Panel 5: Personal Protective Equipment
Research on the efficacy of respirators in preventing the transmission of influenza

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Recommendations for HealthCare Workers

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Presentation Overview

• NIOSH respirator certification program
  – Scope of activities
  – Evaluation of Filter Collection Efficiency

• Fit test science

• Research Initiatives
NIOSH Respirator Certification Program

- **Pre-Certification Activities**
  - Engineering evaluations
  - Performance verification tests
  - Quality Assurance plan evaluations

- **Post-Certification Activities**
  - Product audits
  - Manufacturing site audits
  - Respirator equipment evaluations
    - Performance verification
    - Configuration verification
NIOSH Respirator Certification

• Complete respirator assemblies are certified
  – Air-Purifying: Particulate, Gas & Vapor, Gas masks, Powered air-purifying
  – Atmosphere-Supplying: Self-contained Breathing Apparatus, Supplied-Air (Airline)

• Respirator assemblies
  – System tests
  – Configuration management

• Particulate respirator face fit characteristics currently not evaluated for certification
**Sizes of Common Particles**

Air contaminant size

Sizes of Interest:
- Nanoparticles: 1 - 100 nm (0.001-0.1 µm)
- Viruses: 0.02 – 0.3 µm
- Bacteria: 0.3 – 10 µm
- Fungal spores: 0.5 – 30 µm
- NIOSH Criteria: 0.3 micron (MMAD)

Adapted from: Guidance for Filtration and Air-Cleaning Systems to Protect Building Environments from Airborne Chemical, Biological, or Radiological Attacks, DHHS (NIOSH) Publication No. 2003-136.
Mechanisms of Capturing Particles

Non-absolute capture: Particles travel through a fiber mesh with large holes but a long path
Filter Performance

- Most Penetrating Particle exists
- Filter efficiency tests with most penetrating size particle
- Completely assembled filter

NIOSH Criteria
0.3 micron (MMAD)
## Filter Efficiency Performance Results

<table>
<thead>
<tr>
<th>Respirator/Mask Type</th>
<th>Polydisperse Aerosol Test (PAT) (%)</th>
<th>Monodisperse Aerosol Test (MAT) (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NIOSH N95</td>
<td>98.76 - 99.39</td>
<td>94.8 – 98.0</td>
</tr>
<tr>
<td>FDA Surgical Mask</td>
<td>11.94 – 98.42</td>
<td>27.49 - 91.02</td>
</tr>
<tr>
<td>Unregulated Dust Mask</td>
<td>12.98 - 99.00</td>
<td>4.31 - 81.63</td>
</tr>
</tbody>
</table>

Sample sizes: N95=5; P100=2, Surgical mask=5, Dust mask=5
Verification of most penetrating particle size using nanoparticles (20-400nm)

![Graphs showing efficiency vs. particle diameter for N95 and P100 filters.](chart.png)
N95 respirator filters achieved expected performance with MS2 virus challenge
N95 respirator filters achieved expected performance with *Bacillus globigii* bacteria challenge
Filtration theory applies when testing into the nanoparticle range down to 4 nm.
Validation / Evaluation of Fit Test Methods

- **Multiple research projects conducted between ~1995 – 2005**
  - Validate quantitative & qualitative fit test methods
  - Simulated workplace protection factor studies
  - Workplace protection factor studies
  - New fit testing concepts

- **>10 manuscripts published**

- **Key findings**
  - Quantified fit test error rates
  - Fit testing reduces worker exposure

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*Graphs showing correlation between fit factors and protection factors measured at a steel foundry.*

- CHD Fit Test (Half-Masks)
  - R Squared = 0.81

- Correlation between Fit Factors and Protection Factors Measured at a Steel Foundry (Half-Masks)
Fit test method performance using simulated workplace protection factors

- **Objective** – Assess the impact of fit testing on N95 elastomeric and N95 filtering facepiece respirators

- **Methods**
  - Qualitative and quantitative testing
  - 15 elastomeric N95 respirators
  - 33 filtering facepiece N95 respirators

- > 10 manuscripts published

- **Key findings**
  - Some key findings relevant to fit
# Performance Without Fit Testing

<table>
<thead>
<tr>
<th>Respiratory Protective Device Type</th>
<th>GM</th>
<th>GSD</th>
<th>5th Percentile</th>
</tr>
</thead>
<tbody>
<tr>
<td>N95 Elastomeric Facepiece</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All (15 models)</td>
<td>35.5</td>
<td>2.6</td>
<td>7.3</td>
</tr>
<tr>
<td>Range</td>
<td>22.2-161.1</td>
<td>3.8-25.3</td>
<td></td>
</tr>
<tr>
<td>N95 Filtering Facepiece</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All (33 models)</td>
<td>20.5</td>
<td>3.1</td>
<td>3.3</td>
</tr>
<tr>
<td>Range</td>
<td>3.0-242.6</td>
<td>1.3-48.0</td>
<td></td>
</tr>
<tr>
<td>Surgical Masks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All (6 models)</td>
<td>2.6</td>
<td>1.6</td>
<td>1.2</td>
</tr>
<tr>
<td>Range</td>
<td>1.6 - 4.0</td>
<td>1.0 - 1.9</td>
<td></td>
</tr>
</tbody>
</table>

All devices tested using a 25-member fit test panel performing a SWP protocol
# Performance with Fit Testing

<table>
<thead>
<tr>
<th>Device Type</th>
<th>Fit-Test Method Without</th>
<th>Bitrex™</th>
<th>Saccharin</th>
<th>PortaCount w/Companion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Filtering-Facepiece</td>
<td>3.3</td>
<td>7.9</td>
<td>11.0</td>
<td>20.5</td>
</tr>
<tr>
<td>Elastomeric</td>
<td>7.3</td>
<td>11.1</td>
<td>11.7</td>
<td>13.0</td>
</tr>
</tbody>
</table>

All devices tested using a 25-member fit test panel performing a SWP protocol
Nanoparticle Faceseal Leakage for a N95 FFR at 18 breaths/min
Respirator Fit Research

- 2003 US head and neck anthropometrics survey
- Develop representative respirator fit test panels
- Develop new headforms
- 2006 IOM evaluation of the NIOSH anthropometric survey
- Current research
  - Laboratory Study to Assess Causative Factors Affecting Temporal Changes in Filtering-Facepiece Respirator Fit
  - Facial anthropometric research
2003 Head and Face Anthropometric Survey

- **Goal** – better understanding the sizes and shapes of the heads and faces of the U.S. work force

- **Approach** – 3997 subjects (traditional measurements), 1039 subjects (3-D scan data)

- **Key findings**
  - Los Alamos National Laboratory (LANL) full-facepiece panel excludes > 15% of the current US work force
  - Current U.S. work force has larger heads and faces and is more diverse than 1967 military personnel
Respirator Fit Test Panels

- **Goal** – Develop new respirator fit test panels & sizing systems
- **Background** - respirator fit test panels provide an objective tool for selecting test subjects based upon their facial characteristics for use in research, product development, testing, and certification
- **Key findings** - NIOSH bivariate and the PCA fit test panels are more representative than the LANL panel and cover > 95% of the current U.S. work force
- **Current applications** – used in draft NIOSH total inward leakage test and ISO technical specifications & test methods, cited by FDA as an example test panel, by manufacturers for product design
Total Inward Leakage (TIL) Update

• TIL regulation in rulemaking

• Total Inward Leakage (TIL) Test:
  – Measures total % reduction (inside / outside) mask
  – Includes leakage through all paths (e.g. filter, facepiece-face seal connections, etc.)

• NIOSH conducted benchmark testing on 100 respirators and held public stakeholder meetings to share results and gain stakeholder input on the TIL concept
  – August 25, 2004
  – June 26, 2007
Other Related Research

• Decontamination of filtering facepiece respirators (FFRs) for reuse
• Bacterial/viral particle reaerosolization
• Layered masks/respirators
• N95/P100 studies
• No fit respirator workshop
• Breathing gas studies
• Stored FFRs
Reaerosolization of B. Globigii particles
Reaerosolization of MS2 virus particles
INNOVATIVE RESPIRATORY ENSEMBLES (N95FFR with surgical mask overlay)

- Suggested by IOM and CDC as possibly extending useful life of N95FFR

- Breathing resistance of the N95 is increased by roughly 10% over baseline N95 (Vojtko M, Roberge M, Vojtko R, Roberge R: Effect on breathing resistance of a surgical mask worn over an N95 Filtering Facepiece Respirator. J Intl Soc Resp Protect 2008; 25:1-8)
INNOVATIVE RESPIRATORY ENSEMBLES (N95FFR WITH PAPR)

- Question: How much protection is afforded by a loose-fitting PAPR if the motor or battery fails?
- Answer: A recent study* demonstrated a simulated respirator fit factor of <10.

- Question: How much extra protection is afforded by wearing an N95 filtering facepiece respirator concurrently with a loose-fitting PAPR?
- Answer: An order of magnitude greater protection if the PAPR is functional, and 2-3 orders of magnitude if the PAPR motor or battery is non-functional

*Roberge M, Vojtko M, Roberge R, Vojtko R: Resp Care (in press)
N95/P100 Total Inward Leakage (TIL) Testing

- **Background** – significant interest in assessing the differences in protection provided by an N95 versus P100

- **Current concept**
  - N95 and P100 FFRs, elastomeric half-masks, and full facepiece respirators
  - Quantitative testing – corn oil and ambient with NaCl
  - Qualitative testing – Bitrex
  - Use new NPPTL fit test facility

- **Status**
  - Pilot study
  - Preliminary test results show fitting characteristics of seal contributes more to Total Inward Leakage than filter efficiency.
Reusability of Filtering Facepiece Respirators

- *Effect of decontamination on FFR filter efficiency*
  - Filter efficiency tested after decontamination
  - UV, microwave generated steam, and moist heat (60°C, 80% RH, 4 hours) are considered to be the most promising methods for possible FFR decontamination and will be used for future studies.

- *Effects of decontamination methods on respirator components*
  - Model specific
  - Mechanical strap testing showed FFR strap length and elasticity are affected differently by different methods.
  - Dry heat (160°C, 1 hr) melted straps of three FFR models.
  - Strap tests alone are unlikely to be a good predictor for respirator fit

- *Human subject fit-testing conducted on decontaminated respirators using the three down-selected decon methods (UV light, Moist Heat, and Microwave generated steam)*
  - 16 of the 18 respirator model / decontamination method combinations did not demonstrate any significant change in fit caused by the decontamination process

- *Work continues to address concerns that decontamination of unworn respirators does not replicate used respirator decontamination*
  - Protein buildup on respirator surface
  - “Wrinkled” surface areas of respirators
Presentation Summary

• Comprehensive respirator certification program
  – Pre- and post-approval test and evaluation of product compliance
  – Pre- and post-approval evaluation of quality control effectiveness

• Science of Single Fiber Theory (Interaction of Particulate Collection Mechanisms continues to be exhibited)

• Fit test science has demonstrated the value of Fit Testing respirators

• Research Initiatives are closing the knowledge gaps
NIOSH NPPTL/PPT Program

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http://www.cdc.gov/niosh/npptl

Thank you

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