

Elastomeric and Powered-Air Purifying Respirators in U.S. Healthcare

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N95 Day

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Key Topics

- I. Surgical Masks (SMs) and N95 Filtering Facepiece Respirators (N95 FFRs) as Mainstay
- II. Elastomeric Half-Facepiece Respirators (EHFR) as Alternative
- III. Powered Air-Purifying Respirators (PAPRs) as Alternative
- IV. EHFR and PAPR Policy Research at NIOSH

Requirements and Regulations

- Title 42, Code of Federal Regulations Part 84
- In U.S. workplaces requiring the use of respiratory protective devices, the Occupational Safety and Health Administration (OSHA) requires the use of respirators approved by the National Institute for Occupational Safety and Health (NIOSH)
- The National Personal Protective Technology Laboratory (NPPTL), a Division of NIOSH, tests and approves respirators
- The Food and Drug Administration (FDA) regulates medical devices including N95 respirators



Respiratory Protection in Healthcare:

The View from 30,000 Feet

- Choosing the correct respirator for the exposure level and work task is important
- Respiratory protection in healthcare is sometimes not emphasized
- Most healthcare workers are aware of the N95 respirator, but may not be aware that reusable elastomeric respirators are a viable option for respiratory protection
- PAPRs have received considerable attention in recent years and some have called for PAPRs that are tailored for use in healthcare

Surgical Masks (SMs)

- Disposable coverings, loose-fitting that leave gaps between the mask and the wearer's face through which harmful particles may pass
- Intended to prevent transmission of infection from the wearer to others (source control)
- Not respirators



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N95 Respirators

- Standard N95: NIOSH-approved. Designed to reduce inhalation of aerosolized particles. Fit testing is required.
- Surgical N95: FDA-cleared as a medical device and NIOSH-approved. Designed to reduce inhalation of aerosolized particles. Fit testing is required.
- Most N95s are disposable (single-use) and not designed for repeated or extended use.
 - However, limited reuse may be permitted under certain circumstances
 - EHFRs and PAPRs are designed for reuse



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Elastomeric Respirators (EHFRs)

- Half-facepiece, tight-fitting respirators that are made of synthetic or rubber material permitting them to be repeatedly disinfected, cleaned, and reused
 - Equipped with exchangeable filter cartridges
 - May have disposable components
- NIOSH-approved
- Assigned the same protection classification (APF) as N95s
- Also available as full facepieces, which have a clear lens that covers the eyes as well as the nose and mouth, although not used in civilian healthcare (to our knowledge)



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Powered Air-Purifying Respirators (PAPRs)

- Reusable respirators that are typically loose-fitting hooded or helmeted
- Equipped with a battery-powered blower to force air through a particle filter for the wearer to breathe
- Capable of reducing airborne exposures at efficiencies that typically exceed the N95 and EHFR, using a high-efficiency particulate air (HEPA) filter



Photo Courtesy of MaxAir

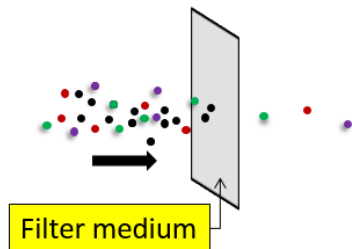


Photo Courtesy of North

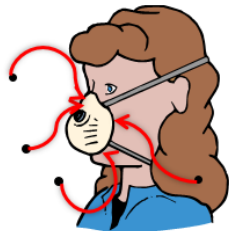
Assigned Protection Factor

- Established by OSHA
- A major difference between SMs and respirators
- Both the standard N95 and the surgical N95 are assigned an APF of 10, meaning the N95 reduces the aerosol concentration by a factor of 10 (one-tenth the number of particles inside compared to outside the N95)

Filter penetration



Face seal leakage



Respirator	SM	N95	EHFR	PAPR
APF	N/A	10	10	25-1000

Key Benefits of EHFRs

- Reusable
 - Durable
 - Maintain fit over time
 - Stand up to repeated disinfection and cleaning
- One EHFR assigned to each worker (e.g., you get your own respirator)
- Potential cost savings
 - Routine use
 - Stockpiling for surges in demand
- Disinfection and cleaning required
 - Prioritizes or codifies a process



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CONCEPTS

in Disaster Medicine

Comparative Cost of Stockpiling Various Types of Respiratory Protective Devices to Protect the Health Care Workforce During an Influenza Pandemic

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ABSTRACT

Specific guidance on the size and composition of respiratory protective device (RPD) stockpiles for use during a pandemic is lacking. We explore the economic aspects of stockpiling various types and combinations of RPDs by adapting a pandemic model that estimates the impact of a severe pandemic on a defined population, the number of potential interactions between patients and health care personnel, and the potential number of health care personnel needed to fulfill those needs. Our model calculates the number of the different types of RPDs that should be stockpiled and the consequent cost of purchase and storage, prorating this cost over the shelf life of the inventory. Compared with disposable N95 or powered air-purifying respirators, we show that stockpiling reusable elastomeric half-face respirators is the least costly approach. Disposable N95 respirators take up significantly more storage space, which increases relative costs. Reusing or extending the usable period of disposable devices may diminish some of these costs. We conclude that stockpiling a combination of disposable N95 and reusable half-face RPDs is the best approach to preparedness for most health care organizations. We recommend against stockpiling powered air-purifying respirators as they are much more costly than alternative approaches. (*Disaster Med Public Health Preparedness*. 2015;0:1-6)

Key Words: pandemics, stockpiles, respiratory protective devices, model

Key Challenges with EHFRs

- Interference with duties
 - Visual field (downward vertical gaze) somewhat limited
 - Speech intelligibility somewhat decreased
- Carried by healthcare personnel during workday
- Storage between work shifts
- Disinfection/cleaning process
- Fit testing is required



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Disinfection and Cleaning of EHFRs

■ Terminology

- Disinfection: destroying, inactivating, or removing potentially infectious microorganisms
- Cleaning: removing non-infectious dirt or debris

■ Sources of Information and Recommendations

- Manufacturers' instructions
- Healthcare Infection Control Practices Advisory Committee (HICPAC)
- CDC/NIOSH
- OSHA
- Peer-reviewed publications

Recommended Guidance for Extended Use and Limited Reuse of N95 Filtering Facepiece Respirators in Healthcare Settings

Background

This document recommends practices for extended use and limited reuse of NIOSH-certified N95 filtering facepiece respirators (commonly called "N95 respirators"). The recommendations are intended for use by professionals who manage respiratory protection programs in healthcare institutions to protect health care workers from job-related risks of exposure to infectious respiratory illnesses.

Supplies of N95 respirators can become depleted during an influenza pandemic (1-3) or wide-spread outbreaks of other infectious respiratory illnesses (4). Existing CDC guidelines recommend a combination of approaches to conserve supplies while safeguarding health care workers in such circumstances. These existing guidelines recommend that health care institutions:

- Minimize the number of individuals who need to use respiratory protection through the preferential use of engineering and administrative controls;
- Use alternatives to N95 respirators (e.g., other classes of filtering facepiece respirators, elastomeric half-mask and full facepiece air purifying respirators, powered air purifying respirators) where feasible;
- Implement practices allowing extended use and/or limited reuse of N95 respirators, when acceptable; and
- Prioritize the use of N95 respirators for those personnel at the highest risk of contracting or experiencing complications of infection.

This document focuses on one of the above strategies, the extended use and limited reuse of N95 respirators only; please consult the [CDC](#) or [NIOSH](#) website for guidance related to implementing the other recommended approaches for conserving supplies of N95 respirators.

There are also non-emergency situations (e.g., close contact with patients with tuberculosis) where N95 respirator reuse has been recommended in healthcare settings and is commonly practiced (5-9). This document serves to supplement previous guidance on this topic.

On this Page

- [Background](#)
- [Definitions](#)
- [Implementation](#)
- [Respirator Extended Use Recommendations](#)
- [Respirator Reuse Recommendations](#)
- [Risks of Extended Use and Reuse of Respirators](#)
- [References](#)

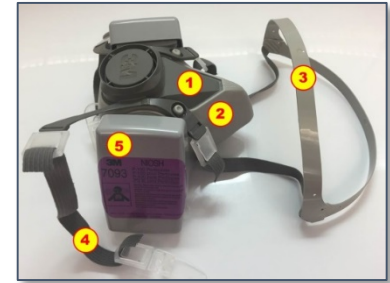
Photo Courtesy of NIOSH

Disinfection and Cleaning of EHFRs

- Disinfection and cleaning issues under study and discussion
 - Disinfectant materials
 - Cleaning materials
 - Frequency (e.g., end of work shift, between uses, between patient interactions)
 - Location (e.g., central processing, dirty utility room)
 - Avoidance of self-contamination
 - Duration of filter cartridge use
 - Duration of exposed filter use
 - Education and training for wearers

EHFR/PAPR Manual Reprocessing Study

- Applied Research Associates (Panama City, Florida) studied the effectiveness of manual cleaning and disinfecting procedures for five EHFRs and three PAPRs
- Respirators were contaminated with influenza virus and soiling agents (artificial skin oil, artificial saliva) on multiple surfaces (facemask, straps, etc.)
- Contaminated respirators were treated with one of two methods:
 - Cleaned (neutral detergent only)
 - Cleaned and disinfected (neutral detergent and disinfectant)
- On average, a 4.5-log reduction was observed across all 41 surfaces tested
- Cleaning alone was found to be sufficient for removing/killing influenza (Lawrence, *et al.*)



Reusable Respirators during a Surge of Infectious Patients

- Nationwide projected N95 need for 1918-like influenza pandemic: 1.7 – 7.3 billion
 - Approximate cost to purchase: \$1-5 billion every several years (shelf life ~ 5 years)
 - Approximate cost to store annually \$100 million
- Shortages of N95 respirators occurred during SARS (2003) and H1N1 influenza (2009)
- Elastomeric respirators are infrequently used for patient care in the U.S.
 - Limited experience and familiarity
 - Many unanswered questions
- Recent studies indicate that HCP willingness to work during a pandemic increases when healthcare organizations have mature respiratory protection programs and adequate numbers of respirators in supply

Key Questions Posed by NIOSH

- (1) In what U.S. workplaces have elastomerics been used successfully?
- (2) Are elastomerics viable for wider or more routine use in U.S. healthcare, and if yes, in what settings?
- (3) Would an elastomeric with a less industrial appearance, such as a model developed by Scott Safety Corporation, be more widely accepted in U.S. healthcare?
- (4) What is the feasibility of U.S. healthcare institutions converting from N95 to elastomeric use if N95 shortages occur (“just-in-time” conversion)?



Photo Courtesy of Scott Safety

NIOSH Elastomeric Endeavors Under Consideration

- National Academy of Medicine Study
- Demonstration projects to understand feasibility routine use in selected settings
- Demonstration project to understand just in time use
- Infection control assessment building on recent unpublished work

Key Benefits of Loose-Fitting PAPRs

- Reusable
 - Durable
 - Stand up to repeated disinfection and cleaning
- Fit testing not required
 - May be used with facial hair
 - May be used when fit testing fails
- Disinfection and cleaning required
 - Prioritizes or codifies a process
- Higher APF



Photo Courtesy of Bullard

Key Challenges with PAPRs

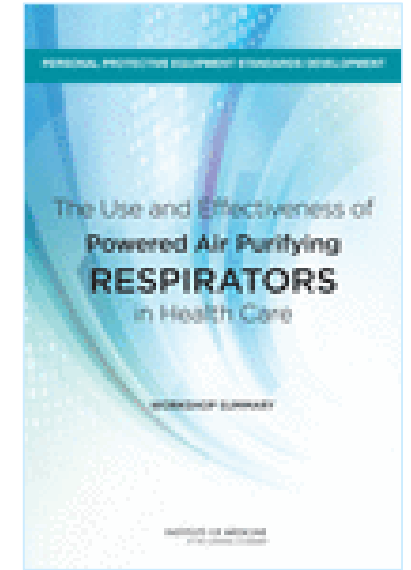
- Interference with duties
 - Visual field (horizontal and downward vertical gaze) often limited
 - Hearing acuity somewhat decreased
 - Stethoscope/otoscope use may be limited
- Batteries must be recharged
- Storage between work shifts
- Disinfection/cleaning process (added requirement)
- Cost
 - N95 ~ \$0.75
 - EHFR ~ \$30.00
 - PAPR ~ \$800.00



Photo Courtesy of Bullard

Development of Performance Criteria for PAPRs in Healthcare

- 2014 Institute of Medicine Report “The Use and Effectiveness of Powered Air-Purifying Respirators in Health Care”
 - Prioritize and accelerate development of performance requirements
 - Improving PAPR designs
 - Creating new design attributes
 - Increasing education and training
- Under consideration are ways to maintain current protections, leverage technologies that enhance PAPR utility, and create the opportunity for smaller, lighter, and more comfortable systems to be designed and approved
- Consideration of non-respiratory requirements
 - Communication effectiveness
 - Resistance to fluids
 - Ocular irritation
 - Use in a sterile field



Key Considerations about Respirators in Healthcare

- N95s, EHFRs, and PAPRs do not provide absolute respiratory protection; they all reduce exposure, but are not designed to eliminate exposure
- Respirators must be worn to be effective
- Correct donning and doffing procedures are important to achieve suitable protection
- EHFRs are a practical option that may be considered for respiratory protection within healthcare institutions, although further study and discussion are necessary
- NIOSH seeks ways to tailor PAPRs for healthcare, your input is valuable

Disclaimer

DISCLAIMER: The findings and conclusions in this report are those of the author(s) and do not necessarily represent the views of the National Institute for Occupational Safety and Health.

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Additional Resources

Additional Resources

- <https://www.cdc.gov/niosh/docs/2015-117/default.html>
- <https://www.cdc.gov/niosh/docs/wp-solutions/2016-109/default.html>
- <https://blogs.cdc.gov/niosh-science-blog/2009/10/14/n95/>
- https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/RespSource.html