Decontamination and Reuse of Filtering Facepiece Respirators

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Overview

• NIOSH respiratory protection research program
• Research on N95 filtering facepiece respirator (FFR) reuse
  – How well do N95 FFRs capture (retain) H1N1 virus containing aerosols?
  – Can viruses survive on FFRs with and without antimicrobial capabilities?
  – Can FFRs be decontaminated for possible reuse in emergency situations?
• Other areas for collaboration with the filtration industry
• Concluding Remarks
NIOSH Respiratory Protection Research Program

• Respirator Fit Research
  – Facial anthropometrics
  – Frequency of fit testing
  – User seal check
  – Towards better fitting respirators workshop
  – Advanced headforms

• Aerosol/Filtration Studies
  – Nanoparticles
  – *Bioaerosols*

• Respirator Comfort & Usability
  – Project BREATHE, novel respirator designs, test methods
  – Physiological studies

• Influenza Pandemic
  – *Reusability of filtering facepiece respirators*
  – *Risks of handling a contaminated respirator*
  – *Antimicrobial respirators*
  – Performance against cough generated aerosols
  – Respirator clinical effectiveness study
Background

• Until recently, CDC recommended the use of fit-tested, NIOSH-certified, disposable N95 FFRs for healthcare personnel in close contact with patients with suspected or confirmed 2009 H1N1 influenza

• During the pandemic, FFRs were often discarded after each patient encounter

• 2006 IOM report - >90 million N95 FFRs will be needed to protect workers in the healthcare sector during a 42-day outbreak
Modes of Contamination

- Sneezing
- Coughing
- Breathing
- Talking

Infected Person

Respirator User

- Droplets (~0.5 - 10+ µm)
- Droplet nuclei (~0.3 - <5 µm)
How well do N95 FFRs capture (retain) H1N1 virus containing aerosols?
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

![Graph showing the efficiency of filtration mechanisms based on particle diameter. The graph divides the particle diameter into three regimes: Diffusion Regime, Diffusion and Interception Regime, and Inertial Impaction and Interception Regime. The filtration mechanisms include inertial impaction, interception, diffusion, and electrostatic attraction.]
Filtration of Aerosols with Viable H1N1 Influenza Virus

• Goal - Validate the filtration performance of FFRs against an emerging respiratory hazard (H1N1 influenza virus)
• Collaboration with Air Force Research Laboratory (Tyndall AFB)
**Test Parameters**

**FFRs:** NIOSH-approved N95 and P100 FFRs (1 model each, 3 replicate samples)

**Virus:** H1N1 Influenza A/PR/8/34 VR-1469 (ATCC VR-95)

**Aerosolization buffer:** Mucin-based artificial saliva*

**Aerosol generation:** 6-jet Collison nebulizer, dried and charge neutralized particles at 85 LPM flow rate

**Viable collectors:** All glass impingers in tissue culture media

**Viable assay:** Tissue Culture Infections Dose 50 (TCID50) assay in Madin Darby Canine Kidney (MDCK) cells

*Described in more detail in ASTM Test Method E2720-2010 Evaluation of the Effectiveness of Decontamination Procedures for Air-Permeable Materials when Challenged with Biological Aerosols Containing Human Pathogenic Viruses*
## Results & Discussion

<table>
<thead>
<tr>
<th></th>
<th>Avg. Filtration Efficiency (N95 FFR)</th>
<th>Avg. Filtration Efficiency (P100 FFR)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>0.8 µm bead</strong></td>
<td>99.85%</td>
<td>99.999%</td>
</tr>
<tr>
<td><strong>H1N1 influenza</strong></td>
<td>99.27%</td>
<td>99.998%</td>
</tr>
</tbody>
</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
Can viruses survive on FFRs with and without antimicrobial capabilities?
Methods

• Approach
  – Determine efficacy of 4 antimicrobial respirators to render MS2 bacteriophage, a surrogate for pathogenic viruses, inactive after various storage times and conditions
  – Compare with control N95 FFRs, which do not contain any known antimicrobial components
Aerosol Production with the Bio-Aerosol Respirator Test System (BARTS)

- MS2 suspended in 1% growth medium
- Virus containing particles (VCPs) generated from Collison nebulizer
- Droplet nuclei formation (MMD of 140 nm) and VCP equilibration within the chamber
- Air flow pulled through the respirator coupons
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 respirator effectiveness is dependent upon the antimicrobial agent and storage conditions.
Can FFRs be decontaminated for possible reuse in emergency situations?
IOM Report on Reusability of Facemasks

- Biological decontamination method must (1) **remove the viral threat**; (2) be harmless to the user; and (3) not compromise the integrity of the FFR
- Conduct research that will lead to understanding the efficacy of simple decontamination techniques (e.g., bleach, microwave, UV) that could be routinely employed without having negative effects on respirator integrity

http://www.nap.edu/catalog.php?record_id=11637
Effect of Decontamination on Physical Appearance, Odor and Laboratory Filtration Performance

- **Experimental Design (3 phases)**
  1. 2 FFR models, 10 decon methods (2 conditions each, 1 cycle)
  2. 9 FFR models, 5 decon methods (1 cycle)
  3. 6 FFR models, 8 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 - even after drying 22 hours.
  - FFRs treated by UVGI, hydrogen peroxide vapor, microwave generated steam, moist heat incubation, and ethylene oxide had expected levels of laboratory filtration performance
Down-selected Decontamination Methods

**Microwave Generated Steam (MWGS)**
2 min on ‘High’ power
(2 pipette-tip boxes each with 50 ml tap water)

**UV-C Light (UVGI)**
254 nm at 2.0 mW/cm² for 15 min

**Moist Heat (MH)**
Incubator (60° C, 80% RH) for 30 min

Note: Photos and details listed for each method are from the NIOSH studies; AFRL (collaborator) methods were similar.
Does Decontamination Reduce N95 FFR Fit?

- Average multi-donning fit factor (MDFF) for FFRs after decontamination 138-181
- Two models demonstrated a reduction in MDFF after MH decontamination compared to the control FFRs
Effectiveness of Biological Decontamination Methods

- Decontamination efficacy increases as a function of dose and time
- Increased organic load (protection factor) in the MS2 viral aerosol challenge reduced decontamination efficacy for bleach, but not MWGS
# Recovery of Viable H1N1 from Untreated and Decontaminated N95 FFRs (AFRL Data)

## Log$_{10}$ TCID$_{50}$ per sample for Droplet Application of H1N1

<table>
<thead>
<tr>
<th>Respirator</th>
<th>UVGI</th>
<th>Untreated</th>
<th>MWGS</th>
<th>Untreated</th>
<th>MH</th>
<th>Untreated</th>
</tr>
</thead>
<tbody>
<tr>
<td>N95-A</td>
<td>0.55± 0.48</td>
<td>5.35± 0.29</td>
<td>*BDL</td>
<td>5.01± 0.38</td>
<td>*BDL</td>
<td>4.10± 0.14</td>
</tr>
<tr>
<td>N95-B</td>
<td>1.37± 0.05</td>
<td>5.85± 0.29</td>
<td>*BDL</td>
<td>6.10± 0.38</td>
<td>*BDL</td>
<td>6.10± 0.38</td>
</tr>
<tr>
<td>N95-C</td>
<td>*BDL</td>
<td>&gt; 5.26</td>
<td>0.26± 0.44</td>
<td>5.93± 0.25</td>
<td>*BDL</td>
<td>5.18± 0.25</td>
</tr>
<tr>
<td>SN95-D</td>
<td>*BDL</td>
<td>4.35± 0.29</td>
<td>0.39± 0.68</td>
<td>6.33± 0.13</td>
<td>*BDL</td>
<td>5.77± 0.14</td>
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<tr>
<td>SN95-E</td>
<td>*BDL</td>
<td>&gt; 5.68</td>
<td>0.31± 0.53</td>
<td>&gt; 5.68</td>
<td>*BDL</td>
<td>6.85± 0.14</td>
</tr>
<tr>
<td>SN95-F</td>
<td>*BDL</td>
<td>6.01± 0.29</td>
<td>*BDL</td>
<td>5.51± 0.38</td>
<td>*BDL</td>
<td>5.18± 0.25</td>
</tr>
</tbody>
</table>

## Log$_{10}$ TCID$_{50}$ per sample for Droplet Nuclei Application of H1N1

<table>
<thead>
<tr>
<th>Respirator</th>
<th>UVGI</th>
<th>Untreated</th>
<th>MWGS</th>
<th>Untreated</th>
<th>MH</th>
<th>Untreated</th>
</tr>
</thead>
<tbody>
<tr>
<td>N95-A</td>
<td>*BDL</td>
<td>4.93± 0.25</td>
<td>*BDL</td>
<td>5.10± 0.14</td>
<td>*BDL</td>
<td>4.85± 0.14</td>
</tr>
<tr>
<td>N95-B</td>
<td>*BDL</td>
<td>5.26± 0.38</td>
<td>*BDL</td>
<td>5.51± 0.29</td>
<td>*BDL</td>
<td>4.76± 0.14</td>
</tr>
<tr>
<td>N95-C</td>
<td>*BDL</td>
<td>5.10± 0.52</td>
<td>*BDL</td>
<td>5.35± 0.38</td>
<td>*BDL</td>
<td>5.60± 0.14</td>
</tr>
<tr>
<td>SN95-D</td>
<td>*BDL</td>
<td>5.35± 0.14</td>
<td>*BDL</td>
<td>4.51± 0.29</td>
<td>*BDL</td>
<td>5.35± 0.14</td>
</tr>
<tr>
<td>SN95-E</td>
<td>*BDL</td>
<td>4.60± 0.76</td>
<td>*BDL</td>
<td>4.68± 0.00</td>
<td>*BDL</td>
<td>4.93± 0.25</td>
</tr>
<tr>
<td>SN95-F</td>
<td>*BDL</td>
<td>4.56± 0.18</td>
<td>0.62± 0.56</td>
<td>5.43± 0.25</td>
<td>*BDL</td>
<td>4.93± 0.50</td>
</tr>
</tbody>
</table>

* Below detection limit (1 TCID$_{50}$ infectious dose unit), n = 3
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
Towards Improved PPE

• In 2007-2008, the National Academies (NA) convened a committee of experts to review the NIOSH PPT Program
  – The 2008 NA report discussed the NIOSH PPT program’s relevance and impact, and provided recommendations for future research
• One of the key recommendations (#4) was to increase research on use and usability of PPE
  – PPE that is uncomfortable to use is a major cause of noncompliance and a significant barrier to use
  – Understanding that comfort is fundamentally a safety issue is a necessary prerequisite to improved PPE
• NIOSH response to the NA report
  – In FY09, $700K discretionary funds were earmarked for supporting projects addressing recommendation #4.
Possible Applications for Nanofibers & Nanotechnology?

- Reduced filter airflow resistance
  - Surgical masks and respirators that are easier to breathe through without reducing filtration efficiency
- Better fitting respirators
  - Less face seal leakage without increased strap tension
  - Possible solutions include “gecko-inspired” nanofiber adhesives, shape memory fibers
- Antimicrobial
  - Nanofibers that incorporate inherently antimicrobial technologies in them to render trapped viruses inactive (reduce potential for the respirator to act as a fomite)
Project BREATHE - Better Respirator Equipment using Advanced Technology for Healthcare Employees

**Objective** - To improve respirator use compliance among healthcare workers (HCW) 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**
1. Interagency working group report
2. Research
   a) Improving HCW compliance with N95 FFR use
   b) Comfort & tolerability research
   c) Respirator clinical effectiveness study
   d) Partnership / prototype development
3. Prototype lab & field trials
4. Commercialization / standards development
Concluding Remarks

- NIOSH has an active research program focusing on respiratory protection
- FFRs can capture and retain viable virus containing aerosols and may serve as a fomite
- Efficacy of the antimicrobial respirators tested was dependent upon the storage conditions and type of antimicrobial agent and further improvements are necessary to assure they reduce the risks of handling after contamination
- Results from UVGI, MH, and MWGS are promising (minimal impact on FFR performance, harmless to the user, available in many settings, provide > 3-log reduction of viable MS2 and H1N1 virus, etc.), but additional research is still necessary before these methods can be implemented in practice
- Focus for improved PPE—use and usability
  - Reduced filter air flow resistance, better face seals, and integrated antimicrobial technologies
  - Opportunities for collaboration with Project BREATHE
Acknowledgements

• Brian Heimbuch from AFRL for the H1N1 respirator filtration and decontamination data

• Members of the NIOSH/NPPTL FFR reuse team (Evanly Vo, Samy Rengasamy, Dennis Viscusi, Ed Fisher, and Mike Bergman)
References (NIOSH and Collaborators)

- Wander J., and Heimbuch, B., Challenge of N95 and P100 Filtering Facepiece Respirators with Particle Containing Viable H1N1, Final Report, NIOSH IAA 09-42, December 2009 (available upon request).
Thank you

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Quality Partnerships Enhance Worker Safety & Health

Disclaimer:

The findings and conclusions in this presentation have not been formally disseminated by the National Institute for Occupational Safety and Health and should not be construed to represent any agency determination or policy.
42 CFR, Part 84 Air-Purifying Particulate Respirator (APR) Certification

<table>
<thead>
<tr>
<th>Minimum Efficiency</th>
<th>NaCl Test</th>
<th>DOP oil Test</th>
<th>DOP oil Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>95%</td>
<td>N95</td>
<td>R95</td>
<td>P95</td>
</tr>
<tr>
<td>99%</td>
<td>N99</td>
<td>R99</td>
<td>P99</td>
</tr>
<tr>
<td>99.97%</td>
<td>N100</td>
<td>R100</td>
<td>P100</td>
</tr>
</tbody>
</table>

- N - not resistant to oil mist
- R - resistant to oil mist
- P - protective against oil mist
- 95, 99, 100 - minimum filter efficiency using certification test conditions
Filtering Facepiece Respirators (FFR)

- N95 and P100 most common
- Designed to form tight face seal
- Entire facepiece is composed of the filtering medium
- Approximate cost: $0.70 - $2.34 each
- Mostly fixed-length straps
- Disposable