AN ALTERNATIVE TO DISPOSABLE N95S: THE REUSABLE ELASTOMERIC HALF-MASK RESPIRATOR EXPERIENCE

AUGUST 19, 2020
<table>
<thead>
<tr>
<th>WEBINAR SERIES PARTNERS</th>
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<tbody>
<tr>
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<td>American Academy of Emergency Medicine (AAEM)</td>
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<td>American Academy of Emergency Nurse Practitioners (AAENP)</td>
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<td>European Association of Poison Centers and Clinical Toxicologists (EAPCCT)</td>
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MODERATORS

Paul M. Wax, MD FACMT
- Executive Director, American College of Medical Toxicology (ACMT)

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- Past President, American College of Medical Toxicology (ACMT)
LESSONS LEARNED FROM HOSPITAL ELASTOMERIC RESPIRATOR USE PRE-COVID-19

MEDICAL AND PUBLIC HEALTH CONSIDERATIONS OF COVID-19

Stella Hines, MD, MPSH

Associate Professor, University of Maryland School of Medicine
Baltimore, MD
Disclosure/Disclaimer

• I receive research funding to my institution to study elastomeric respirator use in healthcare by:
  – CDC NIOSH (1R211OH010868-01, completed; contract 75D30118C02646, active)
  – CleanSpace Technology (active)

• The findings and conclusions in this report are those of the author and do not necessarily represent the views of the University of Maryland Medical Center or School of Medicine. Mention of specific products does not imply endorsement.
Strategies for Optimizing the Supply of N95 Respirators

Updated February 29, 2020

Conventional Capacity Strategies

Contingency Capacity Strategies

Crisis Alternate Strategies
Elastomeric Respirators and N95s share many features

- Both are **tight-fitting, air-purifying, particulate** respirators

<table>
<thead>
<tr>
<th>Parameter</th>
<th>N95 FFR</th>
<th>Elastomeric half-face</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assigned Protection Factor (APF)</td>
<td>10</td>
<td>10*</td>
</tr>
<tr>
<td>Filtration Efficiency</td>
<td>95%</td>
<td>≥95%</td>
</tr>
<tr>
<td>Fit-test required?</td>
<td>√</td>
<td>√</td>
</tr>
</tbody>
</table>
Elastomeric respirators in use at Univ of Maryland-Baltimore since 2009

• 2009 H1N1 caused N95 shortages
  – Safety Director familiar with elastomerics from general industry

• Workers in Hospital and Ambulatory Practices
  – Inpatient units: i.e. Medicine, MICU, ED, Peds, Radiology

• Duration
  – Practice continued after 2009, transitioned away from late 2016
    • ~25% wanted to remain (NASEM 2017)

Devices

• 3M 7500 Series Elastomeric Respirators
  – Small, medium, large face masks
• 3M 7093 P100 particulate cartridge filters
  – Covered, cleanable
Figure: Employees enrolled in Respiratory Protection Program (RPP) TFR = Tight-fitting respirator; PAPR = Powered Air Purifying Respirator

- 9300 Employees
  - 5630 in RPP
    - 2113 in TFR
    - 3517 in PAPR
    - 1972 in Elastomeric
    - 141 in Disposable N95
2015-2016 Study using Key Informant interviews, Focus Groups and Electronic Surveys

Are elastomeric respirators an alternative to N95s in healthcare?

- Acceptable (i.e. user acceptability)
- Feasible (logistics – storage, cleaning, supply)

alternative to N95s in healthcare?

- 1152 respondents
- 432 elastomeric respirator users
UMMC respirator study of 1152 participants – User Acceptance

• **Elastomeric**s scored highest in **sense of protection** from disease & **confidence** that the respirator will protect.

• **Despite** lower comfort & communication ratings, elastomeric users still **PREFERRED** to use them in certain risk scenarios.

Hines et al, AJIC 2019
## Availability

Is the respirator model and size you were assigned to use available when you need it?

<table>
<thead>
<tr>
<th>Frequency</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Never</td>
<td>2</td>
</tr>
<tr>
<td>Sometimes</td>
<td>0</td>
</tr>
<tr>
<td>About half the time</td>
<td>2</td>
</tr>
<tr>
<td>Usually</td>
<td>19</td>
</tr>
<tr>
<td>Always</td>
<td>75</td>
</tr>
</tbody>
</table>

94% according to Hines et al., Health Security, 2019
Storage Location

When my reusable elastomeric respirator is not in use, I store it:

<table>
<thead>
<tr>
<th>Storage Location</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>In a drawer near the patient’s room</td>
<td>5</td>
</tr>
<tr>
<td>Somewhere in the patient care area nearby (like a locker)</td>
<td>60</td>
</tr>
<tr>
<td>Somewhere on campus</td>
<td>9</td>
</tr>
<tr>
<td>In my car/at home/don’t know</td>
<td>6</td>
</tr>
<tr>
<td>Other</td>
<td>19</td>
</tr>
</tbody>
</table>

Inconvenient storage location more often reported in non-compliant elastomeric users

Logistics - Decontamination

I wipe my respirator with an alcohol pad or disinfectant wipe after each use.

<table>
<thead>
<tr>
<th>Frequency</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Never</td>
<td>4</td>
</tr>
<tr>
<td>Sometimes</td>
<td>11</td>
</tr>
<tr>
<td>Half the time</td>
<td>6</td>
</tr>
<tr>
<td>Usually</td>
<td>21</td>
</tr>
<tr>
<td>Always</td>
<td>58</td>
</tr>
</tbody>
</table>

I remove the filters and wash inside of my respirator with soap and water.

<table>
<thead>
<tr>
<th>Frequency</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rarely/never</td>
<td>69</td>
</tr>
<tr>
<td>Yearly</td>
<td>11</td>
</tr>
<tr>
<td>Monthly</td>
<td>9</td>
</tr>
<tr>
<td>Weekly</td>
<td>3</td>
</tr>
<tr>
<td>After each shift</td>
<td>8</td>
</tr>
</tbody>
</table>

No difference in reporting between compliant vs non-compliant elastomeric users.

Hines et al, accepted, Workplace Health & Safety
Study Findings

- **User acceptance is not a critical barrier** *(Hines et al., AJIC 2019)*
- **Storage & assuring availability are significant barriers to expected use** *(Hines et al., Health Security 2019)*
- **Disinfection NOT a barrier to expected use, but inadequate compliance with expected cleaning practice when left to the individual** *(Hines et al., accepted, Workplace Health and Safety)*
  - Probably can be taught
  - Strategies to centralize would bypass this
Storage & Availability Options

- Central Cache vs. individual maintenance
  - TCID – backpacks (NASEM 2018)
  - WorkSafe BC (Ciconte & Danyluk, 2013)
    - Failed because dedicated staff had not been identified to transport respirators to/from units to cleaning area

- Take home:
  - Central cache: identify staff in advance, assure job duties
  - Individual maintenance: Provide means of readiness (bag)
Cleaning & Disinfection Options

• Cleaning = removal of soiling agents (dirt)
• Disinfection = removal of microbial agents (virus)
• Strategies
  – Individually based
  – Centrally based
    • Need dedicated staff, resource, time

Effectiveness of Common Healthcare Disinfectants against H1N1 Influenza Virus on Reusable Elastomeric Respirators
Shobha S. Subhash, MS, MPH; Maria Cavaiuolo; Lewis J. Radonovich Jr, MD; Aaron Eagan, RN, BSN; Martin L. Lee, PhD; Sheldon Campbell, MD, PhD; Richard A. Martinello, MD

Disinfection of reusable elastomeric respirators by healthcare workers: A feasibility study and development of standard operating procedures
Mary T. Bessessen MD, Jill C. Adams BSN, Lewis Radonovich MD, Judith Anderson MD

Assessment of half-mask elastomeric respirator and powered air-purifying respirator reprocessing for an influenza pandemic
Caryn Lawrence BS, Delbert A. Harnish MS, Megan Sandoval-Powers BS, Devin Mills BS, Michael Bergman MS, Brian K. Heimbuch MS
Do you have to wash in soap & water or just disinfect with a wipe?

• Halo ARC Study (Hines et al., JISRP 2020)
  – Facial contaminants – yes
  – Need to also get disinfectant residue off
  – Viral contaminants – yes, at some interval
Current COVID19 Respirator Program at University of Maryland

- Ambulatory practices
  - Elastomerics main form of respiratory protection
    - Individually-assigned
    - Practices expected to clean & maintain
  - Policies, protocols and videos available to public on website

Current COVID19 Respirator Program at University of Maryland

• Hospital
  – Elastomerics part of pandemic plan
  – Disinfect with wipes after each use
  – End of Shift Centralized Cleaning
    • Bessesen/Lawrence protocol
  – Shared supply

https://www.n95decon.org/implementa#other-ppe
Summary

- Elastomeric respirators have been used in healthcare, prior to COVID19.
- Facilities must have plans for assuring storage, availability, cleaning & disinfection.
- Cleaning & Disinfecting protocols exist & can be adapted for local use
- Elastomeric respirators can alleviate some N95 shortage burden
What is an Elastomeric Respirator?

Elastomeric respirators are reusable air purifying respirators with replaceable filters that filter 95-100% of airborne particles, depending on filter type. They can cover the nose and mouth (half face respirators) or the entire face (full face respirators). Many elastomeric respirators allow unfiltered exhaust of the user’s exhaled breath.

Facemask: A conformable face mask is held in place by adjustable straps.

Elastomeric Seal: Air is pulled through the filters into the breathing zone due to a tight seal between the mask and the face. Fit-testing is required.

Filters: Replaceable filters are attached to the facemask. Filters covered by a plastic casing can be repeatedly reused, provided they are not soiled, damaged, or become difficult to breathe through.

Exhalation port: Most elastomeric respirators have an unfiltered exhalation port for easier breathing. Those with unfiltered exhalation ports are not recommended for use in sterile procedures where barrier face masks are required, such as surgery. The presence of infectious particles in exhaled breath has not been studied. It may be possible to filter exhausted air.

https://www.n95decon.org/publications

Questions? shines@som.umaryland.edu
PROTECTING YOUR STAFF IN PANDEMIC TIMES

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  Vice President of Perioperative Services
  Allegheny Health Network, Pittsburgh, PA

- **Sara Angelilli, MSN, RN, CNOR**
  Operating Room Education Manager
  Allegheny Health Network, Pittsburgh, PA
CONFLICT OF INTEREST

THE FOLLOWING SPEAKERS DO NOT HAVE ANY CONFLICTS OF INTEREST TO DISCLOSE
HEALTH SYSTEM BACKGROUND

9 Hospital Health System
21,000 Employees
Western PA

Clinician Led Organization
PARTNERSHIPS FOR RESPIRATORY PROTECTION

Sourcing
• Sharp increases in need for N95 created issues for supply chain management and increased costs

Reprocessing
• Options for extended use and reprocessing traditional N95's explored

Innovating
• Partnership with local company for reusable protection meets need and decreases costs
Implementation of an Elastomeric Mask Program as a Strategy to Eliminate Disposable N95 Mask use and Resterilization: Results from a Large Academic Medical Center

- **Lower Cost**
  - 10x cheaper than disposable N95s after one month of use

- **Operational Efficiency**
  - 94% successful in fit testing
  - Multiple users with single mask

- **Sustainability**
  - No limit to number of uses. Ready for next surge.

**Table 2.** Phased Approach to Distributing Elastomeric Masks

<table>
<thead>
<tr>
<th>First wave, high risk, front line</th>
<th>Second wave, moderate risk</th>
<th>Third wave, at risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anesthesia CRNA, physicians, extenders</td>
<td>EP nurses, physicians, extenders</td>
<td>OR staff for at risk cases</td>
</tr>
<tr>
<td>ED nurses, physicians, extenders</td>
<td>Cath lab nurses, physicians, extenders</td>
<td>PACU staff for at risk cases</td>
</tr>
<tr>
<td>EMS, life flight nurses, physicians</td>
<td>TEE nurses, physicians, extenders</td>
<td>Preop nurses</td>
</tr>
<tr>
<td>Pulmonary and respiratory techs</td>
<td>Trauma OR nurses, physicians, extenders</td>
<td>Transplant surgery nurses, physicians, extenders</td>
</tr>
<tr>
<td>Pulmonary nurses, physicians, extenders</td>
<td>OR staff for moderate risk cases</td>
<td>SICU nurses, physicians, extenders</td>
</tr>
<tr>
<td>GI Nurses, physicians, extenders</td>
<td>PACU staff for moderate risk cases</td>
<td>CCU nurses, physicians, extenders</td>
</tr>
<tr>
<td>Critical care nurses, physicians, extenders</td>
<td>Ophthalmology nurses, physicians, extenders</td>
<td>Orthopaedic nurses, physicians, extenders</td>
</tr>
<tr>
<td>PACU nurses, physicians, extenders</td>
<td>Cardiovascular nurses, physicians, extenders</td>
<td>Others as deemed necessary by PPE committee</td>
</tr>
<tr>
<td>ENT, OMFS nurses, physicians, extenders</td>
<td>Dental nurses, physicians, extenders</td>
<td>—</td>
</tr>
<tr>
<td>Colorectal nurses, physicians, extenders</td>
<td>Hospitalist physicians, extenders</td>
<td>—</td>
</tr>
<tr>
<td>Thoracic nurses, physicians, extenders</td>
<td>Urology nurses, physicians, extenders</td>
<td>—</td>
</tr>
<tr>
<td>Plastics nurses, physicians, extenders</td>
<td>CT techs</td>
<td>—</td>
</tr>
<tr>
<td>Neurosurgery nurses, physicians, extenders (performing endo access procedures)</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>IR techs, nurses, physicians, extenders</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

As masks were procured, they were distributed to the caregivers in phases as listed.

CCU, cardiac care unit; CRNA, certified registered nurse anesthetist; ED, emergency department; EMS, emergency medical services; ENT, ear, nose, and throat; EP, electrophysiology; GI, gastrointestinal; IR, interventional radiology; OMFS, oral and maxillofacial surgery; OR, operating room; PACU, post-anesthesia care unit; SICU, surgical intensive care unit; TEE, transesophageal echocardiogram.
Figure 2. Flowchart of mask disinfection and redistribution to caregivers. AHN, Allegheny Health Network; EPA, Environmental Protection Agency; PPE, personal protective equipment.
STAFF EDUCATION

Electronic Print Material

In Person Demonstration

Return Demonstration

QR Code Quick Links

Scan to open video link
OBSTACLES FOR CONSIDERATION

- Comfort / Skin breakdown
- Communication
- Exhalation Valves
THANK YOU!
PLEASE REACH OUT IF YOU HAVE ANY QUESTIONS

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PANEL Q&A
PANELISTS

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- **Sricharan Chalikonda, MD, MHA, FACS**, Chief Medical Operations Officer, Allegheny Health Network, Pittsburgh, PA
- **Maryann D’Alessandro, PhD**, Director, National Personal Protective Technology Laboratory, National Institute for Occupational Safety and Health, Pittsburgh, PA
- **Lee Greenawald, PhD**, Physical Scientist, National Personal Protective Technology Laboratory, National Institute for Occupational Safety and Health, Pittsburgh, PA
- **Stella Hines, MD, MSPH**, Associate Professor, University of Maryland School of Medicine, Baltimore, MD
- **Hope Waltenbaugh, MSN, RN, NE-BC, CNOR**, Vice President of Perioperative Services, Allegheny Health Network, Pittsburgh, PA
Q1: Are EHMRs authorized to be used in a healthcare setting?
Q2: I heard exhalation valves allow unfiltered air out. Are healthcare workers allowed to wear EHMRs because of this exhalation valve?

Q3: Does putting a surgical mask over the exhalation valve affect breathing resistance and are EHMRs comfortable to wear during a full shift?
Q4: Do healthcare workers have difficulty communicating to patients or colleagues while wearing an EHMR?
Q5: What type of cartridges/filters do I use with the EHMR facepiece? Would gas/vapor cartridges protect against COVID?

Q6: How do you know when to replace the EHMRs cartridges/filters?
Q7: What is the supply chain like currently? Can we get these respirators now?

Q8: What other efforts are occurring to expand EHMRs use in healthcare settings?
Q&A
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  Jeffrey A. Kline, MD  
  Professor of Emergency Medicine  
  Indiana University School of Medicine
Webinar Series Prospectus available at:

www.acmt.net/covid19web