Personal Protective Equipment:
Key Projects at the Veterans Health Administration

Lew Radonovich, MD
Institute of Medicine Workshop
August 12-13, 2009
Topics

• Practicability: Occupational Interference and Respirators
• New Respirator Development (Project B.R.E.A.T.H.E.)
• The Respiratory Protection Clinical Effectiveness Trial
# HHS Pandemic Flu Planning Assumptions

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Moderate (1958/68-like)</th>
<th>Severe (1918-like)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Illness</td>
<td>90 million (30%)</td>
<td>90 million (30%)</td>
</tr>
<tr>
<td>Outpatient medical care</td>
<td>45 million (50%)</td>
<td>45 million (50%)</td>
</tr>
<tr>
<td>Hospitalization</td>
<td>865,000</td>
<td>9,900,000</td>
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<tr>
<td>ICU care</td>
<td>128,750</td>
<td>1,485,000</td>
</tr>
<tr>
<td>Mechanical ventilation</td>
<td>64,875</td>
<td>742,500</td>
</tr>
<tr>
<td>Deaths</td>
<td>209,000</td>
<td>1,903,000</td>
</tr>
</tbody>
</table>
VHA as a Stakeholder

• VHA: largest integrated healthcare system in the U.S.
  ~ 150 hospitals
  ~ 900 outpatient medical centers
  ~ 240,000 employees
  ~ 130,000 healthcare workers

• Uses ~ 1.6 million respirators per year
Respirators: Not an Ideal Solution

Discomfort 1-5
↓ Visual acuity 6, 7
↓ Vocal acuity 6, 7
↓ Auditory acuity 11
Excessive humidity 7
Excessive heat 2, 5, 7, 8
Headaches 1, 9
Facial pressure 2
Skin irritation or itchiness 1, 2, 7, 8

Excessive fatigue or exertion 1, 2, 4, 5, 7, 8

Malodorousness 2, 5
Anxiety or claustrophobia 1, 8, 10, 11
Facial pressure 2
Skin irritation or itchiness 1, 2, 7, 8
Excessive fatigue or exertion 1, 2, 4, 5, 7, 8
Other occupational interferences 5, 12-14
Respirator Tolerance

• Field assessment in 27 Healthcare Workers
  • Accustomed to wearing respirators or surgical/medical masks for brief periods
• Conducted during the course of typical duties
• 8 hour work shift
• With 8 different respirator ensembles, assessed:
  • Time Tolerated
(1) Medical Mask (MM)  
*Precept 15320*  
$1.40

(2) Cup N95  
*3M 1860*  
$1.75

(3) Cup N95 + Valve  
*3M 8511*  
$2.11
(4) Cup N95 + MM  
Precept 15320  
3M 1860  
$3.15

(5) Cup N95 + Valve + MM  
Precept 15320  
3M 8511  
$3.51

(6) Duck Bill N95  
KC PFR95170  
$1.43
(7) Half-face elastomeric Resp (HER)  
*North 5500 series*  
$20.80

(8) PAPR  
*3M Helmet: BE-12*  
$768.20
<table>
<thead>
<tr>
<th>Ensemble</th>
<th>Manufacturer (Model)</th>
<th>Included Equipment</th>
<th>Cost, $</th>
<th>Reusability</th>
<th>Tolerance Time (Q75, Q25), h (^a)</th>
<th>Probability of Tolerance at 8 h (95% CI) (^b)</th>
<th>HR (95% CI) (^b)</th>
<th>P Value (^h)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Powered air-purifying respirator</td>
<td>3M (BE-12)</td>
<td>Gown, gloves, hood, air hose, filter cartridge, battery pack, and charger</td>
<td>768.20</td>
<td>Yes</td>
<td>7.6 (1.8, 8.0)</td>
<td>0.56 (0.36-0.72)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cup N95 + exhalation valve</td>
<td>3M (8511)</td>
<td>Gown, gloves, goggles</td>
<td>2.11</td>
<td>No</td>
<td>7.7 (4.1, 8.0)</td>
<td>0.55 (0.35-0.72)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical mask (no respirator)</td>
<td>Precept (15320)</td>
<td>Gown, gloves, goggles</td>
<td>1.40</td>
<td>No</td>
<td>7.7 (4.9, 8.0)</td>
<td>0.52 (0.32-0.69)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duckbill N95</td>
<td>Kimberly-Clark (PFRG5170)</td>
<td>Gown, gloves, goggles</td>
<td>1.43</td>
<td>No</td>
<td>6.6 (2.9, 8.0)</td>
<td>0.48 (0.29-0.65)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Half-face elastomeric respirator</td>
<td>North (5500 series)</td>
<td>Gown, gloves, goggles, 2 filter cartridges</td>
<td>20.80</td>
<td>Yes</td>
<td>6.8 (2.1, 8.0)</td>
<td>0.41 (0.23-0.58)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cup N95 + exhalation valve + medical mask</td>
<td>3M (8511) or Precept (15320)</td>
<td>Gown, gloves, goggles</td>
<td>3.51</td>
<td>No</td>
<td>4.3 (1.9, 8.0)</td>
<td>0.41 (0.23-0.58)</td>
<td>1.70 (1.04-2.78)</td>
<td>.03</td>
</tr>
<tr>
<td>Cup N95</td>
<td>3M (1880)</td>
<td>Gown, gloves, goggles</td>
<td>1.75</td>
<td>No</td>
<td>5.8 (4.1, 8.0)</td>
<td>0.33 (0.17-0.51)</td>
<td>1.79 (1.15-2.79)</td>
<td>.03</td>
</tr>
<tr>
<td>Cup N95 + medical mask</td>
<td>3M (1880) or Precept (15320)</td>
<td>Gown, gloves, goggles</td>
<td>3.15</td>
<td>No</td>
<td>4.1 (1.7, 7.2)</td>
<td>0.30 (0.14-0.47)</td>
<td>1.14 (0.72-1.80)</td>
<td>.57</td>
</tr>
</tbody>
</table>

Abbreviations: CI, confidence interval; HR, hazard ratio; N95, filters >=95% of particles approximately 0.3 μm in size; Q75, tolerance time reached by 75% of participants; Q25, tolerance time reached by 25% of participants.

* All respirators were commonly used by the local and national Veterans Health Administration hospitals and were certified by the National Institute for Occupational Safety and Health. Equipment changes between patients were in accordance with airborne transmission-based infection control precautions from the Centers for Disease Control and Prevention unless the clinical setting required otherwise.

b 3M is located in St Paul, Minnesota; Precept Medical Products, Arden, North Carolina; Kimberly-Clark, Neenah, Wisconsin; and North Safety Products, Cranston, Rhode Island.


d Designated to be used for more than 1 patient encounter, as specified by the manufacturer.

* Kaplan-Meier estimates without considering correlation.

f Based on extended Cox model to account for within-participant correlation.

Risk of intolerance (doffing) before 8 h, comparing 2 ensembles.

Bonferroni step-down method.

Compared with cup N95 + exhalation valve.

Compared with medical mask.

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**Respirator Tolerance in Health Care Workers**

Lewis J. Radonovich, Jr; Jing Cheng; Brian V. Shenal; et al.


[http://jama.ama-assn.org/cgi/content/full/301/1/36](http://jama.ama-assn.org/cgi/content/full/301/1/36)
Table 2. Reported Reasons for Discontinuing Respirator Use Before 8 Hours Among 27 Participants

<table>
<thead>
<tr>
<th>Ensemble</th>
<th>Terminated &lt;8 hrs (N=27)</th>
<th>Diminished Communication Acuity</th>
<th>Head and Facial Discomfort</th>
<th>Other Somatic Complaints</th>
<th>Complaints Per Ensemble</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Visual</td>
<td>Auditory</td>
<td>Vocal</td>
<td>Heat</td>
</tr>
<tr>
<td>Powered air-purifying respirator</td>
<td>13 (48)</td>
<td>0</td>
<td>6 (22)</td>
<td>3 (11)</td>
<td>0</td>
</tr>
<tr>
<td>Cup 95 + exhalation valve</td>
<td>14 (52)</td>
<td>3 (11)</td>
<td>0</td>
<td>0</td>
<td>10 (37)</td>
</tr>
<tr>
<td>Medical mask (no respirator)</td>
<td>13 (48)</td>
<td>6 (22)</td>
<td>0</td>
<td>1 (4)</td>
<td>6 (22)</td>
</tr>
<tr>
<td>Duckbill N95</td>
<td>16 (62)</td>
<td>2 (8)</td>
<td>0</td>
<td>0</td>
<td>7 (27)</td>
</tr>
<tr>
<td>Half-face elastomeric respirator</td>
<td>17 (63)</td>
<td>0</td>
<td>0</td>
<td>9 (33)</td>
<td>7 (25)</td>
</tr>
<tr>
<td>Cup 95 + exhalation valve + medical mask</td>
<td>16 (59)</td>
<td>1 (4)</td>
<td>0</td>
<td>0</td>
<td>8 (30)</td>
</tr>
<tr>
<td>Cup 95</td>
<td>18 (67)</td>
<td>2 (7)</td>
<td>0</td>
<td>0</td>
<td>10 (37)</td>
</tr>
<tr>
<td>Cup N95 + medical mask</td>
<td>19 (70)</td>
<td>1 (4)</td>
<td>0</td>
<td>0</td>
<td>10 (37)</td>
</tr>
<tr>
<td>Total complaints</td>
<td></td>
<td>15</td>
<td>6</td>
<td>13</td>
<td>58</td>
</tr>
</tbody>
</table>

Abbreviation: N95, filters >=95% of particles approximately 0.3 μm in size.

*One hundred twenty-six of 215 sessions (59%) terminated before 8 h because of intolerance. Participants reported up to 3 reasons for discontinuation for each ensemble; a total of 162 complaints were cited as leading to termination before 8 h.

Included fogging of eyeglasses or protective goggles.

Respirator Tolerance in Health Care Workers
Lewis J. Radonovich, Jr; Jing Cheng; Brian V. Shenal; et al.
http://jama.ama-assn.org/cgi/content/full/301/1/36
Speech Intelligibility
Pending Publication (limited data distribution)

Design:
- 15 Respirator Ensembles
- 16 Subjects
- Modified Rhyme Test (% heard correctly)

Findings:
- Diminished speech intelligibility with most respirators
- Filtering facepiece respirators - slightly less intelligible speech than SM
- Half-face elastomeric respirators without speaking diaphragms - substantially diminished intelligibility compared to SM
- Less interference with “speaking membranes”
Project B.R.E.A.T.H.E.
Better Respirator Equipment using
Advanced Technologies for Healthcare Employees

August 6-7, 2008
Washington, DC
Key IOM Reports

REUSABILITY OF FACEMASKS DURING AN INFLUENZA PANDEMIC: FACE THE FLU

In the event of an influenza pandemic, public health officials will need to resort to multiple measures to reduce the impact. If effective vaccination and antiviral medications are not available or are not effective, adequate quantities during a pandemic situation, respirators and medical masks could help prevent or slow influenza transmission. Non-pharmaceutical interventions (e.g., hand hygiene, social distancing, and respiratory hygiene cough etiquette, minimising the use of masks by the public) will also play a critical role in pandemic prevention strategies.

Retooling or repurposing production of respirator and medical masks in addition to adequate planning and training, would ensure a plentiful supply for those who need them, but it is possible that not enough masks and respirators will be available for healthcare workers and the general public. A shortage may require that they modify respirator and medical masks to push beyond their approved uses in the hope that they will provide some level of protection beyond their intended limits of use. Individuals with no access to respirators or masks, even disposable, may seek advice to extend their own resources.

Based on the assumption that efforts to produce stockpile sufficient supplies of disposable masks and respirators may fail short in the event of a pandemic, the Department of Health and Human Services asked the Institute of Medicine (IOM) to assess what measures can be taken to permit the use of disposable N95 respirators in healthcare settings and assess what is known about the use of non-disposable masks for healthcare providers and the general public. The resulting report, Reusability of Facemasks During an Influenza Pandemic: Facing the Flu, concluded that very little is currently known regarding the potential for disinfection and reuse of medical masks or respirators (non-disposable) when both the epidemiology of influenza and the material properties of medical masks and respirators are needed. In the event of a pandemic, it is likely that there will be insufficient quantities of N95 respirators.

INSTITUTE OF MEDICINE
Advancing the Nation, Improving Health

PREPARING FOR AN INFLUENZA PANDEMIC: PERSONAL PROTECTIVE EQUIPMENT FOR HEALTHCARE WORKERS

During an influenza pandemic, healthcare workers will be on the front lines delivering care to patients and preventing the spread of the disease. Protecting the more than 13 million healthcare workers in the United States is critical to limiting morbidity and mortality and preventing progression of a pandemic. The focus is now on preparing for pandemic influenza, multiple scenarios for protecting the health of the public are being carefully considered, ranging from rapid development of appropriate vaccines to quarantine plans should the need arise for their implementation. One critical aspect of pandemic influenza planning is the use of personal protective equipment (PPE) - the respirators, gowns, gloves, shoe coverings, eye protection, and other equipment that will be used by healthcare workers and others in their day-to-day patient care responsibilities.

In 2006, the National Personal Protection Technology Laboratory (NPPTL) at the National Institute for Occupational Safety and Health (NIOSH) asked the Institute of Medicine (IOM) to conduct a study on the personal protective equipment needed for healthcare workers in the event of an influenza pandemic. The IOM committee determined that there is an urgent need to address the lack of preparedness regarding effective personal protective equipment (PPE) for use in an influenza pandemic. Their critical issues were identified that require immediate research and policy action:

1. Understand influenza transmission.
2. Communicate workers and appropriate use of PPE.
3. Implement and maintain PPE design, testing, and certification.

UNDERSTAND INFLUENZA TRANSMISSION

Although it has been 70 years since the influenza virus was discovered and despite the recognition that influenza causes severe morbidity and substantial mortality each year across the globe, little is known about the mechanisms by which the influenza virus is transmitted between individuals. Due to this lack of information, it is not possible to determine what evidence shows that healthcare workers are at risk of exposure to influenza and what level of protection the equipment will provide in a pandemic.
EVIDENCE-BASED PERFORMANCE REQUIREMENTS

**Functionality**
- Protect against influenza virus
- Guard against contact with contaminated fluids and aerosols

**Usability**
- Maintain biomechanical efficiency and sense of touch and feel
- Odor-free
- Hypoallergenic
- Accommodate wide range of users (face and body profiles)
- Compatibility across various elements of the PPE ensemble and with other equipment (e.g., stethoscope)
- Non-startling to patients and families
- Facilitate communication with others (verbal, facial)

**Comfort and wearability**
- Comfortable—no skin irritation or pressure points
- Prolonged use without discomfort
- Breathable—air permeable
- Moisture absorbent—wickability
- Low bulk and weight
- Dimensional stability
- Easy to put on and take off (don and doff)

**Maintenance and Reuse**
- Easy to decontaminate and discard disposable elements
- Easy to clean and replace parts in reusable PPE

**Cost**
- Product cost
- Total life-cycle cost
- Minimal environmental impact

**Aesthetics**
- Variety of styles and colors
- Customizable

**Durability**
- Adequate wear life
- Strength—tear, tensile, burst
- Abrasion resistance
- Corrosion resistance
<table>
<thead>
<tr>
<th>BOX S-1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overview of the Report Recommendations</td>
</tr>
</tbody>
</table>

**Understand Influenza Transmission**
- Initiate and Support a Global Influenza Research Network

**Commit to Worker Safety and Appropriate Use of PPE**
- Emphasize Appropriate PPE Use in Patient Care and in Healthcare Management, Accreditation, and Training
- Identify and Disseminate Best Practices for Improving PPE Compliance and Use
- Increase Research and Research Translation Efforts Relevant to PPE Compliance

**Innovate and Strengthen PPE Design, Testing, and Certification**
- Define Evidence-Based Performance Requirements (Prescriptive Standards) for PPE
- Adopt a Systems Approach to the Design and Development of PPE
- Increase Research on the Design and Engineering of the Next Generation of PPE
- Establish Measures to Assess and Compare the Effectiveness of PPE
- Ensure Balance and Transparency of Standards-Setting Processes
- Strengthen Pre-market Testing of PPE for Healthcare Workers
- Strengthen Post-market Evaluation of PPE for Healthcare Workers
- Coordinate Efforts and Expand Resources for Research and Approval of PPE
Interim Conclusions
(January 2008)
Office of Public Health and Environmental Hazards at VHA

• Respirators currently available in the U.S. marketplace are not sufficient to meet the needs of healthcare workers during a pandemic and they pose serious challenges during routine occupational activities

• Healthcare workers need one or more new respirators that meet their needs

• VHA should initiate Project BREATHE
Phase I – Working Group*

Goal - develop a report that identifies the design features of an improved respirator designed specifically for health care workers.

Technology Transfer team identifies other barriers to commercialization (e.g., policy, regulatory, hospital practice).

User team identifies and prioritizes design requirements.

Science & Technology team assesses feasibility of user requirements.

*Conceptual, subject to change
Overview

- Phase I – Interagency Working Group
  - Recommend new designs and technologies
- Phase II – Prototype Development
- Phase III – Lab/Field Testing
- Phase IV – Commercialization
Phase I Recommendations
(28 Total)

• Respirators should function effectively and safely (9 recommendations).
• Respirators should not interfere with occupational activities (5 recommendations)
• Respirators should be comfortable and tolerable (10 recommendations).
• Respiratory protective programs should meet local policies and standards (4 recommendations).
Incidence of Respiratory Illness In Healthcare Workers Who Wear Respirators, Surgical Masks or “Usual Protective Measures” while Caring for Patients

The Respiratory Protection Clinical Effectiveness Trial

Law Radonovich, Trish Perl, Michael Boul, Ron Effer:

For the U.S. Respiratory Protection Clinical Research Consortium

June 12, 2009
Collaborators – Jointly Funded

• Veterans Health Administration
• Centers for Disease Control and Prevention
• National Institute for Occupational Safety and Health
• Johns Hopkins Health Systems
Hypothesis

The incidence of respiratory viral infections, including influenza and influenza-like illness (ILI), will be different among healthcare workers (HCWs) who care for patients while using respirators or surgical masks or "usual protective measures."
Specific Aims

- **Incidence Determination:**
  To improve understanding about the burden of ILI and organism specific viral illnesses among HCWs, compared to the local community

- **Protective Effects:**
  To compare the magnitude of reduction (if any) of influenza, ILI and organism specific viral illnesses in HCWs:
  - Wearing N95 respirators or surgical masks or "usual protective measures“ compared to community incidence.
  - Wearing N95 respirators or surgical masks compared to "usual protective measures."
Methods

- Prospective
- Un-blinded
- Cluster-randomized
- Cross-over
- Comparative effectiveness
- Outpatient clinics/emergency departments/urgent care clinics
Chart 1: Randomization Scheme

Randomize clinics each at JHH and VA, assign to one of 3 arms

Arm 1, JHH and VA
- Usual Method
- N-95 Mask
- Surgical Mask

Arm 2, JHH and VA
- Surgical Mask
- Usual Method
- N-95 Mask

Arm 3, JHH and VA
- N-95 Mask
- Surgical Mask
- Usual Method
Table 3. Respiratory infection surveillance case definition

<table>
<thead>
<tr>
<th>Signs</th>
</tr>
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<tbody>
<tr>
<td>Fever (T &gt; 37.8° C)</td>
</tr>
<tr>
<td>Tachypnea (respiratory rate &gt;25)</td>
</tr>
<tr>
<td>Coryza</td>
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<tr>
<td>Lymphadenopathy</td>
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<table>
<thead>
<tr>
<th>Symptoms</th>
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<tbody>
<tr>
<td>Cough</td>
</tr>
<tr>
<td>Sputum production</td>
</tr>
<tr>
<td>Fatigue</td>
</tr>
<tr>
<td>Malaise</td>
</tr>
<tr>
<td>Headache</td>
</tr>
<tr>
<td>Sore throat</td>
</tr>
<tr>
<td>Dyspnea</td>
</tr>
<tr>
<td>Chills</td>
</tr>
<tr>
<td>Chills</td>
</tr>
<tr>
<td>Sweats</td>
</tr>
<tr>
<td>Arthralgias/myalgias/body aches</td>
</tr>
</tbody>
</table>

*a A respiratory infection will be defined as the presence of at least 1 sign or 2 symptoms, each representing a change from baseline prior to infection.*
Laboratory: Nasopharyngeal Swabs

- Multiplex PCR analyses for respiratory viruses
  - Respiratory syncytial viruses (A and B)
  - influenza A, influenza B
  - parainfluenza virus types 1-4
  - human metapneumovirus
  - adenoviruses
  - rhinoviruses
  - Coxsackie/echoviruses
  - coronaviruses (NL63, HKU1, 229E, and OC43)
  - bocavirus.
Thank You

• Bopper Deyton
• Vicky Davey
• Michael Hodgson
• Brad Bender
• Paul Hoffman
• Parker Small
Superscripted References


Common Respirators +/- Surgical Masks

(a) Surgical Mask

(b) Cup-shaped N95 without Exhalation Valve

(c) Cup-shaped N95 without Exhalation Valve + Surgical Mask

(d) Duck Bill-shaped N95

(e) Cup-shaped N95 with Exhalation Valve

(f) Cup-shaped N95 with Exhalation Valve + Surgical Mask

(g) Half-face Elastomeric (Reusable) Respirator

(h) Powered Air-Purifying Respirator
Half-Face Elastomeric Respirators

(d) Survivair 2000 Series

(e) Survivair Blue1 Series

(f) Scott Xcel Series

(a) North 5500 Series

(b) 3M 7500 Series

(c) Sundstrom SR100 Series
IBIS T5000 Biosensor System

- Novel assay
- To identify newly emerging (novel or unique) virus sub-types and influenza strains
- Process:
  - DNA extraction and PCR with universal primers and callibrant plasmids
  - Electrospray products in mass spectrometer
  - Signal processing (ID organism) using Mass Spec data from multiple primers
Figure 3: Procedures of RT-PCR/ESI-MS: broad range reverse transcription followed by electrospray ionization mass spectrometry

STEP #1 - DNA extraction and PCR with universal primers and calibrant plasmids

STEP #2 - Electrospray products into mass spectrometer

STEP #3 - Signal Processing - ID organism using Mass Spec data from multiple primers