FFRs with SMs, and our findings show similar patterns. Roberge *et al.* studied the impact of wearing ASTM Type II SMs over cup-shaped N95 FFRs, with and without exhalation valves, among participants walking on a treadmill for 1 h. They found no differences in endpoints of $tcPCO_2$, SpO_2, respiratory rate (RR), tidal volume (Vt), and minute ventilation (Ve) (Roberge *et al.*, 2010c). They observed, however, higher HRs among uncovered N95 FFR users compared with the covered N95 FFR users at low work rates. They concluded that placing a SM over an N95 does not negatively affect the wearer. In contrast, in a study of intensive care unit nurses wearing N95 FFRs with or without SMs during a work shift, $tcPCO_2$ values significantly increased by an average of 1 mmHg compared with uncovered N95 FFRs, although there were no differences in HR or SpO_2 (Rebmann *et al.*, 2013). In another study of healthy HCWs who wore SM over un-valved N95-equivalent FFRs (filtering facepiece FFP2 respirators) at rest, nasal end tidal CO_2 was statistically elevated compared with resting without a mask, but the study did not compare results to those from uncovered respirators (Özdemir *et al.*, 2020). In that study, SpO_2 and HR did not change compared with resting without a mask, and no participants experienced symptoms.

This study's outcomes are similar to previous research showing less favorable user perception data with EHMRs. One study showed that HCWs may find EHMRs less comfortable and harder to communicate through, compared with N95 FFRs (Hines *et al.*, 2019). Test subjects have also reported higher anxiety scores during EHMR use compared with N95 FFRs (Wu *et al.*, 2011). HCWs, however, have expressed preference in using EHMRs over N95 FFRs in certain high risk scenarios, such as pandemic influenza, in spite of some of these issues (Hines *et al.*, 2019). None of these assessments, however, evaluated user perception or physiological outcomes when the exhalation valve was covered.

Changes to respirator wearers' CO_2 or SpO_2 endpoints might occur due to alterations in breathing pattern. Prior studies have shown that EHMR wearers have longer inspiratory times and shorter expiratory times, compared with N95 FFR wearers, with variable impacts on Vt and Ve (Bansal *et al.*, 2009; Harber *et al.*, 2010). The alterations experienced during EHMR exhalation valve coverage may result due to impacts on expiratory airflow resistance or added dead space. Addition of a SM would not alter inspiratory resistance, however, which when increased can result in decreased Ve, RR, and Vt, which would lead to increases in $tcPCO_2$ (Harber *et al.*, 1982; Caretti *et al.*, 2006). The addition of a SM may prolong the expiratory time, potentially leading to greater elimination of CO_2. Further, studies have shown that added dead space volume from a respirator leads to Vt increase (Harber *et al.*, 1982). If SM application led to higher mask-related dead space volume, this could have led to greater Vt, potentially leading to higher Ve or more specifically, higher alveolar ventilation, yielding the difference in gas exchange. While our study cannot explain the mechanism behind the lower $tcPCO_2$ in the covered EHMR users, the magnitude of the impact was extremely low and likely clinically inconsequential.

Questions remain as to whether covering the exhalation valve is truly necessary as a form of microbial source control (Chang *et al.*, 2020). Early COVID-19 pandemic recommendations to cover the exhalation valve of a valved respirator with a SM, drape, or face shield occurred prior to availability of supporting data (Cal/OSHA, 2020; Greenawald *et al.*, 2020; Eric Berg, 2020). Since then, studies have demonstrated the presence of exhaled breath particles from N95 FFRs with valves, but lower or similar in amount compared with that emitted from SMs and procedure masks, the expected practice for source control in healthcare settings (NIOSH, 2020; Staymates, 2020). SMs and procedure masks fit loosely and allow inward leakage (Oberg and Brosseau, 2008; Rengasamy *et al.*, 2009; Yan *et al.*, 2020; Runde *et al.*, 2021). In experimental studies of outward leakage more relevant to source control, two to 17% of particles penetrated SMs, while FDA-cleared procedure masks allowed up to 85% penetration (Rengasamy *et al.*, 2009; NIOSH, 2020). This highlights the expected benchmark for source control in healthcare settings as of July 2021, which is not complete elimination of outward leakage. Additionally, one study exploring sterile field bacterial contamination associated with uncovered, valved EHMR use showed no difference compared with SM, un-valved N95 FFR, or EHMR + SM (Howard *et al.*, 2020). While lack of bacterial exhaled breath-induced sterile field contamination is reassuring, several solutions to limit EHMR exhalation emissions currently exist, including exhalation valve filters and EHMRs without valves (Fernando *et al.*, 2021; Schwartz, 2021). Any solution, however, should be implemented in accordance with respirator manufacturer guidance. As of 9 April 2021 CDC continues to advise against EHMR use with unfiltered exhaust during sterile procedures (Centers for Disease Control and Prevention (CDC), 2021). Until there is evidence-based consensus on the potential risks and need for limitation of exhalation emissions from EHMRs, several solutions do exist.

This study has several limitations. First, we assured placement of the SM over the exhalation valve by visual and tactile inspection only. We did not quantify the amount or geographic distribution of exhaled air emitted. Therefore, we are unable to describe how effectively the SM strategy limits emission of breath. Our strategy, however, reflects practical usage in a hospital setting. Thus, we feel our method is reasonable. Second, our population included almost all young, normal weight women. It is possible that our results could differ with inclusion of more men, older HCWs and HCWs with higher BMIs. However, we performed statistical adjustment for these factors. Whether we evaluated age or BMI as continuous or categorical variables, we saw similar results. Furthermore, the general population of HCWs is primarily female (U.S. Department of Health and Human Services, Health Resources and Services Administration, National Center for Health Workforce Analysis, 2017; Day and Christnacht, 2019). Thus, we feel that our results from a population sample of young women provides an appropriate evidence base. Third, we assessed outcomes based on 30-min periods of EHMR use. Results following longer EHMR use may differ from those observed in this study. Additionally, we studied only one EHMR model, and our results may not be generalizable to all EHMRs. Finally, the study used new EHMRs and new filters. One of the benefits of EHMR use in healthcare is that these respirators and filters can be repeatedly cleaned, disinfected, and re-used. It is possible that an older, used filter could have a higher airflow resistance due to entrapment of particles or moisture. This higher airflow resistance could theoretically lead to greater user work of breathing and ultimately adverse changes to HR, $tcCO_2$, or SpO_2 (Mapelli *et al.*, 2021). However, prior work evaluating filter function such as pressure drop among EHMR filters similar to the ones used in this study showed that the filters met NIOSH acceptability criteria, even after 150 cycles of cleaning (Heimbuch and Harnish, 2019). Given the low likelihood of EHMR filter loading when worn in healthcare environments, as opposed to dusty industrial environments, the contribution from ambient particulate loading of the filter is likely negligible in these settings, resulting in no impact on user physiological endpoints. Finally, we did not repeat fit-testing on participants while wearing the EHMR + SM configuration. While it is possible that placement of a SM over an N95 FFR may create alterations in fit, this is less likely to occur with EHMRs, due to the surface area and conformability of the seal to the face (National Academies of Science Engineering and Medicine, 2019; Lawrence *et al.*, 2006). Therefore, our study's limitations are reasonable with respect to validity and potential for practical application.

Our study has several strengths. Importantly, HCWs in this study performed simulated tasks that are often required for care of patients with COVID-19, such as proning and CPR. Both tasks require significant work and movement from the HCW and occur during periods of stress, all of which would add to physiological burden. We simulated proning of a 172 lb manikin, which provided a realistic comparison to the mechanical load a HCW might potentially face, during and after the COVID-19 pandemic ends. Second, we included tasks routinely required during in-hospital CPR, including a total of 4 min for each participant performing chest compressions. Furthermore, participants received feedback on quality of their chest compressions in real time, which facilitated standardization of the degree of work performed by each participant. These activities are representative of the types of tasks HCW face during the care of COVID-19 and other critically ill patients, and thus support the external validity of our physiology findings during respirator use.

Our study highlights several research needs. Most importantly, scientists must determine whether covering the exhalation valve of an EHMR is truly needed and under what scenarios. If exhalation valve coverage is needed, similar testing should occur among users wearing nonvalved EHMRs or respirators that have ability to filter the exhaled breath. Further, our research suggests that EHMRs should be improved to provide better user comfort and less perceived exertion. Improvements in design features may increase user acceptance even further among HCWs (Radonovich *et al.*, 2019). Finally, future research should include more older and obese participants to provide greater clarity on physiological impacts during healthcare tasks in this population of respirator users.

Conclusions

Covering the exhalation valve of an EHMR used during common COVID-19-relevant HCW tasks, including CPR, proning, and supining of patients, does not lead to adverse physiological effects on the user. If exhalation valve coverage is required to limit exhaled breath contaminants, wearers can do this without adverse health effects.

Funding

This project was funded by the Centers for Disease Control and Prevention—National Institute for Occupational Safety and Health, contract # 75D30120P09044—project: Best Practices and Preferred Uses of Reusable Elastomeric Half Mask Respirators (EHMR) in Healthcare. This study was approved by the Institutional Review Board of the University of Maryland, Baltimore (IRB HP-00093921).

Acknowledgements

The authors appreciate the assistance of Dr Olga Kolesnik, who was the study coordinator, University of Maryland Shock Trauma Center staff Mr Benjamin Neustein, for use of the

Simulation Center, Ms Amanda Zambrano, for design of the proning protocol, and of Mr Jason Rohrer, in use and monitoring of the SenTec device.

Conflict of interest

Dr Hines receives contract funding from CDC NIOSH to her institution to study implementation of elastomeric respirator programs in hospitals. She also receives grant funding not related to this research to her institution by CleanSpace Technology to study implementation of a novel respiratory protective device in healthcare. The remaining authors declare no other conflict of interest relating to the material presented in this article.

Data availability

The data underlying this article cannot be shared publicly due to the privacy of individuals that participated in the study. The data will be shared on reasonable request to the corresponding author.

References

Bach M. (2017) *Understanding respiratory protection options in Healthcare: The Overlooked Elastomeric [Internet]*. 2017. Avaialbel at https://blogs.cdc.gov/niosh-science-blog/2017/07/06/elastomerics/. Accessed 23 August 2021.

Bansal S, Harber P, Yun D *et al.* (2009) Respirator physiological effects under simulated work conditions. *J Occup Environ Hyg*; **6**: 221–7.

Barros AJ, Sifri CD, Bell TD *et al.* (2021) Effectiveness of elastomeric half-mask respirators vs N95 filtering facepiece respirators during simulated resuscitation. A nonrandomized controlled trial. Research letter. *Occup Health*; **4**: e211564.

Borg G. (1998) *Borg's perceived exertion and pain scales*. Champaign, IL: Human Kinetics.

Cal/OSHA. (2020) *Cal-OSHA interim guidance on COVID-19 for health care facilities: severe respiratory supply shortages*.

Caretti DM, Coyne K, Johnson A *et al.* (2006) Performance when breathing through different respirator inhalation and exhalation resistances during hard work. *J Occup Environ Hyg*; **3**: 214–24; quiz D45.

Centers for Disease Control and Prevention (CDC). (2021) Personal protective equipment: questions and answers. CDC. Available at https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirator-use-faq.html#Respirators. Accessed 27 May 2021.

Chalikonda S, Waltenbaugh H, Angelilli S *et al.* (2020) Implementation of an elastomeric mask program as a strategy to eliminate disposable N95 mask use and resterilization: results from a Large Academic Medical Center. *J Am Coll Surg*; **231**: 333–8.

Chang JC, Johnson JS, Olmsted RN. (2020) Demystifying theoretical concerns involving respirators with exhalation valves during COVID-19 pandemic. *Am J Infect Control*; **48**: 1564–5.

Day JC, Christnacht C. (2019) *Your health care is in women's hands*. United States Census Bureau. Available at www.census.gov/library/stories/2019/08/your-health-care-in-womens-hands.html. Accessed 27 August 2021.

Eric Berg (Cal/OSHA Webinar Presentation). (2020) *Use of elastomeric respirators in health care settings*. Available at https://www.dir.ca.gov/dosh/coronavirus/webinars.html. Accessed 23 August 2021.

Fan LM, Collins A, Geng L *et al.* (2020) Impact of unhealthy lifestyle on cardiorespiratory fitness and heart rate recovery of medical science students. *BMC Public Health*; **20**: 1012.

Feinmann J. (2020) PPE: what now for the global supply chain? *BMJ*; **369**: m1910.

Fernando R, Peterson J, Portnoff L. (2021) Advancements in elastomeric respirator technology for use as source control | Blogs | CDC. NIOSH Science Blog. Available at https://blogs.cdc.gov/niosh-science-blog/2021/03/01/elastomeric_source-control/. Accessed 2 April 2021.

Fikenzer S, Uhe T, Lavall D *et al.* (2020) Effects of surgical and FFP2/N95 face masks on cardiopulmonary exercise capacity. *Clin Res Cardiol*; **109**: 1522–30.

Fisher KA. (2020) Factors associated with cloth face covering use among adults during the COVID-19 pandemic—United States, April and May 2020. *MMWR Morb Mortal Wkly Rep*; **69**: 933–7.

Fryar C, Carroll M, Gu Q *et al.* (2021) Anthropometric reference data for children and adults: United States, 2015–2019. *Vital Health Stat*; **3**: 2,8,10.

Greenawald L, Cichowicz JK, D'Alessandro MM. (2020) Supplementing the supply of N95s with reusable elastomeric half mask respirators | Blogs | CDC. Available at https://blogs.cdc.gov/niosh-science-blog/2020/09/08/elastomeric/. Accessed 11 September 2020.

Hafen BB, Sharma S. (2021) *Oxygen saturation*. Treasure Island, FL: StatPearls Publishing.

Hamby C. (2020) *They evoke Darth Vader, but these masks may save your doctor's life*. The New York Times. 2020. Available at https://www.nytimes.com/2020/05/27/us/coronavirus-masks-elastomeric-respirators.html. Accessed 23 August 2021.

Harber P, Joseph Tamimie R, Bhattacharya A *et al.* (1982) Physiologic effects of respirator dead space and resistance loading. *J Occup Med*; **24**: 681–4.

Harber P, Santiago S, Wu S *et al.* (2010) Subjective response to respirator type: effect of disease status and gender. *J Occup Environ Med*; **52**: 150–4.

Harber P, Tamimie J, Emory J *et al.* (1984) Effects of exercise using industrial respirators. *Am Ind Hyg Assoc J*; **45**: 603–9.

Heimbuch BK, Harnish DA. (2019) *Contract number: HHSF223201400158C title: Research to mitigate a shortage of respiratory protection devices during public health emergencies report for the period: September 30,2014 – September 30, 2019*. Available at https://www.ara.com/mitigate-rpd-shortage/.

Hines SE, Brown C, Oliver M *et al.* (2019) User acceptance of reusable respirators in health care. *Am J Infect Control*; **47**: 648–55.

Hopkins SR, Dominelli PB, Davis CK *et al.* (2021) Face masks and the cardiorespiratory response to physical activity in health and disease. *Ann Am Thorac Soc*; **18**: 399–407.

Howard B, Clinic M, Ryan A *et al.* (2020) *Sterile field contamination by elastomeric respirators versus surgical masks and N95s*. Available at https://doi.org/10.21203/rs.3.rs-81198/v1. Accessed 23 August 2021.

Kim JH, Benson SM, Roberge RJ. (2013) Pulmonary and heart rate responses to wearing N95 filtering facepiece respirators. *Am J Infect Control*; **41**: 24–7.

Lawrence RB, Duling MG, Calvert CA *et al.* (2006) Comparison of performance of three different types of respiratory protection devices. *J Occup Environ Hyg*; **3**: 465–74.

Louhevaara V, Smolander J, Korhonen O *et al.* (1986) Effects of industrial respirators on breathing pattern at different work levels. *Eur J Appl Physiol Occup Physiol*; **55**: 142–6.

Mapelli M, Salvioni E, de Martino F *et al.* (2021) "You can leave your mask on": effects on cardiopulmonary parameters of different airway protection masks at rest and during maximal exercise. *Eur Respir J*: 2004473. doi:10.1183/13993003.04473-2020. Online ahead of print.

Mathews KS, Soh H, Shaefi S *et al.* (2021) Prone positioning and survival in mechanically ventilated patients with coronavirus disease 2019-related respiratory failure. *Crit Care Med*; **49**: 1026–37.

Messina Z, Patrick H. (2020) *Partial pressure of carbon dioxide*. Treasure Island, FL: StatPearls Publishing.

Nanchen D. (2018) Resting heart rate: what is normal? *Heart*; **104**: 1048–9.

National Academies of Science Engineering and Medicine. (2019) *Reusable elastomeric respirators in health care: considerations for routine and surge use*. Washington, DC: National Academies Press.

National Center for Immunization and Respiratory Diseases (NCIRD), Division of Viral Diseases, Centers for Disease Control and Prevention. (2020) *Strategies for Optimizing the Supply of Facemasks: COVID-19 | CDC*. Available at https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/face-masks.html. Accessed 23 August 2021.

NIOSH. (2020) *Filtering facepiece respirators with an exhalation valve: measurements of filtration efficiency to evaluate their potential for source control*. By Portnoff L, Schall J, Brannen J, Suhon N, Strickland K, Meyers J. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 2021-107. doi:10.26616/NIOSHPUB2021107.

Oberg T, Brosseau LM. (2008) Surgical mask filter and fit performance. *Am J Infect Control*; **36**: 276–82.

Özdemir L, Azizoğlu M, Yapıcı D. (2020) Respirators used by healthcare workers due to the COVID-19 outbreak increase end-tidal carbon dioxide and fractional inspired carbon dioxide pressure. *J Clin Anesth*; **66**: 109901.

Radonovich LJ, Wizner K, LaVela SL *et al.* (2019) A tolerability assessment of new respiratory protective devices developed for health care personnel: a randomized simulated clinical study. *PLoS One*; **14**: e0209559.

Rebmann T, Carrico R, Wang J. (2013) Physiologic and other effects and compliance with long-term respirator use among medical intensive care unit nurses. *Am J Infect Control*; **41**: 1218–23.

Rengasamy S, Miller A, Eimer BC *et al.* (2009) Filtration performance of FDA-cleared surgical masks. *J Int Soc Respir Prot*; **26**: 54–70.

Roberge RJ, Coca A, Williams WJ *et al.* (2010a) Physiological impact of the N95 filtering facepiece respirator on healthcare workers. *Respir Care*; **55**: 569–77.

Roberge RJ, Coca A, Williams WJ *et al.* (2010b) Reusable elastomeric air-purifying respirators: physiologic impact on health care workers. *Am J Infect Control*; **38**: 381–6.

Roberge RJ, Coca A, Williams WJ *et al.* (2010c) Surgical mask placement over N95 filtering facepiece respirators: physiological effects on healthcare workers. *Respirology*; **15**: 516–21.

Runde DP, Harland KK, Van Heukelom P *et al.* (2021) The "double eights mask brace" improves the fit and protection of a basic surgical mask amidst COVID-19 pandemic. *J Am Coll Emerg Physicians Open*; **2**: e12335.

Schwartz S. (2021) Elastomeric respirator innovations play a critical role in response to COVID-19 | FDA. Available at https://www.fda.gov/news-events/fda-voices/elastomeric-respirator-innovations-play-critical-role-response-covid-19. Accessed 27 May 2021.

Sentec. (2020) *Instruction manual for the SenTec Digital Monitoring System, software version SW-V08.03 and higher*. Terwil, Switzerland: SenTec AG.

Springer ML. (2021) Letter to the Editor. *Am J Infect Control*; **49**: 530–1.

Staymates M. (2020) Flow visualization of an N95 respirator with and without an exhalation valve using schlieren imaging and light scattering. *Phys Fluids (1994)*; **32**: 111703.

Suzanne RK. (2020) *Why some cities and counties are banning face masks with valves*. Forbes. Available at https://www.forbes.com/sites/suzannerowankelleher/2020/05/26/why-some-cities-and-counties-are-banning-face-masks-with-valves/?sh=741340b06d92. Accessed 23 August 2021.

U.S. Department of Health and Human Services, Health Resources and Services Administration, National Center for Health Workforce Analysis. (2017) *Sex, race, and ethnic diversity of U.S, health occupations (2011–2015), Rockville, Maryland*.

U.S. Department of Labor. (2015) *Hospital Respiratory Protection Program Toolkit: Resources for Respirator Program Administrators*. 3767th-05–20th edn. Washington D.C: OSHA.

Wetter TJ, Harms CA, Nelson WB *et al.* (1999) Influence of respiratory muscle work on VO_2 and leg blood flow during submaximal exercise. *J Appl Physiol*; **87**: 643–51.

Wizner K, Stradtman L, Novak D *et al.* (2016) Prevalence of respiratory protective devices in U.S. health care facilities:

implications for emergency preparedness. *Workplace Health Saf*; **64**: 359–68.

Wu S, Harber P, Yun D *et al*. (2011) Anxiety during respirator use: comparison of two respirator types. *J Occup Environ Hyg*; **8**: 123–8.

Yan R, Chillrud S, Magadini DL *et al*. (2020) Developing home-disinfection and filtration efficiency improvement methods for N95 respirators and surgical facial masks: stretching supplies and better protection during the ongoing COVID-19 pandemic. *J Int Soc Respir Prot*; **37**.