Purpose: To Connect Policy to Practice
Mission: To help the VA solve challenges in:
            Occupational health
            Biosafety
            Infection control
            industrial hygiene
The Respiratory Protection Clinical Effectiveness Trial

The Centers for Disease Control and Prevention
The Veterans Health Administration
Johns Hopkins Health System
Protection of Healthcare Workers from Respiratory Infectious Diseases

Surgical Mask versus N95 Respirator
Respirators – vs – Surgical Masks

Complex Issue & Many Influences
  – Science
  – Politics
  – Bureaucracy
  – Pragmatics
  – Regulation & Enforcement
  – Compliance

Cost? $Thousands → $Millions
Key Organizations

- **Centers for Disease Control and Prevention**
  - National Institute for Occupational Safety and Health
  - National Personal Protective Technology Laboratory
  - Division of Healthcare Quality and Promotion
  - Office of the Director

- **Veterans Health Administration**
  - Office of Public Health and Environmental Hazards
  - National Center for Occupational Health and Infection Control

- **Johns Hopkins Health System**
  - School of Medicine, Division of Infectious Diseases
  - School of Public Health, Department of Epidemiology
  - Hospital Epidemiology and Infection Control
Principal Study Team Members

**Investigators**
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- Alex Valsamakis
- Others to be named as new sites identified

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**Federal Scientists and Collaborators**
- Dixie Snyder
- Michael Bell
- Vicky Davey
- Michael Hodgson
- Ron Shaffer
- David Weissman

*Principal Investigators
Null Hypothesis

The incidence of influenza and other respiratory infections will not be different between HCWs who practice respiratory protection 2007 CDC guidelines (medical masks) and 2009 H1N1 CDC guidelines (N95 respirators).
Two Arms

• 2007 CDC Respiratory Protection Guidelines for Flu (Medical Masks)

• 2009 CDC Respiratory Protection Guidelines for Flu (N95 Respirators)
Specific Aims

1. Incidence Determination:
   To better understand the occupational burden of influenza (primary) and other respiratory infections (secondary) at the study sites.

2. Protective Effects:
   To determine the risk of becoming infected with influenza and other organism-specific viral respiratory pathogens while HCWs wear N95 respirators (2009 guidelines) compared to medical masks (2007 guidelines).

3. Behaviors and Risk
   To explore relationships between exposure risk and becoming infected with influenza and other respiratory infections.
Methods

• Prospective
• Un-blinded
• Comparative effectiveness
• Outpatient clinics/emergency & urgent care settings
• Individual vs Cluster-randomized
• Cross-over vs longitudinal cohort
## Diagnosis

Nasopharyngeal swabs:
- When ill
- Weekly surveillance

<table>
<thead>
<tr>
<th>Signs</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fever (T $&gt; 37.8^\circ$ C)</td>
<td>Cough</td>
</tr>
<tr>
<td>Tachypnea (respiratory rate $&gt; 25$)</td>
<td>Sputum production</td>
</tr>
<tr>
<td>Coryza</td>
<td>Fatigue</td>
</tr>
<tr>
<td>Lymphadenopathy</td>
<td>Malaise</td>
</tr>
</tbody>
</table>

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.

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*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 using Ibis 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.
  – Novel emerging flu strains

• HAI Serologies

• Viral Culture
Lab-Confirmed Diagnosis

- HAI Serology: twice
  - On study enrollment
  - On study termination
- PCR: ≤12 times per year
Key Sample Influences

- Incidence
- Power
- Effect Size
- Difference in Effect Size
- Prediction ("Triggers")
- Accounts for higher influenza vaccination rates
Study Logistics

- Fit Testing for all participants
- Education
- Participant Reminders
- Diaries
- Compliance audits for
  - PPE
  - Hand hygiene
- Database development
- IRB at all sites
Study Logistics

- 4+ study sites from across US
  - Out patient volumes
  - Geographic distribution
  - Scientific infrastructure
  - Experience with respiratory disease

- ~ 4 years

- Natural Pilot in 2010

- CDC-VHA Meeting June 9, 2010


