Factors Impacting Comfort & Tolerance to N95 Filtering Facepiece Respirators: Research Results from Project BREATHE

International Society for Respiratory Protection Biennial Conference

Prague, Czech Republic
September 21-25, 2014

Raymond Roberge, MD, MPH
Research Medical Officer
U.S. National Personal Protective Technology Laboratory/NIOSH/CDC
Project BREATHE - Better Respirator Equipment using Advanced Technology for Healthcare Employees

- Working group identified 28 “Idealized” characteristics
- Need a new type of respirator ("B95") designed specifically for HCW
- Path forward:
  1. Develop clinically-validated “B95” test methods
  2. “B95” prototype development
  3. “B95” standards development

## Current Status

<table>
<thead>
<tr>
<th>Develop clinically-validated “B95” test methods</th>
<th>“B95” prototype development</th>
<th>“B95” standards development</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Multiple research projects and collaborations initiated to study &amp; quantify FFR comfort and measure impact of FFR design on comfort</td>
<td>• Collaborations with Georgia Tech, 3M, and Scott Safety</td>
<td>• In collaboration with the VHA, identified draft set of B95 requirements, criteria, and test methods¹</td>
</tr>
<tr>
<td>• &gt; 20 manuscripts published to date</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• <a href="http://www.cdc.gov/niosh/topics/flu/respiratory.html">http://www.cdc.gov/niosh/topics/flu/respiratory.html</a></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Inputs Affecting Respirator Comfort and Tolerance

- Airflow Resistance
- Hydrophobicity
- Deadspace Volume
- Pressure Distribution
- Exhalation Valve
- Strap Tension
- Weight
- Age
- Proper Use Training
- Skin Sensitivity
- Fitness Level
- Perception of Risk
- Anxiety
- Race/Ethnicity
- Gender
- Previous Experience

HUMAN FACTORS

- Oxygen (O₂)
- Carbon Dioxide (CO₂)
- Air/Skin/RPE Temperature
- Moisture Retention
- Humidity

NPPTL Research to Practice through Partnerships

CDC Workplace Safety and Health
Presentation Overview

- N95 FFR MOISTURE ACCUMULATION
- N95 FFR-ASSOCIATED WARMTH
- N95 FFR FACIAL PRESSURE
- N95 FFR FILTER RESISTANCE
N95 FFR Moisture Accumulation

- MOISTURE SOURCES
  - EXHALED BREATH
  - AMBIENT HUMIDITY
  - SWEAT

- MOISTURE CONCERNS
  - IMPACT ON BREATHING RESISTANCE (clogging of filter pores; collapse of non-rigid facepieces)
  - IMPACT ON RESPIRATOR FIT
  - INFECTION TRANSMISSION
Moisture Accumulation


- N95 FFRs (n=45) sealed to an Automated Breathing and Metabolic Simulator x 4h (@ 40 L/min, 100% tracheal humidity, tracheal temp 39°C):

  Mean moisture gain:
  - N95 FFR (0.19 ±0.10 gm)
  - N95 FFR/EV (0.23±0.09 gm)
  - SN95 FFR (0.35±0.01 gm)

  Not significantly different between models
Moisture Accumulation – N95 FFR Deadspace Relative Humidity


- 2 flat-fold N95 FFR (w/wo EV) and 2 cup-shaped N95 FFR (w/wo an exhalation valve [EV]) (n=68) @ 1h and 2h of treadmill exercise (5.6 km/h):

  Mean 1h deadspace RH% of N95 FFR vs N95 FFR/EV (91.4% vs 87.2%)

  Mean 2h RH% of N95 FFR vs N95 FFR/EV (89.6% vs 93.3%)

  No significant differences between respirators w/wo an EV
## Human Studies - Moisture Accumulation Data

<table>
<thead>
<tr>
<th>Protective Facemask Models</th>
<th>Work Rate</th>
<th>Time</th>
<th>Moisture Accumulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>N95 FFR, N95 FFR/EV⁴</td>
<td>2.7 &amp; 4 km/h</td>
<td>1h</td>
<td>≤0.13 gm</td>
</tr>
<tr>
<td>N95 FFR/SM, N95 FFR/EV/SM⁵</td>
<td>2.7 &amp; 4 km/h</td>
<td>1h</td>
<td>≤0.15 gm</td>
</tr>
<tr>
<td>Surgical Mask⁶</td>
<td>5.6 km/h</td>
<td>1h</td>
<td>≤0.12 gm</td>
</tr>
<tr>
<td>N95 FFR Prototypes⁷</td>
<td>5.6 km/h</td>
<td>1h</td>
<td>≤0.10 gm</td>
</tr>
</tbody>
</table>

N95 FFR = N95 filtering facepiece respirator; EV = exhalation valve; SM = surgical mask
Prototypes = 3 rigid, cup-shaped N95 FFR with nominal filter resistances of 29.4 Pa (3 mm H₂O), 58.8 Pa (6 mm H₂O) and 88.2 Pa (9 mm H₂O) pressure tested @ 85 L/min constant airflow
Moisture Accumulation – Effect of Exhalation Valve


- EVs do not impact $V_D$ RH significantly at low-to-moderate work rates

- Minimum ~30 L/min exhalation airflow needed to develop-streamlined airflows required for EV activation

- Moisture can accumulate on EV inner surface
Synopsis – Moisture Accumulation

Lack of significant moisture accumulation in modern N95 FFR at low-moderate work rates is attributable to:

• Thinness of modern filters

• Hydrophobicity of polypropylene (primary component of most modern N95 FFR)

• Exhalation valve (at higher work rates)

• Work rate (low-moderate in aforementioned studies), length of use, and ambient humidity impact moisture accumulation
N95 FFR-Associated Warmth

- **HEAT SOURCES**
  - AMBIENT TEMPERATURE
  - METABOLIC HEAT RELEASED VIA RESPIRATION
  - IMPAIRMENT OF FACIAL DERMAL CONVECTION, EVAPORATION AND RADIATION OF HEAT

- **CONCERNS**
  - ONE OF THE MOST COMMON COMPLAINTS FROM USERS OF RESPIRATORY PROTECTIVE EQUIPMENT
  - FREQUENT CAUSE OF NON-COMPLIANCE WITH RESPIRATOR USE

<table>
<thead>
<tr>
<th>Complaint</th>
<th>N95 FFR</th>
<th>N95 FFR/EV</th>
<th>EAPR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breathing Difficulty</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Dizziness</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Lightheadedness</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Facial Warmth</td>
<td>6</td>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>Facial Itching</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Facial Irritation</td>
<td>1</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Facial Pinching</td>
<td>0</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Facial Sweating</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Tightness</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Weight</td>
<td>0</td>
<td>0</td>
<td>3</td>
</tr>
</tbody>
</table>


N95 FFR-Associated Warmth – Literature Review


- Protective facemasks (PFMs) negatively impact dermal mechanisms of human thermoregulation (convection, evaporation, and radiation processes)
- The relatively minor reported increases in core temperature directly attributable to the wearing of PFMs suggest that associated perceptions of increased body temperature may have a significant neuro-psycho-physiological component related to:
  - perioral facial skin sending increased afferent signals to the brain (increased “respirator apparent heat index”)
  - elevated inhaled air temperature leading to thoracic warming or brain warming
  - psychological reactions (anxiety, claustrophobia) with associated adrenergic discharge (increased metabolism, skin flushing, etc.)
N95 FFR-Associated Deadspace Temperatures


- 17 subjects wore flat-fold & cup-shaped N95 FFR, w/wo exhalation valve (EV) for 1h and 2h of treadmill exercise (5.6 km/h):

  Significantly higher mean deadspace temperature for N95 FFR (33.89±0.73°C) vs N95 FFR/EV (32.83±1.09°C) at 1h (p=0.01)

  Deadspace temperature at 2h not significantly different from 1h values

  “Respirator apparent heat index” as high as 54°C
N95 FFR-Associated Core and Dermal Temperatures


- 20 subjects treadmill exercising (5.6 km/h) X 1h & 2h wearing 2 models each of flat-fold and cup-shaped N95 FFR and N95 FFR/EV (n=80) and no respirator (n=20):

  No significant difference between controls & trials for $T_{\text{core}}$ increases ($\leq 0.12^\circ C$)

  No significant differences between 1h & 2h temps

  Mean skin temperature under the FFRs increased by $1.25^\circ C$ for N95 FFR and $0.85^\circ C$ for N95 FFR/EV ($p<0.001$)
Surgical Mask-Associated Core and Dermal Temperatures


- 20 subjects treadmill exercising (5.6 km/h) for 1h w/wo a pleated (Type II) surgical mask:

  Mean increase of 0.08°C in $T_{\text{core}}$ with mask

  Mean increase of 1.76°C in temperature of the facial skin covered by a surgical mask
N95 FFR-Associated Warmth – Effect of Exhalation Valves


- Available literature indicates that exhalation valves (EV) improve dead space heat dissipation
- Consequently, EV result in lower temperature of the skin covered by a respirator
- EV especially impact comfort and tolerance when N95 filtering facepiece respirators are worn for extended periods, irrespective of the work rate
Synopsis – N95 FFR-Associated Warmth

- $T_{core}$ is minimally impacted ($\leq 0.12^\circ C$) wearing N95 FFR, N95 FFR/EV or surgical facemasks x 1h at a low-moderate work rate

- The temperature of the facial skin covered by an N95 FFR or N95 FFR/EV increases ~1-2$^\circ C$ over 1h at a low-moderate work rate

- Exhalation valves decrease N95 FFR deadspace temperature and temperature of the skin covered by N95 FFR

- Perceptions of increased body warmth associated with wearing N95 FFR may have a neuro-psycho-physiological basis
Future Directions

• Cooling Strategies
  - incorporation of mini-fans in FFR
  - use of phase change materials for heat transfer
  - evaluation of brain temperatures when wearing FFR (brain tunnel temperature estimations)
  - development of improved exhalation valves
N95 FFR-Associated Facial Pressure – Optimal Fit With Minimal Pressure

- SOURCES OF FACIAL PRESSURE
  - TETHERING DEVICES (STRAPS, BANDS, ETC.)
  - NASAL BARS
  - BONY PROMINENCES (NASAL BRIDGE, CHEEKS, CHIN)

- CONCERNS
  - DISCOMFORT LEADING TO NON-COMPLIANCE
  - IMPACT ON FACE SEAL (HIGH OR LOW PRESSURES CAN CAUSE LEAKS)
  - TISSUE DAMAGE OCCURS WITH 12H USE AT 13,785 Pa (2 psi)

[Sources: CDC/NIOSH](http://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/)
N95 FFR Pressure Distribution – Computational Studies

- Computer simulation studies\(^\text{14}\), and finite element investigations utilizing mannequins\(^\text{15,16}\), have demonstrated that pressure distributions are related to:
  a) respirator size
  b) facial and cranial dimensions (positive Z-directional force of strap tension is the most important parameter related to contact pressure; size of the headform [or head] influences strap tension)
  c) strap locations (traditional, concentrated, dispersal) impact pressure distribution
  d) facial anatomy (areas of the highest pressures are nasal bridge, cheekbone (zygoma), chin (menton process)
  e) softer seal materials cause larger deformations and transfer the location of the maximum pressure from the nasal bridge to the tip of the nose
  f) finite element studies correlate well with surface pressure sensors on advanced headform models (R\(^2\)=0.88)


N95 FFR Tethering Device Forces – Tensometer Studies


- Data from stereophotogrammetry determinations of increase in strain of tethering devices of three N95 FFR models (2 cup-shaped, 1 flat-fold) during human subject (n=20) fit testing were programmed into a tensometer; five 15-min periods of similar strain and 15-min w/o strain, were used to evaluate the effect of multiple donnings and doffings:
  - a progressive decrement in loads was noted for top and bottom tethering devices on all models

- mean decrements in top tethering device loads after the 5th donning = 12.5%, 19.3% and 29.1%

- mean decrements in bottom tethering device loads after the 5th donning were 6.4%, 17.9% and 23.5%

- the N95 FFR with lowest initial loads (4.2 N top strap, 2.7 N bottom strap) passed fit testing and could potentially serve as a baseline for future studies
N95 FFR Stereophotogrammetry Face Seal Area & Pressure Determinations


- Human study (n=20) utilizing stereophotogrammetry scans for Z-force calculations and face seal area pressure (P = F_n/A) determinations of 2 flat fold and 4 rigid cup-shaped N95 FFR (images w/wo an N95 FFR were aligned and slightly rotated so that the intersection of the two scans indicated the face seal area):

- face seal area was 71 and 68 cm² for flat fold models and 59, 60, 67 and 72 cm² for cup-shaped models

- seal pressures were 630N (0.9 psi) and 729N (0.1 psi) for flat fold models, and 1073N (0.15 psi),1167N (0.17 psi), 1246N (0.18 psi), and 1270 N(0.18 psi) for cup-shaped models

- flat fold models had significantly smaller Z-forces (p=0.01) than rigid cup-shaped models
Synopsis – Facial Pressure

- Facial pressure is determined by numerous features (strap forces, tissue density, respirator face seal area, respirator design, etc.)

- Strap restorative forces <5N are associated with passing quantitative respirator fit tests

- Bony facial areas display the greatest pressures (and leaks)

- Finite element computational studies may be useful in evaluating respirator-associated facial pressure levels and distributions

- Stereophotogrammetry is useful in determining respirator face seal area and pressure

N95 FFR Filter Resistance

- **CONCERNS**
  - INCREASES IN ENERGY EXPENDITURE
  - DIFFICULTY BREATHING

- **SOME FACTORS INFLUENCING RESISTANCE**
  - SURFACE AREA
  - FLOW RATE
  - FILTER DENSITY
FFR Filter Resistance


- Study utilizing an Automated Breathing and Metabolic Simulator (RR 24, tidal volume 1670 ml, tracheal temp 39°C, humidity 100%) with attached mannequin headform to test inhalation and exhalation resistances of 3 models each of N95 FFR, N95 FFR/EV, SN95 FFR x 4h indicated no significant differences between models:

<table>
<thead>
<tr>
<th>Respirator</th>
<th>Baseline (5 min) Inhalation</th>
<th>4h Inhalation</th>
<th>Baseline (5 min) Exhalation</th>
<th>4h Exhalation</th>
</tr>
</thead>
<tbody>
<tr>
<td>N95 FFR</td>
<td>-135.3 ±14.7 Pa (-13.8 ±1.5 mm H₂O)</td>
<td>-137.2 ±18.6 Pa (-14.0 ±1.9 mm H₂O)</td>
<td>71.5 ±19.6 Pa (7.3 ±2.0 mm H₂O)</td>
<td>70.6 ±20.5 Pa (7.2 ±2.1 mm H₂O)</td>
</tr>
<tr>
<td>N95 FFR/EV</td>
<td>-137.2 ±9.8 Pa (-14.0 ±1.0 mm H₂O)</td>
<td>-141.2 ±11.7 Pa (-14.4 ±1.2 mm H₂O)</td>
<td>62.6 ±11.7 Pa (6.4 ±1.2 mm H₂O)</td>
<td>64.7 ±10.7 Pa (6.6 ±1.1 mm H₂O)</td>
</tr>
<tr>
<td>SN95 FFR</td>
<td>-141.2 ±6.8 Pa (-14.4 ±0.7 mm H₂O)</td>
<td>-147.0 ±5.8 Pa (-15.0 ±0.6 mm H₂O)</td>
<td>72.5 ±3.9 Pa (7.4 ±0.4 mm H₂O)</td>
<td>78.4 ±2.9 Pa (8.0 ±0.3 mm H₂O)</td>
</tr>
<tr>
<td>Mean</td>
<td>-138.2 ±9.8 Pa (-14.1 ±1.0 mm H₂O)</td>
<td>-142.1 ±11.7 Pa (-14.5 ±1.2 mm H₂O)</td>
<td>68.6 ±12.7 Pa (7.0 ±1.3 mm H₂O)</td>
<td>71.5 ±12.7 Pa (7.3 ±1.3 mm H₂O)</td>
</tr>
</tbody>
</table>
Prototype FFR Low Filter Resistance
Physiologic & Subjective Impact


- Human subject (n=10) study investigating subjective and physiological responses to 3 N95 FFR prototypes with nominal filter resistances of 29.4, 58.8, and 88.2 Pa (tested @ 85 L/min continuous flow) x 1h at 5.6 km/h work rate:
  - no significant differences in HR, RR, SpO\textsubscript{2}, PtcCO\textsubscript{2}, T\textsubscript{tymp}, tidal volume, CO\textsubscript{2} output, O\textsubscript{2} utilization, or subjective ratings (thermal comfort, exertion, inspiratory effort, expiratory effort, breathing discomfort)
  - nominal filter resistances corresponded to 20.5 – 64.7 Pa/L/s (≤ the normal threshold for inspiratory breathing resistance)
  - N95 FFR filter resistances <88.2 Pa may not impact the wearer differently physiologically or subjectively from N95 FFR with filter resistances at this threshold at 1h x 5.6 km/h
Prototype FFR Filter Pressure Drop


- Human subject (n=10) study measuring pressure drop ($\Delta P$) across cup-shaped prototype N95 FFR with nominal filter resistances of 29.4, 58.8, and 88.2 Pa at sedentary and low-moderate work rates determined: 
  - $\Delta P$ of 29.4 Pa prototype <58.8 Pa, 88.2 Pa ($p<0.000$), but no significant differences between 58.8 Pa and 88.2 Pa prototypes
  
  - $\Delta P$ greater with exercise vs sedentary activity and oral vs nasal inhalation and exhalation ($p<0.001$)

  - oral and nasal respiration $\Delta P$ for all three PRs was at, or below, the minimal threshold level for detection of inspiratory resistance (58.8 – 74.5 Pa/L·sec$^{-1}$)
Synopsis – Filter Resistance

- Filter resistances of modern N95 FFR are not excessive and should not result in undue breathing difficulty for most healthy individuals in relatively clean work environments.

- Filter resistances <88.2 Pa pressure do not improve physiological or subjective responses (at sedentary and low-moderate work rates) compared with filter resistances at this threshold.

- The route of breathing (oral, nasal) impacts resistance.
References


Quality Partnerships Enhance Worker Safety & Health

Visit Us at: www.cdc.gov/niosh/npptl

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.
THANK YOU

QUESTIONS?