Overview of NPPTL Research on Healthcare Worker Personal Protective Equipment

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Objectives

• Provide rationale for NPPTL research projects related to personal protective equipment (PPE) for healthcare workers (HCWs)

• Review selected current NPPTL projects and recognize potential outcomes to the workplace
Background – Planning Efforts

- 2006 – IOM report examining issues related to the potential reuse of masks and N95 respirators in the event of an influenza pandemic
- 2007 – IOM report to assess the NIOSH anthropometric survey
- 2007 – IOM report on PPE for healthcare workers (HCW)
- 2011 – IOM PPE for HCW Update Committee
NPPTL HCW PPE Research Program Summary

- **Ensembles Research**
  - Surgical/isolation gowns

- **Filtration Research**
  - Nanoparticles / Bioaerosols

- **Respirator Fit Research**
  - Facial anthropometrics
  - Frequency of fit testing
  - Respirator fit test research (user seal check, novel methods, multiple donnings)

- **Respirator Comfort Research**
  - Physiology studies
  - Project BREATHE

- **Commit to Worker Safety and Appropriate Use of PPE**
  - Demo and Sentinel Surveillance
  - Public Health Practice studies
  - Best practices, outreach

- **Respirator Performance & Usability Research**
  - Performance against cough generated aerosols
  - PPE combinations
  - Respirator clinical effectiveness

- **Influenza Pandemic**
  - Risks of handling a contaminated respirator
  - Decontamination of filtering facepiece respirators
  - Assessing modes of transmission
Filtration
Example Electret Filter Media

- Melt blown - Corona charged (A)
- Melt blown - Highly charged (B)
- Extruded - Split film fiber (C)
- Melt blown - Highly charged (D)

Conventional Single-Fiber Filtration Theory

![Filtration Mechanisms](image)

- Diffusion Regime
- Diffusion and Interception Regime
- Inertial Impaction and Interception Regime

**Filtration Mechanisms**
- Inertial Impaction
- Interception
- Diffusion
- Electrostatic attraction

**Graph**
- Efficiency vs. Particle Diameter (μm)
- X-axis: 0.01 to 1.0
- Y-axis: 0% to 100%

**Legend**

- CDC
- NIOSH
- NPPTL: Research to Practice through Partnerships
## Filter Efficiency Performance Results

<table>
<thead>
<tr>
<th>Respirator/Mask Type</th>
<th>Filtration Efficiency* (%)</th>
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<tbody>
<tr>
<td>NIOSH N95 FFR</td>
<td>98.76 – 99.39</td>
</tr>
<tr>
<td>NIOSH P100 FFR</td>
<td>99.978 - 99.997</td>
</tr>
<tr>
<td>FDA Surgical Mask</td>
<td>11.94 – 98.42</td>
</tr>
<tr>
<td>Unregulated Dust Mask</td>
<td>12.98 - 99.00</td>
</tr>
</tbody>
</table>

Sample sizes: N95 filtering facepiece respirators (FFR) = 5; P100 FFR = 2, Surgical mask = 5, Dust mask = 5

* Polydisperse Aerosol with Mass Median Diameter ~240 nm (TSI 8130, 85 L/min)
Filtration of Aerosols with Viable H1N1 Influenza Virus

<table>
<thead>
<tr>
<th></th>
<th>Avg. Filtration Efficiency (N95 FFR)</th>
<th>Avg. Filtration Efficiency (P100 FFR)</th>
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<tbody>
<tr>
<td>0.8 µm bead</td>
<td>99.85%</td>
<td>99.999%</td>
</tr>
<tr>
<td>H1N1 influenza</td>
<td>99.27%</td>
<td>99.998%</td>
</tr>
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</table>

• FFRs provided equivalent filtration efficiency for inert bead and viable H1N1 influenza aerosols (p > .05)

• NIOSH approved FFRs with N95 and P100 NIOSH performance ratings provide expected levels of filtration performance against tissue culture adapted H1N1
Recent Papers/Reports

Respirator Fit Research
Science of Respirator Fit

Core Science
- Anthropometry
- Measurements
- Materials

Applied R&D
- Respirator Designs
- Fit Test Methods (R&D, Certification)
- Practices & Procedures for OSHA-required Initial & Annual Fit Testing
Faceseal Leakage vs. Filter Penetration

Total Inward Leakage – Manikin Data

- N95
- FFP2
- FFP3

Particle Diameter (nm)

Sucrose NaCl

Sealed

2 x 2.41 mm

Total Inward Leakage (%)

- N95
- FFP2
- FFP3

- Total Inward Leakage – Manikin Data

CDC Workplace Safety and Health

NIOSH Research to Practice through Partnerships
Anthropometrics & Respirator Fit

- Zhuang et al. reported that gender was the largest factor in face size/shape followed by race/ethnicity
- Correlation between respirator size and NIOSH respirator fit test panel face size category was found
- In another study, overall face size and nose area were found to correlate with respirator fit more than other calculated parameters
- Roberge et al. found that leakage detected by IRC was most common in the nose and cheekbone areas

<table>
<thead>
<tr>
<th>NIOSH face size category</th>
<th>Respirator size with highest passing rate</th>
<th>Fit Test Passing Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Small</td>
<td>Medium</td>
</tr>
<tr>
<td>Small (NIOSH Cells 1-3)</td>
<td>Small</td>
<td>22/27 = 81%</td>
</tr>
<tr>
<td>Medium (NIOSH Cells 4-7)</td>
<td>Medium</td>
<td>32/48 = 67%</td>
</tr>
<tr>
<td>Large (NIOSH Cells 8-10)</td>
<td>Large</td>
<td>12/43 = 28%</td>
</tr>
</tbody>
</table>

Number of IRC detected leaks at each location
Recent Papers

Respirator Comfort & Tolerability
Objective
To improve compliance among HCWs by developing information products, respirator performance requirements, and advanced technologies for the next generation of HCW respirators that are more comfortable and tolerable.

Project Tasks / Current Status
1. Interagency Working Group (Completed)
2. Research (in progress)
   a) Improving HCW compliance
   b) Comfort & tolerability research
   c) Respirator clinical effectiveness study
   d) Partnership / prototype development
3. Prototype lab & field trials (not started)
4. Commercialization / standards development (not started)
FFR Comfort / Physiology Studies

- Many factors affect FFR comfort/tolerability

- No standardized test methods or performance requirements for CO₂, O₂, or comfort/tolerability

- In one study involving 10 HCW wearing FFR for 1 hour, Roberge et al. found that:
  - FFR dead space mixed inhalation/exhalation O₂ and CO₂ concentrations do not meet OSHA ambient workplace standards
  - Heart rate, respiratory rate, tidal volume, minute volume, O₂ saturation, transcutaneous CO₂ levels, comfort/exertion scores between controls and FFR were not statistically different

- Current study seeks to develop multivariate models to correlate FFR design features, FFR microenvironment, and human factor data with subjective responses
Recent Papers


Influenza Pandemic
Critical Questions

- Can infectious aerosols survive on FFRs long enough to present a fomite hazard?
- Would FFRs that incorporate antimicrobial technologies prevent the FFR from becoming a fomite?
- Would the use of biological decontamination methods allow for disposable FFRs to be reused?
  - Can decontamination methods render infectious material on an FFR inactive?
  - Does decontamination affect FFR performance?
Long-Term Storage Results

Survival of MS2 deposited as droplet nuclei (♦) or droplets (□) on FFR coupons. Viable MS2 were enumerated after storage.

Survival of MS2 deposited as droplet nuclei on the exterior layers (♦), internal filtering media (■) and interior layers (Δ) of FFR coupons. Viable MS2 were enumerated for each layer after storage.

- All coupons had detectable levels of MS2 after 10 days of storage at 22°C and 30% RH.
- MS2 survivability was similar for each layer.
- FFRs have the potential to serve as a fomite.
Antimicrobial Respirators

Antimicrobial respirator effectiveness is dependent upon the antimicrobial agent and storage conditions.

22°C and 30% RH

37°C and 80% RH

* Significantly different (p < 0.05) from the control N95 respirator.
Effectiveness of Biological Decontamination Methods

- Key findings from several studies include:
  - Decontamination efficacy increases as a function of dose and time
  - Increased organic load (protection factor) in the MS2 viral aerosol challenge reduces decontamination efficacy some methods (e.g., bleach, UVGI), but not others (e.g., heat, steam)

- Project resulted in two test methods: ASTM E2720-10 and E2721-10
Does Decontamination Affect FFR performance?

**Experimental Design (5 phases)**

- **Laboratory**
  - 2 models
  - 20 decon methods
  - 1 cycle

- **Laboratory**
  - 9 models
  - 5 decon methods
  - 1 cycle

- **Laboratory**
  - 6 models
  - 8 decon methods
  - 3 cycles

- **Human Subject**
  - 6 models
  - 3 decon methods
  - 1 cycles

- **Human Subject**
  - 3 models
  - 3 decon methods
  - 3 cycles

**Summary of Findings:**

- FFRs tested have differences in their design (e.g., # of layers, face seal enhancements) and materials (e.g., hydrophobicity), which affects their ability to withstand some decon conditions.

- Autoclave, >100º C heat, isopropyl alcohol, microwave (dry heating), hydrogen peroxide gas plasma, and soap & water caused significant physical or filter degradation to some or all of the models tested, while bleach had noticeable odor and some off-gassing.

- FFRs treated by UVGI, hydrogen peroxide vapor, microwave generated steam, moist heat incubation, and ethylene oxide had expected levels of laboratory filtration performance.

- UVGI, microwave generated steam, and moist heat decontamination resulted in clinically insignificant changes in fit, odor, comfort, and donning ease.
Concept for Regulatory Implementation

- Decontamination capability is not expected to be a requirement (optional)
  - Model dependent
  - Avoids product availability concerns
  - Manufacturer determines capabilities by including decontamination procedure instructions

- Announcement of research results does not constitute approval
Recent Reports/Papers

- Viscusi et al., Impact of Three Biological Decontamination Methods on Filtering Facepiece Respirator Fit, Smell, Comfort, and Donning Ease, Journal of Occupational and Environmental Hygiene (in press)
- Fisher et al, “Evaluation of Microwave Steam Bags for the Decontamination of Filtering Facepiece Respirators”, PLOSone (in press)
Concluding Remarks

• NPPTL has an active research program, involving numerous partners, with current and planned projects related to filtration, respirator fit, comfort/tolerability, understanding barriers to proper use, performance, and specific issues related to Pandemic Influenza

• Priority gaps in the PPE for HCW action plan are being addressed

• Next steps – continue the respiratory protection research projects in accordance with the action plan and expand the NPPTL protective clothing laboratory capabilities
Acknowledgments

• NPPTL Research Staff Working on These Projects:
  - TRB Respiratory Protection Research Team: Ziqing Zhuang, Samy Rengasamy, Evanly Vo, Dennis Viscusi, Ed Fisher, Stacey Benson, Jessica Williams, Stephanie Lynch
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  - Statistical Support: Kim Faulkner

• Other collaborators
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Thank you

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Quality Partnerships Enhance Worker Safety & Health

Disclaimer:

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Representative Headforms for Respirator Testing

- Digital 3-D headforms created for US and for Chinese workers
- Next, combine with skin-like surfaces to mimic respirator fit on a human
- Ultimate goal – fit test panel of articulated manikins
Performance & Usability
Effectiveness of Respirators in Clinical Settings

- Many laboratory studies available to show higher levels of protection provided by filtering facepiece respirators (FFRs) compared to surgical masks (SMs), but few studies have been in clinical settings

- Loeb et al (2010) study*
  - Found that among 446 nurses in Ontario tertiary care hospitals, incidence of laboratory confirmed influenza was similar in nurses wearing SMs vs. FFRs
  - Statistical criterion of non-inferiority was met

- Study limitations made acceptance among some stakeholder groups difficult

* Loeb, Dafoe, Mahoney, et al, Surgical Mask vs. N95 Respirator for Preventing Influenza Among Health Care Workers: A Randomized Trial, JAMA. 2009;302(17):1865-1871
Respiratory Protection Effectiveness Clinical Trial (ResPECT)

- **Objective** – Determine if the incidence of *lab confirmed influenza* is lower among HCWs wearing FFRs (arm #1) vs. those who wear SMs (arm #2)

- **Background** – CDC funded the VHA and Johns Hopkins University (JHU) to conduct this study. NIOSH manages the effort within CDC.

- **Approach** – prospective, unblinded, cluster randomized evaluation

- **Year 1 focus – pilot study at JHU (Jan 2011-April 2011)**
  - 116 HCWs enrolled; nasal swab samples are collected weekly; subjects are asked to complete daily and weekly diaries; Trained researchers observing clinics to determine adherence

- **Years 2 – 4+ – expand to multiple clinical locations**
  - 4 years of data collection with 116 clusters is expected to provide sufficient power to detect a 25% reduction in lab confirmed influenza among subjects in the FFR arm vs. the surgical mask arm