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

Lew Radonovich

N95 Day

September 5, 2017
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
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
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)
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)

<table>
<thead>
<tr>
<th>Respirator</th>
<th>SM</th>
<th>N95</th>
<th>EHFR</th>
<th>PAPR</th>
</tr>
</thead>
<tbody>
<tr>
<td>APF</td>
<td>N/A</td>
<td>10</td>
<td>10</td>
<td>25-1000</td>
</tr>
</tbody>
</table>
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
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
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
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
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 elastomeric been used successfully?

(2) Are elastomeric 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)?
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.
References


References

- Implementing Hospital Respiratory Protection Programs: Strategies from the Field, 2014. Available at: https://www.jointcommission.org/assets/1/18/Implementing_Hospital_RPP_2-19-15.pdf
References


- NIOSH-funded collaboration with The Joint Commission, Hospital Respiratory Protection Programs: Usefulness of Resources and Informational Gaps, 2016-17.

Additional Resources

- https://www.cdc.gov/niosh/docs/2015-117/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