National Academy of Sciences
Use of Elastomeric Respirators in Health Care

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Research Objectives

Ensure Adequate Supply of Respiratory Protection Devices (RPDs) During an Influenza Pandemic

Reprocessing Studies of Half-Mask Elastomeric Respirators (HMERs) and Powered Air-Purifying Respirators (PAPRs)

Develop a Reusable N95 for the Health Care Industry: Elastomeric N95 Surgical (EN95-S)
Project Funding and Support

Food and Drug Administration – Medical Countermeasures Initiative Regulatory Science Extramural Research Program

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Biomedical Advanced Research and Development Authority

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Reusable Respirator Reprocessing Studies

Half-Mask Elastomeric Respirators (HMERs)

- 3M 6200
- 3M 7502
- North 7700
- Scott XCEL
- Sperian Survivair

Powered Air-Purifying Respirators (PAPRs)

- 3M Breathe Easy
- 3M AirMate
- 3M PAPR Hoods
- Syntech MAXAIR
Reusable Respirator Reprocessing Studies

Two Types of Reprocessing:

Manual Reprocessing

- Clean by wiping with a sterile sponge in a warm neutral detergent solution
- Disinfect by soaking in a 0.1% bleach solution for two minutes
- Wipe filter cartridges (only 3M models) and PAPR motor/battery with Saniwipe disinfectant wipe
- Two conditions evaluated: cleaning only and cleaning/disinfection

Automated Reprocessing

- Clean and disinfect using a washer-disinfector with neutral detergent solution
- Temperature reduced to 55 °C per respirator manufacturer-defined limits
- For HMERs, no filters treated; for PAPRs, only hoods and breathing tubes treated
Reusable Respirator Reprocessing Studies

Disinfection Studies

- Multiple surfaces inoculated with influenza and synthetic skin oil
- Inoculated areas swabbed after reprocessing to recover viable virus remaining on surfaces
- Virus quantified using median tissue culture infectious dose (TCID\textsubscript{50}) assay
Reusable Respirator Reprocessing Studies

Disinfection Results

- Manual reprocessing:
  - Across 41 HMER and PAPR surfaces tested, mean log reduction in viable influenza was 4.54 ± 0.97 log TCID₅₀
  - Viable virus was recovered from only three cleaned-only surfaces (two fabric straps and a corrugated PAPR breathing tube) and one cleaned and disinfected surface (fabric strap)

- Automated reprocessing:
  - Across 30 HMER and PAPR surfaces tested, mean log reduction in viable influenza was 4.52 ± 0.74 log TCID₅₀
  - No viable virus was recovered from any surface
Reusable Respirator Reprocessing Studies

**Durability Studies**

- Reusable respirators treated with 150 cycles of manual reprocessing and 100 cycles of automated reprocessing
- HMERs evaluated for fit, inhalation resistance, exhalation resistance, exhalation valve leakage
- PAPRs evaluated for total inward leakage and air flow velocity
  - PAPR hood also evaluated for changes in fluid resistance, material strength, seam strength, and visor transparency using standard test methods

<table>
<thead>
<tr>
<th>Property</th>
<th>Standard Test Method</th>
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<tbody>
<tr>
<td>Fluid resistance</td>
<td>AATCC 127</td>
</tr>
<tr>
<td>Material strength</td>
<td>ASTM D6797</td>
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<tr>
<td>Seam strength</td>
<td>ASTM D1683</td>
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<tr>
<td>Optical transparency</td>
<td>ASTM D1003</td>
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</tbody>
</table>
Reusable Respirator Reprocessing Studies

Durability Results

- **Manual reprocessing (150 cycles):**
  - All HMERs demonstrated adequate fit, inhalation resistance, exhalation resistance, and exhalation valve leakage
  - No significant difference in PAPR total inward leakage and air flow
  - No significant difference in PAPR material properties tested

- **Automated reprocessing (100 cycles):**
  - All HMERs demonstrated adequate fit, except for the Scott XCEL (failed after 50 cycles)
  - All HMERs demonstrated adequate inhalation resistance, exhalation resistance, and exhalation valve leakage
  - No significant difference in PAPR total inward leakage and air flow (blower units not treated)
  - No significant difference in PAPR material properties tested, except for visor transparency
Conclusions

• **Manual reprocessing**
  - The data indicate HMERs and PAPRs can be effectively decontaminated using the manual reprocessing protocol used in this study up to 150 cycles
  - Porous or hard-to-reach surfaces can pose a challenge for these methods
  - Reprocessing instructions are inconsistent across respirator models/manufacturers in level of detail and do not account for biocontainment concerns
  - Manual reprocessing is time consuming and is dependent on the reprocessor’s attention to detail

• **Automated reprocessing**
  - The data indicate most HMERs and PAPR hoods/breathing tubes can be effectively decontaminated using the automated reprocessing protocol used in this study up to 100 cycles, but visibility of PAPR visors may be diminished
  - The decrease in visibility appeared to be due to “soap spots” – methods to remove soap spots post-reprocessing could potentially improve visibility, mitigating this concern
Elastomeric N95–Surgical Respirator (EN95-S)
EN95–S: Design Goals

Project Aim: Develop a Reusable N95 Respirator for the Health Care Industry

• Autoclavable and washable ≥ 100 cycles
• Reprocessing using protocols that adhere to current health care practices
• NIOSH approved and FDA cleared
• Health care worker “approved”
• Out-compete N95 FFR cost on a per cycle use
• Fit large population from pediatric to adult
EN95–S: Why Develop the EN95-S?

• Pandemic Preparedness
• Project BREATHE
• Health Care Worker Compliance
• Discontent with Current N95 FFRs
• Cost
• Stockpiling Logistics
EN95–S: Program Overview

Base Period – Proof of Concept
• Proof of Concept
• Initial Design
• Regulatory Planning
• IRB/OMB Planning

Option 1 – Prototype Production and Evaluation
• Laboratory Test and Evaluation
• Health Care Worker Outreach

Option 2 – Manufacturing Demonstration and Regulatory Filings

Option 3 – Pediatric EN95–S Concept Development
Summary

• HMERs and PAPRs can be effective tools for pandemic preparedness, but are:
  • Limited in their utility and application
  • Not designed for the health care setting
  • Not FDA cleared

• Better respirators are needed that are designed for the health care industry

• We need to push past self-imposed boundaries and develop technology that will solve the FFR shortage problem
Acknowledgements

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Questions

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