

October 12, 2020

Lee Greenawald, PhD
National Institute for Occupational Safety and Health
626 Cochran Mill Road, Building 141
Pittsburgh, PA 15236

Re: Request for Information on a National Elastomeric Half Mask Respirator (EHMR) Strategy
for Use in Healthcare Settings during an Infectious Disease Outbreak/Pandemic

Submitted electronically to ppeconcerns@cdc.gov

Dear Dr. Greenawald:

The American Nurses Association (ANA) is pleased to submit comments in response to the September 14, 2020, Request for Information (RFI) on a national strategy to deploy elastomeric half mask respirators (EHMRs) in healthcare settings during a pandemic or outbreak of infectious disease. ANA is the premier organization representing the interests of the nation's 4.2 million registered nurses (RNs) through its state and constituent member associations, organizational affiliates, and the individual members. ANA members also include nurses practicing in the four advanced practice registered nurse (APRN) roles.¹

Nurses have been on the frontlines of the COVID-19 pandemic, providing direct care in acute care settings, engaged in testing and contact tracing in communities, and leading innovations in health care delivery to meet the needs of all patients during this unprecedented public health emergency (PHE). Because of close contact with COVID-19 patients, many nurses are at risk for infection, and many have suffered severe illness and death during the pandemic so far.²

ANA surveys of nurses have consistently shown that supply of personal protective equipment (PPE) continues to be the top-of-mind concern, and that nurses are highly anxious with emergency measures such as reuse and decontamination as this goes against best practice standards. For example, in a survey of more than 21,000, fielded in mid-July to mid-August 2020, 42 percent of nurses said they are still experiencing PPE shortages. Despite anecdotal reports of hospitals indicating they now have adequate supplies on hand, nurses report having to reuse PPE that may or may not be decontaminated rather than returning to best practice of single use. More than half report re-using single-use respirators for five or more days, and more than half said this practice makes them feel unsafe.³

¹ The Consensus Model for APRN Regulation defines four APRN roles: certified nurse practitioner, clinical nurse specialist, certified nurse-midwife, and certified registered nurse anesthetist. In addition to defining the four roles, the Consensus Model describes the APRN regulatory model, identifies the titles to be used, defines specialty, describes the emergence of new roles and population foci, and presents strategies for implementation.

²See Centers for Disease Control and Prevention. Update: Characteristics of Health Care Personnel with COVID-19 — United States, February 12–July 16, 2020. September 2020. Accessible online at <http://dx.doi.org/10.15585/mmwr.mm6938a3>.

³American Nurses Association. Update on Nurses and PPE: Survey reveals alarming conditions. September 2020. Accessible at: <https://www.nursingworld.org/~4a558d/globalassets/covid19/ana-ppe-survey-one-pager---final.pdf>

ANA appreciates the role of the National Institute for Occupational Safety and Health (NIOSH) in developing and disseminating up-to-the-minute scientific evidence to inform practical and regulatory guidance related to PPE face coverings during the COVID-19 emergency. To the extent that shortages of disposable N95 respirators persist, use of EHMRs in certain healthcare settings may be a promising response. However, ANA continues to urge federal policymakers to ensure a return as soon as possible to application and enforcement of pre-emergency standards for PPE, including safe use of N95 respirators to prevent infection.

Planning and Evaluation Prior to Widespread Deployment

From our perspective, there are a number of unanswered questions about the practical safety and usefulness of deploying EHMRs on a national scale at this time in the nursing workforce. For that reason, ANA urges the agency to carefully study use of EHMRs in a range of health care delivery settings prior to deploying large numbers of EHMRs for widespread use. A good starting point is to assess effectiveness and ease of use of EHMRs in those healthcare delivery settings where they are already in use. Findings from this inquiry would suggest strategies for pilots to fill knowledge gaps.

We have deep concerns about NIOSH promoting EHMRs as a substitute for returning to use of N95 respirators in compliance with existing pre-COVID-19 standards. We would be particularly interested in evidence and analysis to address the following issues:

- **Distribution.** In the current emergency, distribution should be data-driven based upon current and projected areas of concern for COVID-19 surges, as well as cases of other infectious diseases, and adjusted accordingly based upon shifts in case numbers.
- **Production and Supply Capacity.** Though non-disposable and thus longer lasting than the N95 respirators currently in use, EHMRs use filters that need replacement over time. As we have seen with disposable respirators, stockpiles can become strained or depleted over the course of an infectious disease pandemic. There must be demonstrated capacity for the system to produce and move replacement filters, in addition to the masks, to meet a large share of anticipated demand. It remains necessary to forecast and plan for sufficient numbers of disposable N95 respirators to fill any gaps created by EHMR filter shortages, and for situations where reliance on EHMRs is simply not appropriate. Researchers and policymakers should not turn to reliance on EHMRs exclusively. Rather, the goal should be to develop the evidence base to improve system capacity overall.
- **Setting.** More information is needed about the usefulness and appropriateness of EHMRs outside of hospital settings. When selecting participants for deployment and for pilots, we recommend NIOSH meaningfully assess how the strategy supports healthcare workers outside of the acute-care setting, such as long-term care facilities, school, community health providers, ambulatory care, and home health.

Strategic Parameters for Deploying EHMRs

Considering the concerns discussed above, ANA supports limited deployment of EHMRs at this time to meet the needs of the COVID-19 emergency. In response to the RFI, we offer the following recommendations for strategic deployment.

- **Planning, Execution, and Evaluation Partners.** ANA urges NIOSH and its partners to consult with nurses at all phases of its deployment and demonstration strategies. Nurses representing a variety of healthcare settings should be included in planning, execution, and evaluation. Participants should be expected explicitly to include nurses and other frontline workers at all phases, and resources made available for them to do so.
- **Federal Investments.** ANA urges NIOSH to work with federal policymakers to secure sustainable funding not only for production of EMHRs and filters, but also for strategic deployment. Consideration should also be given to the interagency resources needed to incorporate EMHR supply in national preparedness strategies.
- **National Standard for Use and Training.** In partnership with manufacturers and healthcare system partners, federal agencies should develop and disseminate a national standard to guide EHMR use and training, including protocols for disinfection, storage, and reissue.
- **Data Collection and Analysis.** ANA recommends collection of data for at least two years post-deployment, sufficient to assess effectiveness for a range of healthcare workers and impacts on diverse patient populations.
- **Compliance and Enforcement.** ANA urges NIOSH to coordinate with federal and state partners to prevent distribution of non-approved products, and to be prepared to take swift action against counterfeit and noncompliant production.
- **EHMR Handling.** NIOSH should consider best practices and a preferred system for reprocessing, collection, return, and reissue of EHMRs. Product tracking and protocols for discontinuing EHMRs should be part of this process.

In conclusion, ANA believes considerable study is needed to support any plans for widespread use of EHMRs. We support limited, careful piloting of EHMR use, while the necessary data and evidence-based standards are developed and integrated into existing regulatory frameworks. If you have any questions, please contact Brooke Trainum, JD, Assistant Director of Policy and Regulatory Advocacy, at (301) 628-5027 or brooke.trainum@ana.org.

Sincerely,



Debbie Hatmaker, PhD, RN, FAAN
Chief Nursing Officer/EVP

cc: Ernest Grant, PhD, RN, FAAN, ANA President