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Tolerability, User Acceptance and Preference for a Novel Reusable Respirator Among Healthcare Workers

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Highlights

- CleanSpace Halo powered respirators have clear facemasks without belts or hoses.
- Healthcare workers gave favorable tolerability scores to Halo respirators.
- Many Halo users preferred this respirator during routine and COVID-19 patient care.
- Healthcare workers' favorable perceptions of Halo respirators persisted over time.

Abstract:

Background: The CleanSpace Technology Halo respirator combines a clear face mask and a powered air supply, without belts or hoses. Although providing higher protection than other respirators used in healthcare, user acceptance of this device has not been assessed with validated tools.

Methods: We surveyed healthcare workers (HCWs) within a US medical system using Halo respirators in 2021. Subjects completed three surveys over eight weeks, which included the Respirator Comfort, Wearing Experience, and Function Instrument (R-COMFI), a validated tool to assess respirator tolerability. The survey included additional questions about user acceptability and respirator preference. Responses were evaluated for change over time and for significant predictors.

Results: Of 113 HCWs who completed the initial survey (29% response rate), mean ± SD R-COMFI score was 9.1± 5.1, (scale 0-47, lower = more tolerable) and did not change over time (p = 0.42). Fewer years in healthcare significantly predicted better R-COMFI score (p=0.01). Many users preferred Halo in both usual care (45-52%) and care of patients with COVID-19 (60-64%).

Discussion: Halo respirators received favorable tolerability scores by HCWs, who often preferred them, especially during care of patients with COVID-19.

Conclusions: Given demand for respirator use in healthcare, the innovative design provides higher protection than other respirators with a favorable user experience.

Keywords

PAPR, respiratory protection, healthcare, COVID-19, user acceptance, elastomeric

Background

Since the onset of the COVID-19 pandemic, hospital respiratory protection program (RPP) leaders have increasingly used reusable respiratory protective devices (RPDs) to protect healthcare workers (HCWs) from respirable infectious hazards. Such reusable RPDs include loose-fitting powered air-purifying respirators (PAPRs) and elastomeric half-mask respirators (EHMRs). These reusable RPDs have different characteristics compared to traditional disposable N95 filtering facepiece respirators (FFRs), such as materials composition and weight, that influence user acceptance. For example, user acceptance studies about loose-fitting PAPRs suggest that they tend to be well-accepted, but at the expense of lower mobility and impacts on communication (1–3)Among EHMRs, despite lower communication and comfort user ratings compared to N95 FFRs, experienced EHMR users have expressed preference for them in high-risk scenarios (4). This finding suggested that perceived protection of the EHMR drove

preference, more so than comfort or communication. Thus, user acceptance of these reusable RPDs appears to facilitate their use in healthcare settings.

A new style of respirator developed by CleanSpace Technology specifically for use in healthcare incorporates the higher protection of a PAPR, with the size of an EHMR: the Halo respirator. The Halo carries an assigned protection factor (APF) of 50, is reusable, breath responsive, and requires no belts or hoses (Figure 1). In contrast, EHMRs bear APFs of 10 and loose-fitting PAPRs bear APFs of 25. Approved by the National Institute for Occupational Safety and Health (NIOSH) in 2019, this respirator first found use in United States (US) healthcare settings during COVID-19 response.

Figure 1. CleanSpace Halo: a breath-responsive powered air-purifying respirator with clear, elastomeric facemask.

At the onset of COVID-19, it was unclear how well HCWs, who were mainly familiar with N95 FFRs, would accept this new RPD design. Prior studies have identified user comfort as a predictor for compliance with expected respirator use (5–10) . Thus, assessment of comfort and tolerability would benefit hospital respiratory protection leaders in building optimal RPPs. Respirator tolerability and comfort, however, can be challenging to define and assess (11). One tool, though, may present a reliable and valid method in standardizing user assessment of RPDs.

In 2013, a federal stakeholder working group published recommendations for 28 key performance characteristics to prioritize for future RPD designs, including comfortability and tolerability(9). Subsequently, a survey instrument named the Respirator Comfort, Wearing Experience, and Function Instrument (R-COMFI) was designed to measure comfort and tolerability, with a goal of identifying respirators likely to be acceptable and promote adherence in healthcare environments (11). Psychometric testing of the R-COMFI revealed reliability and validity. One simulated healthcare workplace study used the R-COMFI to evaluate commercially available N95 FFR and prototype respirators, also demonstrating external validity (12). However, the R-COMFI has not been used during actual clinical practice. Given the need to understand user acceptance of the novel Halo respirator, the R-COMFI presents an ideal metric to accomplish this task.

This study aimed to understand user perceptions about Halo respirators, to assess whether perceptions changed over time, and to assess predictors of user perceptions. To do so, we surveyed HCWs using Halo in clinical practice using the R-COMFI, along with survey questions about respirator preference and user acceptance. We hypothesized that Halo users would rate their respirators favorably on the R-COMFI and that tolerability ratings would increase over time with greater familiarity with use. Similar to precedent among EHMR users, we also

hypothesized that Halo users would express preference for Halo in higher risk use scenarios. By understanding user perceptions, optimal respirator deployment to protect HCWs can be refined.

Materials and Methods

Setting

This study occurred at five sites within a 13-institution Mid-Atlantic US medical system where the Halo respirator had recently been introduced as part of clinical care. Two of the sites (A and B) were 285- and 253-bed community-based suburban hospitals. Three other sites (grouped together as site C) included 218-bed and 205-bed suburban community hospitals, and a dental surgery practice affiliated with an urban rehabilitation center. At these sites, the Halo respirator was an available option for respiratory protection, in addition to traditional options such as N95 FFRs, EHMRs, and loose-fitting PAPRs. The study occurred during the COVID-19 pandemic, between April – September of 2021. During this time, total daily COVID-19 inpatients for the 13-institution system varied from a high of 308 in April, to a low of 15 in June.

This study was approved by the local university Institutional Review Board (IRB). The IRB granted a waiver of written informed consent, but a written information sheet documenting all the elements of informed consent was provided to all participants.

Study Subjects

HCWs were recruited from multiple clinical roles – including nurses, physicians, advanced practice practitioners (APPs), respiratory therapists (RTs), and other clinical roles – and from multiple unit types – including emergency departments (EDs), dedicated COVID-19 intensive care units (ICUs) and inpatient units, and other units. Subjects were invited to

participate using flyers which were provided to onsite staff, email invitations, and onsite recruitment sessions where study staff traveled to hospital sites and invited eligible HCWs in-person to complete the survey directly on provided electronic tablets. Eligibility criteria included age ≥18 years, employment at a participating system hospital, and being assigned and trained to use the Halo respirator. Those who were not assigned and trained to use the Halo respirator were excluded. At the time of initial survey invitation, a total of 389 HCW were eligible to participate:165 from site A, 116 from site B, and 108 from C sites. Subjects received payment for completion of the initial survey and for each follow-up survey.

Survey

The study surveys were administered using the university's REDCap platform (13,14) . These consisted of an initial (week 0) survey, and subsequent surveys at weeks 4 and 8. The initial survey consisted of 28 questions, including demographics, work role/site, experience with and opinions about the Halo respirator, confidence in the Halo respirator, preferences among different respirator types, and logistics of use (the latter of which are the subject of a separate analysis). The week 4 and week 8 surveys included only questions related to respirator use. All subjects who completed the initial survey were informed of and invited to complete the week 4 and week 8 surveys, using email reminders. Each survey required less than 15 minutes to complete.

Included within the survey was a modified version of the R-COMFI (11). R-COMFI contains three subscales – Discomfort (score 0-20), General Wearing Experience (0-12), and Function (0-15) – giving a total score of 0-47. Higher scores indicate greater discomfort and less tolerability. Other questions about respirator preference in specific scenarios and respirator comfort, communication, sense of protection provided by the respirator, and confidence in

protection based on fit-testing or training were adapted from a prior study about respirator use (4) (Supplemental Table 1). The ratings scale ranged from 1 to 5, with lower scores being more favorable.

Statistical Analysis

Total R-COMFI score, three subscales and Halo respirator user acceptance ratings were considered as continuous variables and represented as mean and standard deviation (SD). The categorical variables such as demographic and occupational characteristics were described by the percentage of each level, and t-test or ANOVA methods were used to examine their association with the R-COMFI score. Linear mixed models, which adjust gender, clinical unit, job category and site and include participants as a random variable, were employed for assessment for change in R-COMFI score, three subscales and Halo respirator user acceptance ratings over time (week 0, 4 and 8). Cumulative multinomial regression model, which includes risk scenarios and time (week 0 vs week 8) as fixed effects and adjusts each participant effect, was implemented for assessment of respirator preference over time and in different risk scenarios. Statistical analysis software SAS version 9.4 was used for statistical modeling and analyses.

Results

Study Population

113 participants completed the initial survey, yielding a 29% response rate. 49 participants completed the Week 4 survey, and 42 completed the Week 8 survey, with 50 participants completing at least one subsequent survey (44% subsequent survey response rate).

Participant characteristics are shown in Table 1. Among initial survey respondents, most were female (91%) and worked in EDs (29.2%) or dedicated COVID-19 ICUs and inpatient units (31.9%). Almost all had ever used N95 FFRs (95.6%), which were the most-used respirators prior to the COVID-19 pandemic for almost 75% of respondents.

Over half reported using respirators >50% of their work time. Demographic characteristics of respondents completing subsequent surveys were similar to the entire population of initial survey participants (all p-values > 0.05 in comparisons of site, gender, race, age, years worked in healthcare, primary unit, job type, prior most-used respirator type, frequency of respirator use).

Table 1: Study participant demographic and occupational characteristics.

	Initial survey respondents (113)	
	n	%
Age		
>=35	56	49.6%
<35	57	50.4%
Years in healthcare		
>9yrs	52	46.0%
<=9yrs	61	54.0%
Gender		
Male	22	19.5%
Female	91	80.5%
Race		
American Indian/Alaska Native	1	0.9%
Asian	11	9.7%
Black or African American	17	15.0%
White	80	70.8%
More than one race	4	3.5%
Job category		
RN	61	54.0%
Physician or Advanced Practice Provider	16	14.2%
Respiratory therapist	24	21.2%
Other	12	10.6%
Clinical unit		
Emergency Department	33	29.2%
Dedicated COVID-19 ICU/inpatient units	36	31.9%
Other units	44	38.9%
Site		
A	69	61.1%
B	34	30.1%
C	10	8.8%
Prior most-used respirator		
N95	83	74.8%
EHMR	10	9.0%
Loose-fitting PAPR	18	16.2%
Frequency of use of respirator during work time		
<10%	14	12.4%
10-25%	14	12.4%
25-50%	27	23.9%
>50%	58	51.3%
Respirators ever used		
N95	108	95.6%
EHMR	89	78.8%
Loose-fitting PAPR	85	75.2%

R-COMFI Results

In the initial survey, Mean (SD) R-COMFI score for the Halo respirator was 9.1 (5.1). Mean subscale scores were 4.0 (3.0) for Discomfort, 0.5 (1.0) for General Wearing Experience, and 4.6 (2.7) for Function (Figure 2). As shown in Figure 2, R-COMFI scores remained stable at Weeks 4 and 8. There was no significant difference in R-COMFI total score (P = 0.42), or in Discomfort (P = 0.36), General Wearing Experience (P = 0.67), or Function (P = 0.87) subscales between week 0 and week 4, or week 8. Fewer years worked in healthcare significantly predicted lower R-COMFI score (p=0.0118). Although R-COMFI scores differed according to characteristics of age, gender, race, job category, clinical unit, site, prior most-used respirator, and frequency of respirator use, none of these achieved statistical significance (Supplemental Table 2).

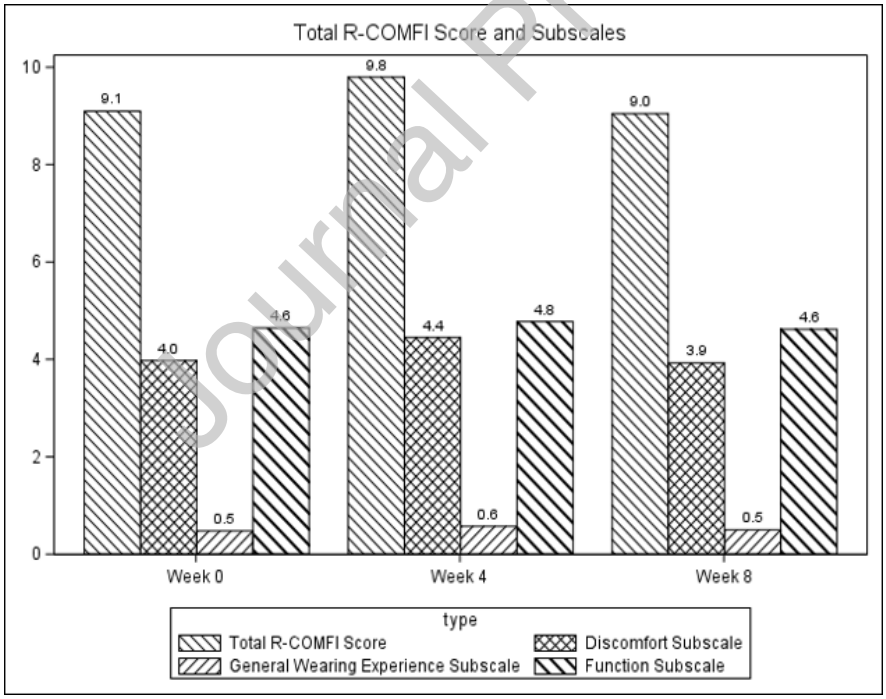

Figure 2: R-COMFI and Subscale Scores Over Time.

Score ranges – Total R-COMFI: 0-47, Discomfort subscale: 0-20, General Wearing Experience subscale: 0-12, Function subscale 0-15. Lower scores represent better comfort and tolerability.

User Acceptance and Respirator Preferences

Table 2 shows participant ratings of Halo respirators regarding comfort, communication, perceived protection, and confidence in protection based on fit-testing and training. Participants rated Halo respirators favorably in all domains, and none of the ratings significantly changed over time ($p>0.05$ for all four domains, at all time comparison points).

Table 2: Halo respirator user acceptance ratings.

How much do you like your Halo respirator?* (Mean (SD))

	Initial survey (n=113)	Week 4 survey (n=49)	Week 8 survey (n=42)
Comfort	2.2 (1.2)	2.0 (1.1)	1.8 (0.8)
Communication	2.6 (1.0)	2.5 (0.9)	2.5 (1.0)
Perceived protection	1.5 (0.7)	1.5 (0.7)	1.4 (0.7)
Confidence in protection	1.5 (0.7)	1.5 (0.6)	1.4 (0.6)

* Scale 1-5, lower scores more favorable

Participants were asked to choose their preferred respirators in usual care situations, such as ruling-out a patient for tuberculosis, or in active COVID-19 patient care situations. As shown in Figure 3, in both usual and active COVID-19 patient situations, the greatest number of respondents preferred the CleanSpace Halo. There was no statistically significant change in respirator preferences between Week 0 and Week 8. There was a trend, however, toward greater preference for the Halo and less preference for N95-FFR in active COVID-19 situations, but this did not reach statistical significance ($P = 0.07$). Among all initial survey responders, site ($P=0.03$) and primary unit ($P < 0.01$) significantly predicted respirator preference in usual care

situations, while years worked in healthcare (P = 0.03), primary unit (P = 0.02), and gender (P = 0.05) significantly predicted respirator preference in active COVID-19 situations.

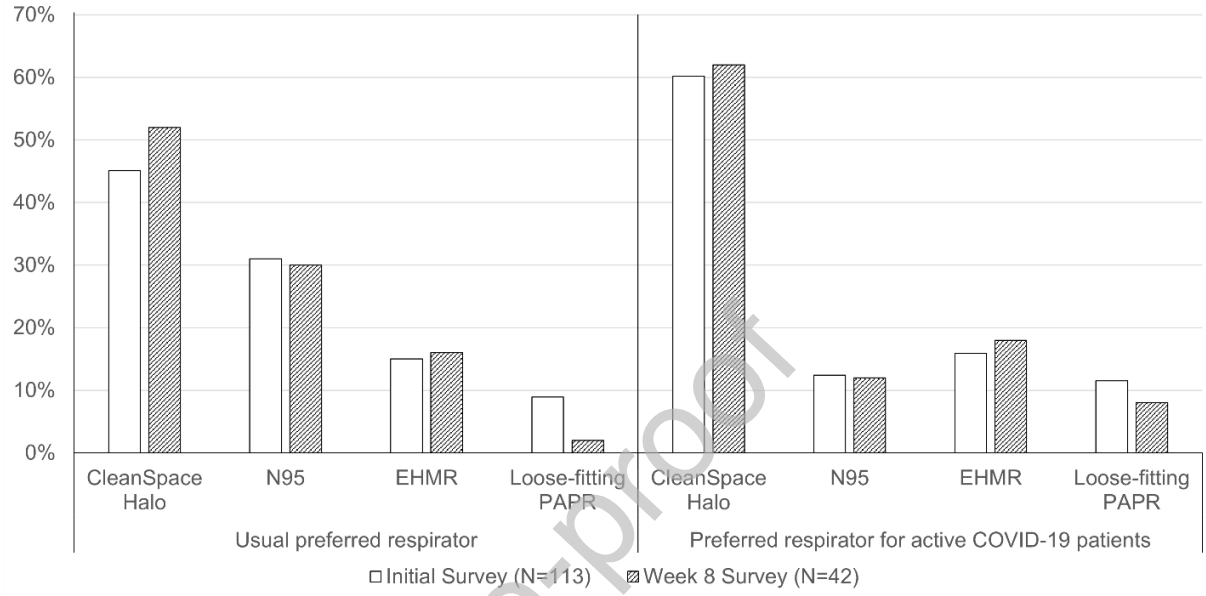

Figure 3: Respirator preferences in Usual Care (such as ruling-out tuberculosis) and Active COVID-19 Situations at Week 0 and Week 8.

Discussion

We aimed to understand user perceptions about Halo respirators, to assess whether perceptions changed over time, and to assess predictors of user perceptions. Consistent with our hypothesis, we found that Halo users rated their respirators favorably based on total and subscale R-COMFI scores, although this did not significantly change over time. HCWs with fewer years working in healthcare rated the Halo more favorably. We also observed that preference for the Halo respirator was high, especially during care of patients with active COVID-19. Respirator preference was influenced by years worked in healthcare, primary unit, and gender. This

preference increased but did not significantly change over 8 weeks. Altogether, our results show that HCW acceptance of this novel respirator is high.

Our results support previous efforts to use the R-COMFI instrument to assess respirator tolerability among HCW. Total R-COMFI scores in our study were similar (8.9-9.8) to the R-COMFI scores observed for two commercially available N95 FFRs evaluated in a healthcare work task simulation study (8.26 and 9.36) (12). Our subscale scores for Discomfort were also similar (3.6-4.4) or slightly better than the N95 FFR scores (4.62 and 4.98) in the simulation study. General Wearing Experience in our study ranged from 0.5-0.6, compared to 1.11 and 1.40 among N95 FFRs in the simulation study, although Function scores in our study ranged from 4.6-4.8 compared to 2.52 and 2.98 among N95 FFRs. These scores suggest that the Halo may provide a similar tolerability experience and better general wearing experience but with less favorable impacts on function not seen during N95 FFR use. With these similar R-COMFI scores, assessment of user preference becomes important in understanding acceptance further.

Two previous studies have examined HCW use of the novel style of CleanSpace PAPRs. Chugtai et al. asked 20 Australian HCWs their opinions about the CleanSpace 2, a similar style respirator, after their fit-testing experience (15). In this pre-pandemic study, 13 of 20 rated the respirator an overall score of 7 or higher on a scale of 1 (very bad) to 9 (very good). 14 of 20 stated that the respirator was comfortable. Like our study, most preferred using this respirator in "high-risk situations and outbreaks of highly infectious pathogens." We also saw favorable ratings for Halo; however, our preference ratings were lower (60% versus 90%). Reasons for this could include survey of participants based only on fit-testing experience (in the Chughtai study) compared to actual clinical use experience in our study, assessed during a respiratory viral pandemic. 51% of our survey participants reported using Halos >50% of their work time since

the start of the COVID-19 pandemic, reflecting high frequency respirator use at time of survey. Thus, our results likely possess greater external validity and reflect assessment based on significant use experience.

Our results also support those of Chong et al. who studied Halo use among 92 HCW in Singapore during October-December 2020 during the COVID-19 pandemic(16) . In that study, 38% of Halo users found the respirator to be comfortable for up to 1 hour of wear, and 40% reported that the Halo was "comfortable or fairly comfortable" with >4 hours of long-term wear. Interestingly, only 45% of participants felt that Halo "conferred an extremely low level of risk" compared to 72% for loose-fitting PAPRs (16). Although we did not ask our participants to compare their perceptions to different types of respirators regarding protection, our populations' responses regarding perceived protection were highly favorable (Table 3). Thus, there are likely influences on perception of protection afforded by this respirator that differ by hospital environment which we are unable to compare. Altogether, our findings support the favorable findings by other investigators examining CleanSpace respirator use among HCW.

Because of similarities with respect to mask style and their reusable nature, we hypothesized that HCW would perceive Halo respirators similarly to EHMRs. The same questions asked in this study about comfort, communication, perceived protection, and confidence in protection were assessed in a prior, pre-pandemic study among users of EHMRs, N95 FFRs, and loose-fitting PAPRs (4). After inverting the 5-point scale to match the directionality in this study, (where low score indicates favorability), mean scores for Halo respirators on all measures at all time points were better than scores for EHMRs, N95 FFRs, or loose-fitting PAPRs (Supplemental Table 3). Although the previous study assessed HCW opinions in non-pandemic time and in different settings, the current study's favorable results are

especially reassuring, given that HCW experienced greater frequency of respirator use during the pandemic and still rated the Halo highly despite ongoing use and fatigue (17) .

This study has several limitations, the first being sample size. We recruited a total of 113 survey participants, representing a 29% response rate. Although we do not know whether survey responders differed significantly from the entire pool of eligible HCW, the proportions of women, nurses, and physicians/advanced practice providers is similar to that seen in a previous respirator survey conducted within the same medical system (4). Thus, we feel we have likely captured consistent response patterns among HCWs interested in sharing their experiences. Our sample size was designed to detect a similar difference in sense of protection provided by the respirator as seen in Hines et al. 2019, requiring a population of 90 participants to see a difference of 0.57 between initial and subsequent surveys (4). Thus, we feel that our enrollment of 113 participants at baseline was adequate to show a similar effect size. We also had over 50% attrition for the subsequent surveys. We attribute this to relying exclusively on email distribution for the subsequent surveys. It is unclear whether participants opened these emails, chose not to participate, or if they never read them. This might lead to a biased sample of subsequent survey participants with different opinions compared to non-responders. However, the demographic characteristics of the subsequent survey completers were similar to the entire group of initial survey completers, suggesting that the non-completers would not have been demographically different. Thus, we do not think the dropout rate significantly impacted the interpretation of the subsequent survey results.

Additionally, we surveyed these HCWs within 6 months of their Halo fit-testing, training and first use. Opinions may have differed with initial use of this new product. If HCWs did not like the Halo and had another respirator option, they might have stopped using it and declined to

answer the study survey. However, we invited anyone who had been trained to use the Halo, even if they were not actively using it at survey time providing equal opportunity to the available pool of Halo users. We also discussed at informational recruitment sessions that we wanted to know opinions regardless of whether they liked or disliked the respirator. Thus, we made every effort to include HCW who might have had unfavorable opinions about the Halo

Finally, we used a standardized survey tool that was originally designed to assess disposable N95 FFRs (11) . Thus, there may be features of a reusable respirator like the Halo that are not fully addressed using this tool. However, the instrument was successfully used in a prior study to assess a prototype reusable hybrid elastomeric/N95 respirator and another prototype FFR with a plastic frame in a prior simulation study (12). Thus, we believe this was a valid tool to assess opinions of reusable Halo respirators.

Strengths of this study include consistency with prior studies of CleanSpace respirator users in healthcare (15,16) and similar patterns of preference seen for EHMRs in higher risk scenarios (4). Additionally, the HCWs surveyed in this study had prior experience with N95 FFR, EHMRs, and loose-fitting PAPRs, representing a knowledgeable HCW population to provide opinions and judgments about respirator use along with relative comparisons. Additionally, this is the first study to use the R-COMFI tool to study active respirator use in clinical practice, which was the intended purpose of this tool (12). Finally, to our knowledge, this is the first study of CleanSpace respirators in general, or Halo use specifically, in a US hospital system. Drawing from observations in the US, Singapore, and Australia, there is consistent positive acceptance of this novel RPD among HCWs.

Our study contributes to the field in several ways. First, an expanding body of literature documents the benefits of using reusable respirators over disposable N95 FFRs, such as averting

supply shortages, economic, and environmental benefits (18–21) . EHMRs cost significantly less than PAPRs, but have lower APFs and, as shown in this study, were less preferred than Halo. PAPRs, in general, provide a higher level of protection than half-mask negative pressure respirators. Studies of loose-fitting PAPRs, however, have shown challenges with sound levels, difficulty hearing and complexity of use (1,3,22–24). We have shown that Halo is an acceptable, preferred form of respiratory protection with the highest APF of any style of respirator used in healthcare. Compared to other PAPRs, where hoods are disposed of at interval thresholds, Halo face masks are intended for repeated cleaning, disinfection, and reuse. Thus, for hospitals planning investments in PAPRs, Halo likely comes at a lower cost over time, with an evidence-base supporting preference.

Second, given the changeover in the healthcare work force during the COVID-19 pandemic, demand for new graduates of health professions training is high (25). Given that shorter time in healthcare predicted better R-COMFI scores in our study, this population of new workers represents a target population group likely to embrace use of this novel respirator.

Conclusions

In summary, HCWs working during the COVID-19 pandemic rated the novel CleanSpace Halo respirator favorably and preferred it compared to other respirator types. HCWs' favorable perceptions of the Halo respirator remained stable over time. These findings indicate that user acceptance of this novel reusable hybrid PAPR with elastomeric face mask is high and not a barrier to expanded use in healthcare settings. Given the influx of new HCWs into the workforce,

hospitals may face optimal timing to integrate innovative respiratory protection solutions into their personal protective equipment strategies.

Conflicts of Interest
S.E.H. reports that a family member is currently employed by CleanSpace Technology, the sponsor of this study, as a trainer in tasks not related to the research study. None of the other authors report any potential conflicts of interest.

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