Using Public Feedback about the use of Elastomeric Half Mask Respirators to Inform a National Deployment Study within Health Settings

Emily J. Haas, PhD*; Lee A. Greenawald, PhD; Alexa Furek, MPH;
Maryann M. D'Alessandro, PhD

National Institute for Occupational Safety and Health, National Personal Protective Technology Laboratory, 626 Cochrans Mill Road, Pittsburgh, PA USA

* Corresponding author and E-mail: ejhaas@cdc.gov

ABSTRACT

Reusable elastomeric half mask respirators (EHMRs) have been encouraged for use during conventional, contingency, and crisis capacity in healthcare delivery settings as an alternative to disposable N95 filtering facepiece respirators (FFRs). However, standard, operationalized guidelines for implementing EHMRs in healthcare and first responder settings are needed to facilitate such integration. Specifically, research is needed to identify and address specialized concerns in healthcare delivery settings beyond hospitals to understand the widespread barriers to EHMR use and how organizational culture can support or hinder EHMR adoption. The Strategic National Stockpile (SNS) requested support from the National Institute for Occupational Safety and Health (NIOSH) to develop its strategy to purchase and distribute EHMRs to interested health organizations. To support this SNS effort, NIOSH published a Federal Register Notice (FRN) to request formative input from the public on the nationwide distribution of EHMRs and provided the technical analysis of the responses. Twenty-two representatives from first responder organizations, healthcare and dental associations, manufacturers, higher education, medical/nursing societies, and a union provided comments for consideration. This feedback was qualitatively analyzed to identify themes among the comments. This paper discusses patterns that emerged in the feedback provided within the primary topics of perceived advantages and disadvantages of EHMRs and key considerations for a successful national deployment of EHMRs. This paper also discusses how the formative feedback received was critical to informing the SNS's strategy to purchase and deploy EHMRs for longitudinal demonstration projects with the goal to produce updated EHMR implementation guidelines and best practices.

Keywords: elastomeric half mask respirator (EHMR); healthcare; public safety; PPT adoption; respiratory protection program; qualitative thematic analysis

INTRODUCTION

A previous article by Greenawald and colleagues (2021) reviewed the background and recent advances of reusable elastomeric half mask respirators (EHMRs) in the workplace prior to and during the COVID-19 pandemic. An EHMR (see Figure 1) is a type of NIOSH-approved air-purifying respirator that offers at least the same level of protection as an N95 filter facepiece respirator (FFR). During the nationwide shortage of FFRs, the Food and Drug Administration (FDA) issued an emergency use authorization (EUA), permitting the use of all National Institute for Occupational Safety and Health

(NIOSH)-approved particulate air-purifying respirators in healthcare settings, including EHMRs with particulate protection (85 FR 17335, March 27, 2020). This EUA was provided for alternative FFR use in healthcare settings to prevent wearer (i.e., worker) exposure to airborne particulates and subsequent life-threatening illness.

Similarly, although the Centers for Disease Control and Prevention (CDC) had already recommended that EHMRs were a respiratory protection option for conventional use within healthcare prior to COVID-19 (Bach, 2017), the agency updated guidelines during the pandemic to indicate that EHMRs are a viable option during a crisis or contingency scenario (CDC, 2020). Also, the National Academies of Science (NAS) recommends wider use of EHMRs in healthcare settings (NAS, 2019). These recommendations further prompt the examination of programs that can support conventional EHMR use to reduce potential FFR shortages that cause a lack of respirator access for workers during incidents of surge demands.

Figure 1. Elastomeric half mask respirator (photo courtesy of MSA Safety Innovation).

Research funded by NIOSH produced draft guidelines for hospitals and has shown that EHMR integration is feasible (Chalikonda et al., 2020; Hines et al., 2021). Still, gaps remain, such as identifying specialized concerns for other healthcare delivery settings (e.g., dental clinics, emergency medical service responders), barriers to widespread use, and how organizational culture supports or hinders adoption. When the Strategic National Stockpile (SNS) prioritized the purchase and distribution of EHMRs, NIOSH recognized this as an opportunity to understand the implementation of these devices in a variety of settings. NIOSH and the SNS coordinated their efforts to post a federal register notice (FRN) to gain public feedback about the implementation of a national EHMR deployment program (85 FR 56618, Vol. 85, No. 178). Approximately 22 comments were received on behalf of various groups and organizations.

The purpose of this paper is to discuss the public feedback received and how it has informed NIOSH's EHMR research plans. First, an overview of EHMR use in healthcare and by the first responders before and during the COVID-19 pandemic is provided. This overview also discusses concerns with the conventional use of EHMRs in health settings.

The Use of EHMRs during COVID-19

During the COVID-19 pandemic, there was a worldwide shortage in N95 FFRs, which are the most used respiratory protection device in healthcare settings (Wizner et al., 2016). This shortage resulted in organizations purchasing and distributing new types of respiratory protection, including EHMRs, to their workers. This change in respiratory protection elucidated questions about how to best support the implementation of EHMRs during and after the pandemic. To date, there are some examples of how EHMRs have been used in such settings.

EHMR use in Healthcare Settings—Although not as widely integrated in healthcare settings (Wizner et al., 2016) before the pandemic, an EHMR is not a new type of respiratory protection. Some healthcare settings began using EHMRs during previous infectious disease outbreaks. For example, the University of Maryland's Medical Center has been using EHMRs in some capacity since the 2009 H1N1 outbreak, which also resulted in a shortage of N95 FFRs (Hines et al., 2017). Results from the hospital's initial studies showed that users felt a higher sense of perceived protection, higher level of confidence in their EHMRs and, despite being less comfortable to wear, still preferred the EHMRs during higher-risk scenarios in comparison to an N95 FFR (Hines et al., 2019a). From a sustainability perspective, one hospital network decreased reliance on N95 FFRs by 95% during the COVID-19 pandemic within one month of acquiring EHMRs (Chalikonda et al., 2020).

EHMR use by First Responders—The National Fire Protection Association (NFPA) reported in 2018 that 64% of calls to fire departments were for medical aid reasons. During the COVID-19 pandemic, these types of calls drastically increased, with one study showing that calls per day during the COVID-19 pandemic increased two to three times more for COVID-19-related symptoms (Jaffe et al., 2021). Consequently, firefighters and emergency medical service (EMS) providers, such as those at the Fire Department of New York City, switched from using disposable N95 FFRs to EHMRs on every call by the end of 2020 (Tracy, 2020). Despite some departments switching to EHMR use 100% of the time during the COVID-19 pandemic, this respiratory protection has historically been used in first responder settings to prevent exposure to other contaminants (Dietrich et al., 2015). The advantages to first responders using EHMRs have been documented, including reusability and filter interchangeability (Luce, 2020) and more size options to increase comfort and fit (MSA, 2020).

Gaps in Current EHMR Research

Although there is an increased interest in different types of respiratory protection including EHMRs, concerns still need to be studied and addressed to support wider use of EHMRs in health settings. A decade of research has shown consistent barriers to adoption, including those documented from a cooperative effort between NIOSH and the U.S. Department of Veterans Affairs (BREATHE, 2009). The project involved nine federal agencies in developing 28 recommendations to reduce longstanding barriers to EHMR use during occupational work. Examples identified were facial irritation, difficult speech intelligibility, and a reduced visual field.

Research has sought to overcome barriers to implementation in healthcare settings. For example, two healthcare organizations have developed EHMR implementation guidelines for hospitals (Chalikonda et al., 2020; Hines et al., 2021). These efforts showed that fit testing many workers quickly is feasible and offered useful practices for other organizations to consider. Regarding feasibility, the University of Maryland's Medical Center was able to fit test 7,000 healthcare workers over six weeks (Hines et al., 2021). Researchers learned several things that worked post-implementation for future consideration and integration into their RPP. For example, they utilized an initial supply of 500 semi-permanent string bags as an EHMR carrying case for mobile workers, which were found to facilitate worker readiness (Hines et al., 2021) and can be considered for future, more systematic efforts. Other studies have shown no statistically significant difference in the time it takes to fit test for an EHMR versus N95 FFR (Pompeii et al., 2020). Specifically, Pompeii and colleagues (2020) found that it took 6 minutes and 47 seconds to fit test for an EHMR and it took 6 minutes and 29 seconds to fit test participants for an N95. Additionally, 92.2% of EHMR users passed their fit test on the first attempt while 88.5% of N95 users passed their fit test on the first attempt. However, some studies (Hines et al., 2020) have shown logistics such as EHMR cleaning and disinfection to be major barriers to optimal implementation of EHMRs. For example, Hines and colleagues found in one deployment cohort that only a little over half of EHMR users always wiped down and disinfected their EHMRs after use (Hines et al., 2020).

Therefore, although previous research offers valuable insights, critical gaps remain. Firstly, storage of and access to EHMRs are still prevalent barriers to user compliance. This was found by Hines and colleagues (2019a) when HCP were assigned an EHMR to use as their primary or secondary form of respiratory protection. The University of Maryland Medical Center ultimately found that a centralized storage and distribution program was critical to support compliant EHMR use (Hines et al., 2019a). However, additional studies are needed to better understand viable storage and access solutions for organizations of different sizes and types. Secondly, there are gaps in the literature pertaining to how a respiratory protection program (RPP) can support the implementation of EHMR best practices and how the utility of these practices may shift with varying levels of resources available. To illustrate, Hines and colleagues (2021) discussed the expediency of fit testing through establishing a fit testing center that remained open from 6 am to 11 pm daily. This practice is likely not sustainable or practical for smaller organizations with fewer resources. Consequently, it is important to include and understand the nuances of different-sized organization's RPPs to identify opportunities for easier implementation. Thirdly, research has been limited to hospital settings and has not been validated with other types of health organizations such as dentist's offices or long-term care facilities. Finally, the perspective of first responders such as firefighters and police officers has been absent. Therefore, research that involves a variety of occupational settings is necessary to update and establish relevant guidelines.

Objectives moving forward—As discussed, there are isolated studies of EHMR pilot deployments in hospitals (Hines et al. 2019a, b) and fire departments (Tracy, 2020), but research has not operationalized lessons learned for widespread implementation and conventional use (CDC, 2020; Fernando et al., 2021; Greenawald et al., 2020). With the introduction of any new piece of technology or equipment, understanding perceived barriers to using as well as maintaining patient care during integration is critical (Carayon et al., 2011). Additionally, understanding organizational and end-user perceptions toward and intentions to use new types of PPE have predicted eventual respiratory protective behaviors including consistent use of PPE during work tasks (Robertsen et al. 2018), making such research critical for technology adoption practices that protect worker and patient health.

Formative data are used to explore and confirm what is known about a problem, who may be affected, enabling factors that influence behaviors around the problem, and the most effective strategies for future interventions (Andreasen, 1995). The formative information NIOSH received served as a basis to narrow the scope of EHMR concerns and potential solutions based on empirical data.

MATERIALS AND METHODS

NIOSH published a Request for Information (RFI) in the Federal Register titled, "A National Elastomeric Half Mask Respirator (EHMR) Strategy for Use in Healthcare Settings During an Infectious Disease Outbreak" – Vol. 85, No. 178. The *Federal Register* is published daily and contains information about proposed rules and notices of interest to the public. When comments or information are requested, the public can respond in the docket established for that Federal Register notice. The docket for this RFI was open September 14–December 14, 2020, and provided an opportunity for the public to provide input on EHMR demonstration projects by using EHMRs in their respiratory protection programs (RPPs) and providing user acceptability and feedback on a variety of implementation parameters including the following as outlined on page 56620 of the RFI:

a. Defining the strategic parameters of this distribution program; for example, considerations about fit testing, training, education, filter change-out schedule, cleaning/disinfection, storage considerations, and appropriate clinical care settings for EHMR use; and
b. The potential criteria to be used to determine how the purchased devices should be distributed; for example, the technical approach of the use of the EHMRs, and technical qualifications of key staff who would lead the initiative.

The comments allowed researchers to identify how EHMRs were perceived and being used in dental offices, fire departments, law enforcement, EMS, long-term care facilities, and hospitals (85 FR 56618). Any organization, group, or individual was allowed an equal opportunity to respond with information, concerns, or experiences. Comments provided answers to the following questions:

- What barriers or concerns to EHMR use must be addressed prior to a national deployment?
- What benefits or advantages must be included in an EHMR national deployment?
- What criteria must be included in the design of EHMR deployment strategies for health settings?

Commenter Sample

Twenty-two representatives from first responder organizations, healthcare and dental associations, manufacturers, higher education, medical/nursing societies, and a nursing union provided comments on a national deployment strategy for EHMRs (see Figure 2 for a breakdown of the commenters and Figure 3 for the geographic representation of the comments).

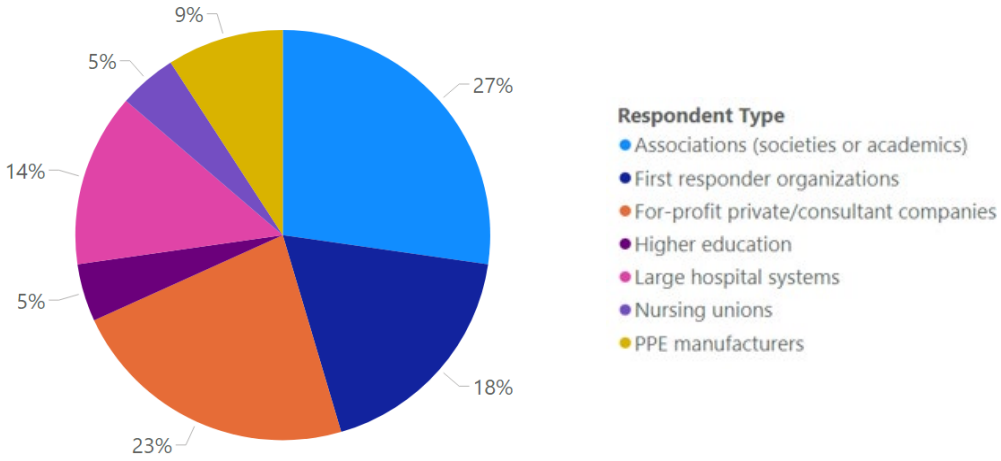

Figure 2. Affiliations of commenters.

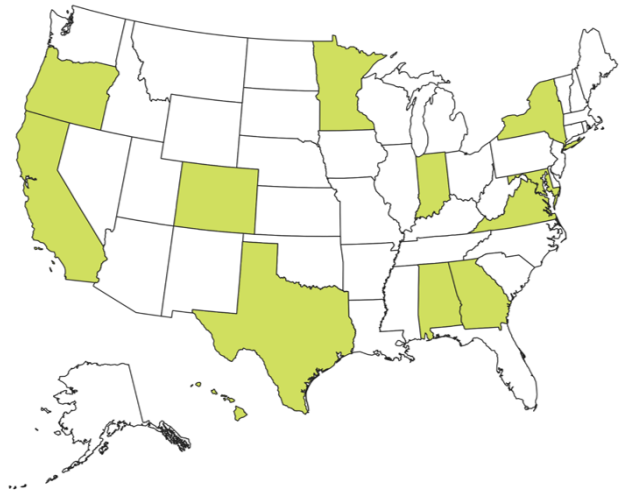

Figure 3. Geographic breakdown of commenters.

Of the commenters, 45% (n=10) were currently overseeing the administration and/or use of EHMRs. In several cases, those who commented had purchased EHMRs in early phases of the COVID-19 pandemic because of N95 FFR shortages. Organizations started with purchasing a small amount (50–200) as a pilot effort. Several groups had implemented EHMRs with their fire, police, EMS, and sheriff's offices, with upwards of 2,000 EHMRs deployed at the time of their response to the RFI. Other commenters did not have experience implementing or using EHMRs on the job but were familiar with research and uses of EHMRs in health settings. For example, commenters who were affiliated with an association reported overseeing EHMR implementation across hospitals. Additionally, over half of the commenters were aware of the recent implementation guidelines (Chalikonda et al., 2020; Hines et al., 2021) published and that these hospitals were able to use EHMRs in place of other respiratory protection in acute care settings while maintaining the same work operations.

Thematic Analysis

Thematic analysis of qualitative information is used to objectively analyze and describe written communication (Neundorf, 2002; Sandelowski, 1995). It is defined as "a method for identifying, analyzing, and reporting patterns (themes) within data" (Braun & Clarke, 2006, p. 79). This approach is particularly useful when making comparisons across different groups' experiences (Hsieh & Shannon, 2005; Elo & Kyngäs, 2008). Using thematic analysis is also helpful when several documents address a similar topic, but the information needs to be condensed into fewer categories to characterize recurring themes (Braun & Clarke, 2006). Additionally, this method is helpful when the data are not dependent on a quantifiable measure but rather need to provide important direction for a research question (Spencer et al., 2003). Such attributes made this approach particularly useful during NIOSH's formative efforts. The coding process was adapted from Braun and Clarke (2006, p. 87) and consisted of preparing and becoming familiar with the responses; conducting initial and focused coding, assigning, and reviewing themes within each identified category; and revising the focused codes to present results.

Preparing and becoming familiar with the responses—Researchers saved each response into a separate folder for analysis. All 22 comments were substantial, and none were excluded. Feedback ranged from 1–10 single-spaced pages per commenter with most responses being at least several pages. The analysis was deductive in nature as most feedback was provided using the probes presented in the FRN. The FRN provided umbrella areas that allowed researchers to identify patterns and themes within the experiences and perceptions shared to form a broader view of the advantages, disadvantages, and considerations for future EHMR research and implementation efforts.

Coding—During initial coding the first author read each response line by line to identify similar categories within the feedback, including concerns, advantages, and elements needed for effective EHMR implementation. This method of line-by-line reading reduced the chances of excluding important information that may have been shared throughout commenters' feedback and not just within the RFI's predetermined response format (Hallgren, 2012).

After organizing content by concerns, advantages, and implementation strategies to consider, feedback was further refined and grouped into specific patterns (Corbin & Strauss, 2008; Saldaña, 2016). After the primary researcher initially populated these categories and defined patterns within them, patterns and examples from commenters were provided to two coauthors for review, feedback, and confirmation of the interpretation of the feedback. Changes were not made to the codes and examples noted as there was general agreement on the organization of themes received in the responses. Finally, after data were organized within these broad categories and supported by examples, a final review occurred to ensure that no codes should be combined, renamed, or moved to a different category. It was important to conduct a final review of the codes to not only ensure saturation but also to highlight areas that needed attention in future research efforts (Boyatzis, 1998).

RESULTS

Each commenter consistently answered the questions outlined in the RFI, which contributed to the saturation of the results. Results are summarized in Table 1 and are further discussed in subsequent sections.

Table I. Summary of Commenter Feedback

Main categories and respective patterns in commenter feedback
Perceived benefits of EHMR use • Reusable resource in comparison to N95 FFRs • Beneficial to worker health and safety
Perceived concerns and barriers of EHMR use • Concerns for worker and patient safety regarding source control • Stockpiling questions around a national deployment strategy • Lack of evidence-based policies and procedures (including components of an RPP)
Implementation strategies • Include a representative sample of organizations and healthcare/first responder employees • Engage frontline workers in demonstration efforts • Apply a sociotechnical model to assess safety culture

Perceived advantages of EHMR use in health settings

Of the 10 commenters that reported using EHMRs, they were also using N95 FFRs in the workplace. For these organizations who were using both types of respiratory protection, advantages to using EHMRs were discussed within the formative feedback received. Although these benefits are already well supported in the literature, they are worth highlighting to illustrate that stakeholders and users have similar viewpoints towards EHMRs.

Reusable respiratory protection—Commenters discussed the advantages of EHMRs being reusable, including potential cost savings in comparison to using disposable N95 FFRs. Although N95 FFRs were temporarily permitted to be decontaminated during the COVID-19 pandemic, this was a short-term stopgap measure. Commenters indicated that EHMRs are a beneficial resource in healthcare settings because they can withstand extended reuse between patient interactions and storage periods in comparison to N95 FFRs. Some commenters provided examples of their RPPs and how they were able to make changes to accommodate EHMR fit testing with relative ease.

Worker health and safety—Several points were made in the comments related to perceived changes in workers' health and safety. The comments included references to NIOSH research showing that EHMRs provide the same level of protection as disposable N95 FFRs (Greenawald et al., 2020). Some commenters urged that healthcare employers should adopt EHMRs as a "key component in their RPP to protect workers from exposure to SARS-CoV-2 and other airborne infectious diseases" (Commenter 15). Other comments discussed that EHMR use can help avoid pressure injuries that have resulted from wearing N95 FFRs for an extended period. Pressure injuries were documented during the pandemic (e.g., Singh et al., 2020; Lin et al., 2020; Jiang, 2020) and, although extended use of respiratory protection may not be needed long-term, the use of EHMRs could minimize these types of injuries.

Perceived disadvantages and concerns of EHMR use in health settings

Although the advantages of EHMR use were repeatedly mentioned in the comments, so were the concerns about widespread integration.

Source control concerns— Source control refers to the filtering of respiratory secretions to prevent the transmission of disease agents from the source person to others. At the time of the Federal Register posting, all NIOSH-approved EHMRs included exhalation valves where the user's exhaled breath exited the respirator facepiece without being filtered. Exhalation valves were ubiquitous among EHMRs because they provide increased user comfort (Fernando et al., 2021). Consequently, almost all commenters had concerns about the exhalation valve on an EHMR and questioned whether source control could be addressed. For example, Commenter 10 said "I have concerns about valves/unfiltered air causing contamination and increasing the risk for patient infection." The same concern was expressed by representatives of fire departments during medical incidents, exemplified by Commenter 2 who stated, "Workers may be asymptomatic but contagious and infect others." However, some commenters cited literature indicating that EHMRs without exhalation valves could be considered for use in some infection control settings. Since these concerns were expressed, several NIOSH-approved EHMRs without an exhalation valve or with a filtered valve have come to market (see Greenawald et al., 2021).

EHMR availability and integrity during stockpiling—Commenters brought up concerns about EHMR acceptability beyond the COVID-19 pandemic. For example, commenters urged additional research in EHMR stockpiling. There was a desire that a generous stockpile of the same EHMR models and ample sizes and components of the same model be available to prevent additional fit testing for organizations if supply chains are disrupted. This includes resources to aid fit testing and other training. Along these lines, one commenter stated it was imperative to understand how to "domestically produce devices in a way that supports routine and surge capacity so manufacturers could adequately supply the SNS with appropriate EHMRs" (Commenter 6). This commenter continued to discuss aspects of logistics, including manufacturing capacity, lead time, and scaling. Along a similar vein, commenters expressed concerns that the national distribution of EHMRs should be supplemented with appropriate data points, including "quantitative metrics and qualitative feedback" (Commenter 13). More specifically, Commenter 14 noted that data collection for approximately two years post deployment is necessary to sufficiently assess the effectiveness of EHMRs for a diverse group of workers. Given the many unanswered questions about EHMRs and the ability to deploy them on a national scale, commenters cautioned that there is still a need to produce and stockpile N95 FFRs.

Commenters also questioned the storage requirements and shelf life for EHMRs and their filters. One commenter said it was imperative to compare the "storage requirements for EHMRs, including filter media and other replacement parts, in a contamination-free environment with space for inspection and maintenance, to the requirements for N95 FFRs" (Commenter 17). More simply put, another commenter asked if EHMR filters had a longer shelf life than stockpiled N95 FFRs (Commenter 7). Many had specific concerns about dust building up on the filters while being stockpiled and whether this impacted the efficacy of the PPE's protection. Interagency resources and partnerships may be necessary to incorporate EHMR supplies into national preparedness strategies and to examine these concerns.

Communication and coordination of EHMR guidance—An overarching concern at the time of the Federal Register posting was the absence of a coordinated RPP or communication plan for EHMR integration and implementation. Commenters indicated that clarity was needed in what is being communicated and supported among federal groups, including the Occupational Safety and Health Administration (OSHA), the FDA, NIOSH, and the manufacturers. Many argued that clear policies were needed prior to the deployment of EHMRs to effectively use EHMRs either in combination with or to replace the conventional use of N95 FFRs. Commenters referenced that guidance from OSHA and NIOSH pertaining to specific aspects of an RPP such as disinfection, storage, and filter life/change out is

necessary to maintain consistent use. Commenters also felt that evidence-based policies and procedures on implementation, including fit testing and disinfection of equipment, was needed. For example, Commenter 13 said that there is a "need to show commitment by having an RPP that follows OSHA requirements with the use of EHMRs." In addition to the initial cost to stockpile EHMRs, commenters felt that more training and education was needed prior to widespread deployment, including the availability of resources to comply with the provisions of 29 CFR 1910.134 for EHMRs *and* N95 FFRs. This feedback illustrated that, although there is support for the widespread deployment of EHMRs, more planning and resources are needed to prepare for an expansive effort.

Elements of an EHMR Implementation Strategy

Lastly, commenters provided considerations to develop a national implementation strategy for EHMRs. Patterns emerged in relation to worker engagement, recruiting representative groups and organizations, and devising a systematic implementation strategy.

Recruit representative feedback from end users and organizations—Commenters discussed the need to involve frontline workers and various organizations in implementing a viable approach for adopting EHMRs. Regarding frontline workers, commenters felt they could provide accurate input on workflow and obstacles to EHMR use. For example, Commenter 15 stated that healthcare workers' involvement in the decision-making and implementation of any EHMR program is crucial to success because workers can "explain if they have difficulty accessing respiratory protection when they need them due to where they might be stored away from patient areas." Similarly, Commenter 14 indicated that consulting with nurses at all phases of deployment was needed to "understand planning, execution, and evaluation," while Commenter 11 specified that those nurses involved should have public health backgrounds to help with adoption efforts. Commenters also discussed the need to involve a variety of staff in deployment efforts including those with experience or credentials in industrial hygiene and infection control, respirator fit testing, training, and use. Involving these job roles could support the development of safety assessments and improve a coordinated communication approach to EHMR integration into workplaces.

Commenters also discussed the need for a representative sample when designing demonstration projects for EHMRs. Although commenters were aware of EHMR research in hospitals, they were unsure of their appropriateness in other settings. Correctional facilities, homeless shelters, and long-term care facilities that foster large, congregated groups, were specifically referenced as organizations of interest for future EHMR deployments. Additionally, commenters encouraged the completion of studies in unionized facilities. Finally, in addition to considering the organization type, commenters noted the importance of targeting a variety of geographic areas.

Technical and cultural sustainability of EHMRs—Comments discussed the importance of longitudinal and systematic approaches to drive organizational solutions that can be maintained over time. One commenter indicated that it is necessary to examine EHMR "efficacy, compliance, and commitment" (Commenter 13). This commenter further indicated that metrics of success can include proper use of EHMRs, the organizational safety culture, logistics of implementation, and economics of deploying EHMRs. Many commenters also mentioned the importance of leadership in creating an autonomous environment in which EHMRs are supported and championed as a form of respiratory protection to use during conventional, contingency, and crisis strategies to protect workers. The use of safety and health assessments or instruments over time was discussed to improve education and training that would resonate with EHMR users to maintain use and reuse over time.

DISCUSSION

The root cause of ineffective programs and interventions often stems from not understanding the target audience and consequently developing inaccurate research to practice models (Mattson & Basu, 2010; McCallum, 1995). This paper supports the importance of collecting formative information prior to educational programs and intervention design to help recognize stakeholder perspectives and consider reliable solutions to address challenges. It is clear from the feedback that a comprehensive and cohesive deployment strategy is needed to facilitate the adoption and maintenance of this type of respiratory protection. Accordingly, NIOSH researchers utilized the feedback provided by commenters to aid in the design of future EHMR demonstration projects (refer to FRN Vol. 86, No. 135, 38098). Aspects of these demonstration projects are highlighted below.

Targeted EHMR Demonstration Projects

In 2021, the SNS purchased 375,000 EHMRs for distribution. Organizations that receive these EHMRs have the option to participate in NIOSH research efforts to enhance EHMR implementation information for healthcare settings and new guidance for first responders. Additionally, manufacturers may be able to glean ways to improve the design of their products from a comfort, usability, maintenance, cleaning and disinfection, or fit perspective. Aspects of this initiative that were informed by this feedback are described below.

Resources— All 22 commenters referenced the need for additional resources and information on EHMR use and integration including fit testing and disinfection procedures. More than half of the commenters referenced the two existing EHMR guideline documents as trusted information demonstrating the utility of using EHMRs in healthcare settings. NIOSH plans to provide these publicly available guidelines to organizations participating in the demonstration projects as both a source of vetted information and a mechanism to elicit targeted feedback from employers about what was relevant in these guidelines, what was not, and why. This feedback will allow NIOSH to further validate the available guidelines while also allowing for the development of more refined implementation guidelines that resonate with other kinds of workplace settings such as fire or police departments.

Source control—Noting the prevalence of comments on the concern about EHMR exhalation valves, NIOSH encouraged the inclusion of mandatory criteria within the SNS's public request for quotes to purchase a large quantity of EHMRs. One of these mandatory criteria followed CDC's guidance to reduce the risk of COVID-19 transmission, which is to not use masks with unfiltered exhaust valves (CDC, 2021). Specifically, the public request stated:
"The direction of the exhalation channel has an impact on both worker and patient safety, as it could direct airflow towards an unprotected individual. In a pandemic situation, this could increase the rate of hospital-associated transmission. [An EHMR with] no exhalation valve is optimal or [if not available] a filtered exhalation valve. The exhalation valve directs exhaled breath and moisture downward to reduce face shield fogging (SAM.gov, np)."

Establishing this mandatory criterion for qualifying EHMRs helps to alleviate concerns over EHMR use in certain healthcare settings and supports conventional use of EHMRs.

Longitudinal, multi-site efforts—NIOSH recognized the need to establish longitudinal studies within various occupational settings to track outcomes that may vary based on organization type, size, and location. By conducting several studies at healthcare and first responder locations, NIOSH can improve the reliability and validity of any revised implementation guidance. NIOSH is working to establish collaborations with a diverse group of organizations who represent several healthcare settings that include first responders. Additionally, some of these sites will be unionized and reside in a variety of geographic locations, as suggested in the FRN comments received.

Individual worker (end user) and management involvement—NIOSH efforts seek to involve individual workers as the end users of EHMRs as well as organizational management who may be involved with developing and executing parts of the RPP. Additionally, multi-methods in the form of pre- and post-use surveys and interviews will be used to allow for triangulation of the results (Flick, 2018). Using a sociotechnical approach that considers human factors and workflow has been recommended in previous PPE healthcare studies (e.g., Visnovsky et al., 2019). This also feeds into the greater issue of considering a workplace's culture. This study is designed to elucidate best practices through the lens of a positive safety culture and aims to understand how leadership roles can help enhance a safe working environment and the consistent use of EHMRs. These efforts will allow for the identification of trends in organizational safety culture that support or hinder EHMR adoption and can, for the first time, be included in PPE implementation guidance.

Limitations

Although this study offers a variety of insights based on the responses to the RFI, the findings cannot be generalized to all healthcare settings or other occupational sectors. These responses, while recruited on a nationwide scale, represent a convenience sample of those who saw and chose to provide a public response. Disadvantages of convenience sampling, most notably sampling bias, must be considered when interpreting the feedback and determining appropriate next steps for developing a national EHMR deployment strategy. For example, hospitals vary substantially based on bed capacity, geographic location, personnel, and other resources that need to be considered when trying to implement and study the deployment of EHMRs. Additionally, the Federal Register notice only sought comments about EHMRs and not N95 FFRs. It is likely that manufacturers are seeking to improve the design, fit, and use of FFRs in addition to EHMRs which may impact stakeholder feedback at a different point in time.

CONCLUSIONS

It is anticipated that EHMR use will increase steadily in a variety of health settings as manufacturers enhance models' comfort, fit, and usability. However, there is often resistance to fully adopting new technological advancements in the workplace by both organizations and end users (Sjöberg, 2002; Wahlström, 1992). Research has identified implications and discussed ways to encourage adoption of EHMRs in healthcare settings for several years, but conventional use during non-surge demand situations is still minimal (Brown et al., 2018; NAS, 2019; Friese et al., 2020; Lawrence et al., 2017). Perhaps one of the reasons it has been difficult to sustain EHMR use has been the absence of specific use cases and information for various situations that end users and organizations may encounter. However, as hospitals start to use new EHMR models without exhalation valves in different settings, such as Allegheny Health Network has done in their operating room settings (Chalikonda et al., 2020), researchers, organizations, and end users will have additional use points to consider if conventional use of EHMRs works for their specific setting and employees in comparison to only using EHMRs as a contingency or crisis strategy. Typically, the collection and use of knowledge, attitudes, and experiences are represented within frameworks to inform the development, implementation, and evaluation of any intervention that intends to influence health behaviors (Fishbein & Yzer, 2003; Goldenhar et al., 2001). The patterns detected in this formative feedback are intended to be used to design a targeted study that can be deployed within a variety of occupational settings.

This paper reported on formative data that were analyzed to glean perceived advantages, disadvantages, and critical components to consider for a successful deployment of EHMRs in a conventional capacity. Engaging stakeholders early in the planning process allowed NIOSH to present a problem and brainstorm solutions independent of recruiting efforts. Through the targeted use of stakeholder feedback, NIOSH aims to accurately anticipate potential barriers to EHMR deployments, and to study and develop relevant, tailored guidelines to help organizations enhance their RPPs.

Consequently, organizations and workers may be more willing to replace or substitute N95 FFRs with EHMRs to reduce PPE supply shortages during future infectious disease outbreaks or pandemics. These engagement efforts are likely to facilitate more effective implementations of this work. Specifically, some commenters also notified NIOSH that their organizations are interested in participating in the NIOSH research study described above in hopes of improving EHMR implementation efforts for their own organization and for all health settings.

Disclaimer

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC). Mention of any company or product does not constitute endorsement by NIOSH, CDC.

REFERENCES

Andreasen AR. Marketing social change. Jossey-Bass; 1995.

Bach M (2017). Understanding respiratory protection options in healthcare: The overlooked elastomeric. NIOSH Science Blog, July 6, 2017. Available at: http://blogs.cdc.gov/niosh-science-blog/2017/07/06/elastomerics/. Accessed January 26, 2021.

Boyatzis RE. (1998) *Transforming qualitative information: Thematic analysis and code development.* Thousand Oaks, CA: Sage Publications.

Braun V and Clarke V (2006). Using thematic analysis in psychology. *Qualitative research in psychology*. 3(2):77–101.

BREATHE. (2009) Better respiratory equipment using advanced technologies for healthcare employees: A report of an interagency working group of the U.S. Federal government. Available at: https://www.cdc.gov/niosh/npptl/hospresptoolkit/pdfs/ProjectBREATHE-final-report-508.pdf. Accessed January 27, 2021.

Brown LM, Rogers B, Buckheit K, Curran JP. (2018) Evaluation of 9 health care organizations' respiratory protection programs and respiratory protective device practices: Implications for adoption of elastomerics. *American journal of infection control*. 46(3):350–2.

Carayon P, Bass EJ, Bellandi T, Gurses AP, Hallbeck MS, Mollo V. (2011). Sociotechnical systems analysis in health care: a research agenda. IIE transactions on healthcare systems engineering. 2011 Jul 1;1(3):145-60.

Chalikonda S, Waltenbaugh H, Angelilli S, Dumont T, Kvasager C, Sauber T, Servello N, Singh A, Diaz-Garcia R. (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. *Journal of the American College of Surgeons*. 231(3):333–8.

CDC. (2021). Your guide to masks: How to select, properly wear, clean, and store masks. Retrieved from https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/about-face-coverings.html on December 13, 2021.

CDC. (2020). Elastomeric Respirators: Strategies During Conventional and Surge Demand Situations. Retrieved from https://www.cdc.gov/coronavirus/2019-ncov/hcp/elastomeric-respirators-strategy/index.html on December 4, 2020.

Chalikonda S, Waltenbaugh H, Angelilli S, Dumont T, Kvasager C, Sauber T, Servello N, Singh A, Diaz-Garcia R. (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. Journal of the American College of Surgeons. 2020 Jun 11.

Cichowicz JK, Casey M, D'Alessandro MM. (2020) Respiratory protection vs. source control – what's the difference? NIOSH Science Blog, September 8, 2020. Available at: https://blogs.cdc.gov/niosh-science-blog/2020/09/08/source-control/. Accessed August 16, 2021.

Corbin J and Strauss A. (2008). Strategies for qualitative data analysis. Basics of Qualitative Research. Techniques and procedures for developing grounded theory, 3rd ed. Sage Publications.

Dietrich J, Yermakov M, Reponen T, Kulkarni P, Qi C, Grinshpun SA. (2015) Protection of firefighters against combustion aerosol particles: simulated workplace protection factor of a half-mask respirator (pilot study). *Journal of Occupational and Environmental Hygiene.* 12(6):415–420.

Elo S and Kyngäs H. (2008) The qualitative content analysis process. *Journal of advanced nursing.* 62(1):107–15.

Federal Register. (2020, 03/27/2020). Notice of emergency use authorization declaration, 85 FR 17335, pgs 17335-17336. Document number: 2020-06541. Published March 27, 2020. Available at: https://www.federalregister.gov/documents/2020/03/27/2020-06541/emergency-use-authorization-declaration.

Federal Register. (2020, 09/14/2020). A National Elastomeric Half Mask Respirator (EHMR) Strategy for Use in Healthcare Settings During an Infectious Disease Outbreak/Pandemic. 85 FR 56618, Vol. 85, No. 178. https://www.govinfo.gov/content/pkg/FR-2020-09-14/pdf/2020-20115.pdf.

Federal Register. (2021). Evaluating the use of EHMRs in health settings to improve organizational implementation and worker adoption during and after the COVID–19 pandemic. Volume 86, No. 135, pgs. 38098-38100. Monday, July 19, 2021. https://www.govinfo.gov/content/pkg/FR-2021-07-19/pdf/2021-15228.pdf

Fernando R, Portnoff L, and Haas EJ (2021). Reusable respirators for healthcare use: Advancements in elastomeric respirator technology address source control. *The Synergist*, November Issue. Available at: https://synergist.aiha.org/202111-reusable-respirators.

Fishbein M and Yzer M. (2003) Using theory to design effective health behavior interventions. *Communication Theory.* 13(2):164–83.

Friese CR, Veenema TG, Johnson JS, Jayaraman S, Chang JC, Clever LH. (2020) Respiratory protection considerations for healthcare workers during the COVID-19 pandemic. *Health security.* 18(3):237–40.

Greenawald L, Haas EJ, D'Alessandro MM (2021). Elastomeric half mask respirators: An alternative to disposable respirators and a solution to shortages during public health emergencies. *Journal of the International Society for Respiratory Protection,* 38(2), 74–91.

Greenawald L, Cichowicz JK, D'Alessandro MM (2020). Supplementing the Supply of N95s with Reusable Elastomeric Half Mask Respirators | | Blogs | CDC. Published 2020. Available at: https://blogs.cdc.gov/niosh-science-blog/2020/09/08/elastomeric/. Accessed September 11, 2020.

Goldenhar LM, LaMontagne AD, Katz T, Heaney C, Landsbergis P. (2001) The intervention research process in occupational safety and health: an overview from the national occupational research agenda intervention effectiveness research team. *J Occup Environ Med*. 43:616–22.

Hallgren KA. (2012) Computing inter-rater reliability for observational data: an overview and tutorial. *Tutorials in quantitative methods for psychology.* 8(1):23.

Hines SE, Mueller N, Oliver M, Gucer P, McDiarmid M. (2017) Qualitative Analysis of Origins and Evolution of an Elastomeric Respirator-based Hospital Respiratory Protection Program. *Journal of the International Society for Respiratory Protection*. 34(2):95–110.

Hines SE, Brown C, Oliver M, et al. (2019a). Storage and Availability of Elastomeric Respirators in Health Care. *Health Security*. 17(5):384–392.

Hines SE, Brown C, Oliver M, et al. (2019b). User acceptance of reusable respirators in health care. *American Journal of Infection Control*. Published online 2019. doi:10.1016/j.ajic.2018.11.021.

Hines SE, Thurman P, McDiarmid M. (2021) Implementation guide to support use of elastomeric half mask respirators in healthcare. University of Maryland. Available at: https://archive.hshsl.umaryland.edu/handle/10713/14748. Accessed July 22, 2021.

Hsieh HF and Shannon S. (2005) Three approaches to qualitative content analysis. *Qualitative Health Research.* 15:1277–1288.

Jaffe E, Sonkin R, Strugo R, Zerath E. (2021) Evolution of emergency medical calls during a pandemic–An emergency medical service during the COVID-19 outbreak. *The American Journal of Emergency Medicine.* 43:260-6.

Jiang Q, Song S, Zhou J, Liu Y, Chen A, Bai Y, Wang J, Jiang Z, Zhang Y, Liu H, Hua J. (2020). The prevalence, characteristics, and prevention status of skin injury caused by personal protective equipment among medical staff in fighting COVID-19: a multicenter, cross-sectional study. *Advances in Wound Care.* 1;9(7):357-64.Krippendorff K. (1980) *Content analysis: An introduction to its methodology*. Sage Publications, Newbury Park.

Lawrence C, Harnish DA, Sandoval-Powers M, Mills D, Bergman M, Heimbuch BK. (2017) Assessment of half-mask elastomeric respirator and powered air-purifying respirator reprocessing for an influenza pandemic. *American journal of infection control.* 45(12):1324–30.

Lin P, Zhu S, Huang Y, Li L, Tao J, Lei T, Song J, Liu D, Chen L, Shi Y, Jiang S. (2020). Adverse skin reactions among healthcare workers during the coronavirus disease 2019 outbreak: a survey in Wuhan and its surrounding regions. The British journal of dermatology. 2020 Jul 1.

Luce K (2020). They Evoke Darth Vader, but These Masks May Save Your Doctor's Life. The New York Times. Available at: https://www.nytimes.com/2020/05/27/us/coronavirus-masks-elastomeric-respirators.html. Accessed January 20, 2021.

Mattson M and Basu A. (2010) Centers for Disease Control's DES Update: a case for effective operationalization of messaging in social marketing practice. *Health Promot Pract.* 11(4):580–8.

McCallum DB. (1995) Risk communication: a tool for behavior change. In: Backer TE, David SL, Saucy G, editors. Reviewing the behavioral science knowledge base on technology transfer. National Institute on Drug Abuse. NIDA Research Monograph 155. Rockville MD. pp. 65–89. Available at: file:///C:/Users/wcq3/Downloads/Creating_strong_attitudes_two_routes_to_persuasion.pdf. Accessed August 16, 2021.

MSA (2020). Why reusable half-mask respirators are a good option for the fire service and EMS. Available at: https://blog.msafire.com/why-reusable-half-mask-respirators-are-a-good-option-for-the-fire-service-and-ems/. Accessed January 26, 2021.

NAS (2019) *Reusable Elastomeric Respirators in Health Care : Considerations for Routine and Surge Use.* National Academies of Science Engineering and Medicine. National Academies Press; 2019. doi:https://doi.org/10.17226/25275.

Neundorf K. (2002) *The Content Analysis Guidebook.* Sage Publications Inc., Thousand Oaks, CA.

OSHA Occupational Safety and Health Administration. *Respiratory Protection. - 1910.134 | Occupational Safety and Health Administration*. Available at: https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=12716&p_table=standards. Accessed September 11, 2020.

OSHA and NIOSH (2015). Hospital respiratory protection program toolkit: Resources for respirator program administrators. Available at: https://www.cdc.gov/niosh/docs/2015-117/pdfs/2015-117.pdf?id=10.26616/NIOSHPUB2015117. Accessed January 20, 2021.

Patton MQ. (1990) *Qualitative evaluation and research methods*. Sage Publications, Newbury Park.

Pompeii LA, Kraft CS, Brownsword EA, Lane MA, Benavides E, Rios J, Radonovich LJ. (2020). Training and fit testing of health care personnel for reusable elastomeric half-mask respirators compared with disposable N95 respirators. *JAMA.* 323(18):1849–52.

Robertsen Ø, Siebler F, Eisemann M, Hegseth MN, Føreland S, Vangberg HCB. (2018) Predictors of respiratory protective equipment use in the Norwegian smelter industry: The role of the theory of planned behavior, safety climate, and work experience in understanding protective Behavior. *Frontiers in psychology*. 9:1366.

Saldaña J. (2016) *The coding manual for qualitative researchers.* London, UK: Sage Publications.

Sandelowski M. (1993) Theory unmasked: the uses and guises of theory in qualitative research. *Research in Nursing & Health*. 16:213–218.

Sandelowski M. (1995) Qualitative analysis: what it is and how to begin? *Research in Nursing & Health.* 18:371–375.

Singh M, Pawar M, Bothra A, Maheshwari A, Dubey V, Tiwari A, Kelati A. (2020). Personal protective equipment induced facial dermatoses in healthcare workers managing Coronavirus disease 2019. Journal of the European Academy of Dermatology and Venereology. 2020 Aug 1.

Sjöberg L. (2002) Attitudes toward technology and risk: Going beyond what is immediately given. *Policy Sciences.* 35:379–400.

Spencer L, Ritchie J, O'Connor W. (2003) Analysis: practices, principles and processes. In J Ritchie and J Lewis, eds. *Qualitative research practice: A guide for social science students and researchers,* pgs. 199-218. Thousand Oaks, CA: Sage Publications.

Tracy T. (2020) FDNY to switch from disposable to reusable masks. New York Daily News, November 11, 2020. Available at: https://www.firerescue1.com/fire-products/personal-protective-equipment-ppe/articles/fdny-to-switch-from-disposable-to-reusable-masks-gfPDvcpfups5kMpr/. Accessed January 25, 2021.

Vaismoradi M, Turunen H, Bondas T. (2013). Content analysis and thematic analysis: Implications for conducting a qualitative descriptive study. *Nursing & health sciences.* 15(3):398-405.

Visnovsky LD, Zhang Y, Leecaster MK, Safdar N, Barko L, Haroldsen C, Mulvey DL, Nevers M, Shaughnessy C, Stratford KM, Drews FA. Effectiveness of a multisite personal protective equipment (PPE)–free zone intervention in acute care. Infection Control & Hospital Epidemiology. 2019 Jul;40(7):761-6.

Wahlström B. (1992) Avoiding technological risks: The dilemma of complexity. *Technological Forecasting and Social Change.* 4:351–365.

Wizner K, Stradtman L, Novak D, Shaffer R. (2016) Prevalence of Respiratory Protective Devices in U.S. Health Care Facilities: Implications for Emergency Preparedness. *Workplace health & safety*. 64(8):359-368.