Key Topics

I. Regulation and Approval
II. Elastomeric Half-mask Respirators (EHMR) in Context
III. EHMR to Protect Against Infectious Diseases
IV. National Academy of Medicine Consensus Report about EHMR
V. Recent Developments with EHMR at CDC/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 filtering facepiece respirators (N95) in collaboration with NIOSH
OSHA requires the use of NIOSH-certified respirators in U.S. workplaces requiring RPDs

NIOSH has authority to approve respirators
- Authority rooted in creation of the Bureau of Mines, 1910
- Occupational Safety and Health Act of 1970
- FCMSHA of 1977
- 42 CFR 84 current
Infectious Occupational Hazards in Healthcare

- Healthcare Personnel (HCP) work in unique settings where they are routinely exposed to infectious diseases (virus, bacteria, fungi)
- HCP may be at increased risk for acquiring infections, compared to the general population
  - HCP ~ 2x odds of infection with H1N1 influenza (2009 pandemic) compared to non-HCP (Lietz et al)
  - HCP 21-32x more likely to be infected with ebola in 2014-15 than general population (www.who.int)
  - HCP ~ 44% of SARS cases in 2003 in Greater Toronto Area (McDonald et al.)
- Respirators are an important component of infection prevention and control: to protect HCP from aerosol-transmissible infections
Respirator Recommendations, Regulation, and Policies

- The Centers for Disease Control and Prevention (CDC) recommends HCP wear respiratory protection to protect against aerosol-transmissible infections in certain settings and when performing specific tasks placing them at risk (HICPAC 2007)

- The Occupational Safety and Health Administration (OSHA) requires employers to provide respiratory protection to HCP “where respirators are necessary to protect the health of the employee.” (CFR 1910.134)

- Healthcare delivery organizations’ policies and practices (e.g., hospitals, clinics) from across the nation call for respiratory protection to protect HCP from exposures to aerosol-transmissible infectious diseases
NIOSH Respirator Approvals

- NIOSH approves ‘individual, completely assembled respirators’; 42 CFR 84.30(a)
- NIOSH will not issue approval of ‘any respirator component or any respirator subassembly; 42 CFR 84.30(b)
- Concept makes it easy to track actual configurations and identify critical performance characteristics
OSHA Required Fit Testing Process

Example Method: PortaCount® Quantitative Fit Testing

1. Normal Breathing
2. Deep Breathing
3. Head Side-to-Side
4. Head Up and Down
5. Talking
6. Grimace
7. Bending
8. Normal Breathing
For Respirators to be Effective, They Must Fit Correctly

- OSHA requires fit testing at least annually
- Cost ~ $200,000 per year per U.S. hospital

Qualitative Fit Testing

Sources:
(b) CFR 1910.134; Occupational Safety and Health (OSHA) Respiratory Protection Regulation

Photos courtesy of Veterans Health Administration
Surgical Masks

- Disposable coverings, loose-fitting that leave gaps between the mask and the wearer’s face through which infectious aerosols may pass

- Intended to prevent transmission of infection *from* the wearer to others (source control)

- Not respirators

- Worn with droplet precautions (not airborne precautions)

- Regulated/cleared by FDA
Filtering Facepiece Respirators
(N95 is most common in healthcare)

- **Standard N95**: NIOSH-approved (Meets all requirements of 42 CFR 84 Subpart K). Designed to reduce inhalation of aerosolized particles. Fit testing is required.

- **N95-F**: Meets all requirements of Standard N95. Meets three additional performance requirements: 1) Biocompatibility (in vitro test, sensitivity, irritation), 2) Flammability, 3) Fluid Resistance. 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. **N95-F replaces this designation as of August 2018.**

- Most N95s are disposable (single-use) and not designed for repeated or extended use.
  - However, limited reuse may be permitted under certain circumstances (e.g., extreme shortages during a pandemic)
  - EHMRs and PAPRs are designed for reuse
Powered Air-Purifying Respirators (PAPRs)

- Reusable respirators that are typically loose-fitting, tight-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 EHMR, using a high-efficiency particulate air (HEPA) filter
- NIOSH approved
Elastomeric Half-mask Respirators (EHMRs)

- Half-mask, tight-fitting respirators that are made of synthetic or rubber material permitting them to be repeatedly disinfected, cleaned, and re-donned
  - Equipped with exchangeable filter cartridges
  - May have disposable components
- NIOSH-approved
- OSHA assigned protection classification (APF) same as N95s

Photo Courtesy of MSA
Closing the national respirator gap with EHMRs: Why we need EHMRs 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 (Veterans Health Administration)

- Gap in national surge needs:
  - ASTHO Report (2014): Total number of N95 held by U.S. acute care hospitals ≈ 60M
  - This means, hospitals have about 1% of expected national demand for a severe pandemic

- Shortages of N95 respirators occurred during SARS (2003) and H1N1 influenza (2009)

- Shortages pose substantial operational and policy challenges during public health emergencies
  - Approximate percentage of U.S. HCPs willing to work during moderate-severe influenza pandemic: 80%
  - Percentage of U.S. HCPs willing to work during a moderate-severe influenza pandemic in midst of a widespread respirator shortage: unknown
  - Recent studies: HCP willingness to work during a pandemic increases when their organizations have mature respiratory protection programs and adequate numbers of respirators in supply
Using EHMRs during an Emergency

- During public health emergencies, healthcare systems may need EHMRs temporarily to fill a surge gap
- Rapidly fit-testing and training HCP may be necessary
- Validated methods to rapidly achieve fit and training have not been described
- NIOSH is engaged in efforts to fit, train and educate HCP to use EHMRs during a public health emergency
Established by OSHA

A major difference between SMs and respirators

The standard N95 and the N95-F/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>EHMR</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>
EHMRs: Examples

Photo courtesy of Gershon

Photo courtesy of JSP

Photo courtesy of Honeywell

Photo courtesy of Moldex

Photo courtesy of Moldex

Photo courtesy of SAS

Photo courtesy of North

Photo courtesy of Gershon
Elastomeric Half-mask Respirators

- Most equipped with removable filter(s)
Elastomeric Half-mask Respirators (EHMRs)

- May have
  - Cartridge cover

Photo Courtesy of SEA
Elastomeric Half-mask Respirators (EHMRs)

- May have a pre-filter
  (large particulates)

Photo Courtesy of SEA
Elastomeric Half-mask Respirators (EHMRs)

- Particulate filter

Photo Courtesy of SEA
Elastomeric Half-mask Respirators (EHMRs)

- May have a charcoal filter
  (Chemicals/gasses)

Photo Courtesy of SEA
Elastomeric Half-mask Respirators (EHMRs)

- May have an exhalation valve
Elastomeric Half-mask Respirators (EHMRs)

- Facepiece

Photo Courtesy of SEA
Elastomeric Half-mask Respirators (EHMRs)

- Head harness

Photo Courtesy of SEA
Elastomeric Half-mask Respirators (EHMRs)
Hybrid/combination models

Combination EHMR and PAPR

Photo Courtesy of Draeger

Combination EHMR and Filtering Facepiece

Photo Courtesy of North
Elastomeric **Full-Facepiece Respirators**

- Equipped with a clear lens that covers the eyes, nose and mouth
- Rarely used for infection prevention in civilian sector, including healthcare

Photo Courtesy of North

Photo Courtesy of Draeger
Key Benefits of EHMRs

- Reusable
- One EHMR assigned to each worker
- Potential cost savings
- Close the national RPD surge gap
Benefit: Reusability

- Can be reused after
  - Disinfection
  - Cleaning
- Durable
  - Maintain fit over time
  - Stand up to repeated manipulation and storage between uses

Adapted from Bessesen et al. (2015)
Benefit: one per worker

- Each worker is assigned his/her own device
- Name or ID number may be applied

Photo Courtesy of Texas Center for Infectious Diseases
Benefit: potential cost savings

<table>
<thead>
<tr>
<th>TABLE 4</th>
<th>C0mparative Cost of Stockpiling Various Types of Respiratory Protective Devices to Protect the Health Care Workforce During an Influenza Pandemic</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baracco et al. (2015)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Number of RPDs</th>
<th>N95&lt;sup&gt;b&lt;/sup&gt; Single Use&lt;sup&gt;c&lt;/sup&gt;</th>
<th>Elastomeric&lt;sup&gt;d&lt;/sup&gt;</th>
<th>PAPR&lt;sup&gt;e&lt;/sup&gt;</th>
<th>Mixed&lt;sup&gt;f&lt;/sup&gt; Single Use</th>
<th>N95</th>
<th>Mixed</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>6,112</td>
<td>10,612</td>
<td>2,653</td>
<td>N95: 2,791</td>
<td>1,222</td>
<td>N95: 558</td>
</tr>
<tr>
<td></td>
<td>500</td>
<td></td>
<td></td>
<td>500</td>
<td>300</td>
<td></td>
</tr>
</tbody>
</table>

| RPD acquisition cost, per year (thousand US$) | 306–800 | 69–122 | 17,889–18,048 | 177–429 | 61–159 | 65–139 |
| Warehouse<sup>h</sup> and management<sup>i</sup> cost, per year (thousand US$) | 207 | 5 | 455 | 97 | 42 | 22 |

Baracco et al. (2015)
Benefit: closing the gap
EHMRs during a Surge of Infectious Patients

- Nationwide projected N95 need for 1918-like influenza pandemic: 1.7 – 7.3 billion
- ASTHO Report (2014): Total number of N95 held by U.S. acute care hospitals ≈ 60M
- Shortages of N95 respirators occurred during SARS (2003) and H1N1 influenza (2009)
Key Challenges with EHMRs

- Lack of familiarity/experience among healthcare and first responders/receivers
- Interference with duties
- Carried by healthcare personnel during workday
- Storage between work shifts
- Disinfection/cleaning process
- Fit testing is required
Challenge: Lack of Familiarity and Experience

- EHMRs are rarely used in U.S. health care delivery
- Two known U.S. healthcare systems using EHMRs for patient care
  - Texas Center for Infectious Diseases (TB-only facility)
  - University of Maryland, Baltimore
- Used by maintenance workers in healthcare organizations
Challenge: interference with duties

- Speech intelligibility: ~10% decrease

### TABLE III. Speech Intelligibility Associated with Half-Face Elastomeric Respirators Equipped with and without Speech Augmentation Devices

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Model</th>
<th>Filter Type</th>
<th>Filter Model</th>
<th>Voice Augmentation Device</th>
<th>MRT % Mean [SD] 3 ft</th>
<th>MRT % Mean [SD] 7 ft</th>
<th>MRT % Mean [SD] 3 and 7 ft</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control (none)</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>98 [2.4]</td>
<td>97 [2.2]</td>
<td>97 [2.3]</td>
</tr>
<tr>
<td>Sundström</td>
<td>SR100</td>
<td>P100</td>
<td>SR510</td>
<td>Electronic voice amplifier</td>
<td>87 [6.2]</td>
<td>91 [5.5]</td>
<td>89 [6.0]^a</td>
</tr>
<tr>
<td>Survivair</td>
<td>Blue</td>
<td>P100</td>
<td>1050</td>
<td>Mechanical vibration membrane</td>
<td>90 [4.7]</td>
<td>88 [5.8]</td>
<td>89 [5.3]^a</td>
</tr>
<tr>
<td>North</td>
<td>5500</td>
<td>P100</td>
<td>7580P100</td>
<td>None</td>
<td>88 [4.6]</td>
<td>86 [4.1]</td>
<td>87 [4.5]^a</td>
</tr>
<tr>
<td>3M</td>
<td>7500</td>
<td>P100</td>
<td>7093</td>
<td>None</td>
<td>86 [6.8]</td>
<td>87 [7.1]</td>
<td>86 [6.9]^a</td>
</tr>
<tr>
<td>Survivair</td>
<td>2000</td>
<td>P100</td>
<td>1050</td>
<td>Computer-aided acoustical design</td>
<td>83 [8.5]</td>
<td>85 [5.2]</td>
<td>84 [7.0]^a</td>
</tr>
</tbody>
</table>

Radonovich et al. (2009)
Challenge: interference with duties

- Downward visual gaze

Photo courtesy of MSA
Challenge: carried from room to room

- During work shift, typically carried in belt pack (fanny pack) or satchel with shoulder harness – Ideally rigid to protect device from damage
- Sometimes stored temporarily at nurses station, personal locker, or utility cart
- Typically do not fit in coat pockets
- Generally viewed as a nuisance

Photo Courtesy of Texas Center for Infectious Diseases
Challenge: storage

- Must be stored between work shifts
- Typically stored in personal locker
  - Sometimes in utility room(s)
  - Sometimes taken home (unpublished data)
- Long-term storage/stockpiling
  - Some materials, such as rubber, may become brittle or degrade if stored for 12+ months and may need to be replaced
  - Replacement parts necessary for on-site for emergency and routine maintenance
  - All components must be NIOSH approved for use with respirator
Challenge: Fit-testing

- Fit-testing required with EHMRs

- Fit-testing not required with loose fitting PAPRs

Photos courtesy of Veterans Health Administration

Photo Courtesy of North
Challenge: Disinfection and Cleaning
Required

- **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

Bessesen et al. (2015)
Challenge: Disinfection and Cleaning of EHMRs

- 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 EHMRs and three PAPRs in lab setting.

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.).
Challenge: Disinfection

• Best method to disinfect is unclear
Contemporary Practices: Disinfection and Cleaning

- Cleaning and Disinfection Frequency
  - “Follow manufacturer recommendations”
  - Some manufacturers recommend wiping with disinfectant impregnated swab (e.g., alcohol) after each patient exposure; others lump disinfection and cleaning in fashion not directly translatable to clinical healthcare setting
  - Complete cleaning after each shift (immersion in cleaning solution)
  - Frequency of filter change
    - Industrial norm is when filters become clogged (breathing becomes difficult). Some industrial customers change filters daily.
    - In healthcare, may not need to change unless visibly soiled because typical particulate load is low

- Methods
  - Industrial washers are available
  - On-site or with off-site contractor
  - Not all materials used in facepieces can withstand autoclave process
British Columbia Study, 2013

- Speech intelligibility was 7% lower with EHMRs compared to N95s
- Challenges with identifying storage space
- Challenges with cleaning at end of work shifts
- Disinfection using central processing proved challenging and took longer than expected
Key Questions being 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) To what extent does the respirator's appearance affect acceptance in 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)?
Conclusions Reached by the NAM Consensus Study (2018)

▪ **Conclusion 1: Efficacy of Reusable Elastomeric Respirators.** “…research studies in controlled laboratory settings have demonstrated the efficacy of reusable elastomeric respirators.”

▪ **Conclusion 2: Routine Use of Elastomeric Respirators.** “…reusable elastomeric respirators could be a viable option for respiratory protection programs for routine use in health care when logistic and implementation challenges are addressed…”.

▪ **Conclusion 3: Surge Use of Elastomeric Respirators.** “…reusable elastomeric respirators could be a viable option for use as needed in surge situations...when logistic and implementation challenges are addressed…”.

▪ **Conclusion 4: Health Care Needs Regarding Respirator Protection.** “…addressing the respiratory health needs of health care workers...will require the design of innovative reusable respirators and the implementation of robust respiratory protection programs…”.

▪ **Conclusion 5: Implementation Gaps.** “…urgent action is needed to resolve gaps in knowledge and leadership on reusable respiratory protection in order to protect the health and safety of health care workers, particularly in an influenza pandemic or an epidemic of an airborne transmissible disease...”.
Nascent NIOSH/CDC Elastomeric Projects

- Demonstration project to understand just-in-time use in U.S. Healthcare
  - Timeline: Ongoing

- Head-to-head comparison of disinfection methods in clinical setting
  - ~ Timeline: October 2019 – December 2020

- Demonstration projects to understand feasibility for routine use in selected clinical settings
  - ~ Timeline: October 2020 – December 2021
Key Points about Respiratory Protection

- N95s, EHMRs, and PAPRs do not provide absolute respiratory protection; they all are designed to reduce exposure, but not eliminate exposure.
- Respirators must be correctly worn to be effective.
- OSHA requires initial (pre-employment) and annual fit-testing with N95s and EHMRs.
- Correct donning, wearing, and doffing procedures are important to achieve suitable protection and avoid self-contamination.
- U.S. workforce, including health care, has limited experience with EHMRs for protection against infectious aerosols.
- EHMRs may be a practical option for use in selected healthcare settings, although further study and discussion are necessary.
Disclaimer

The findings and conclusions in this presentation are the authors’ own and do not necessarily represent the views of the National Institute for Occupational Safety and Health, the Centers for Disease Control and Prevention, or other affiliates. Mention of product names does not imply endorsement.
Additional Reference Slides
Key References

Key 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
Key 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