Respiratory Protective Equipment – Overview of Recent Research

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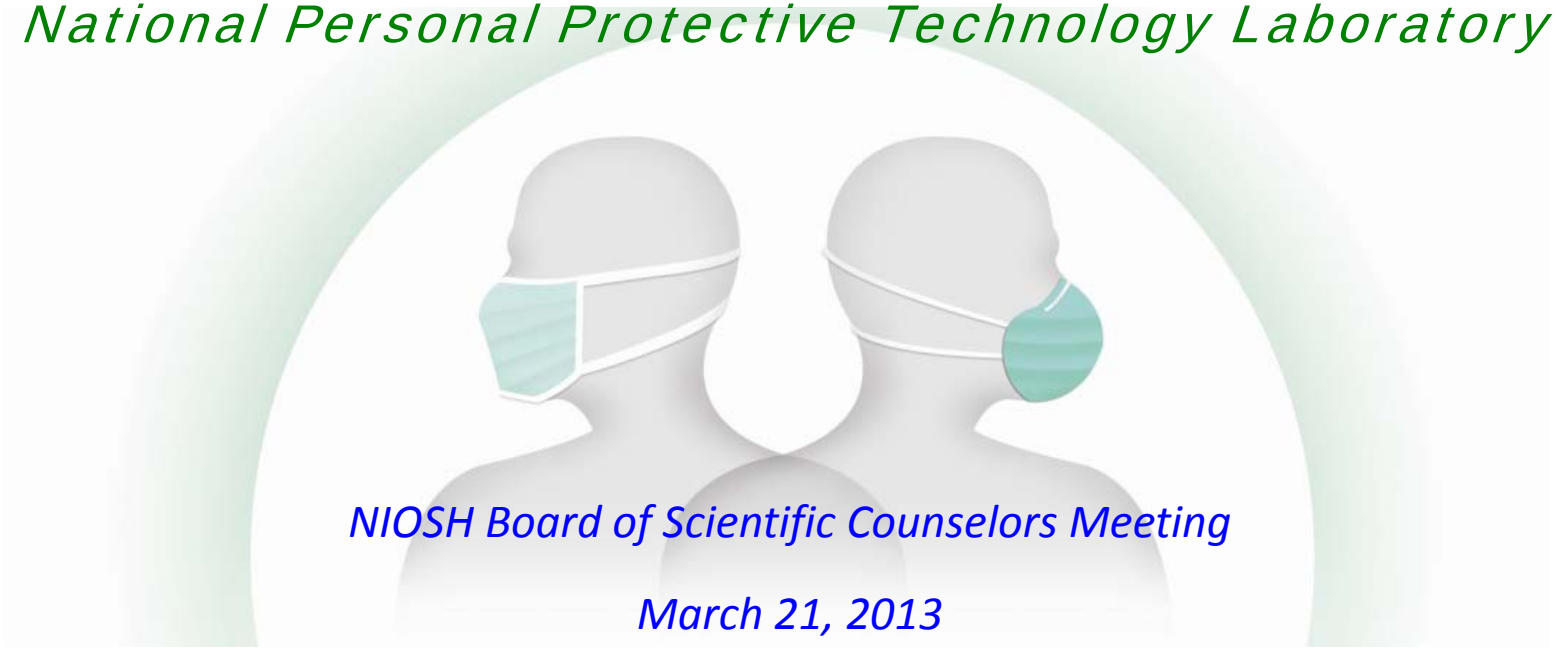


NIOSH Board of Scientific Counselors Meeting

March 21, 2013

NIOSH PPT Healthcare Worker (HCW) Research Program

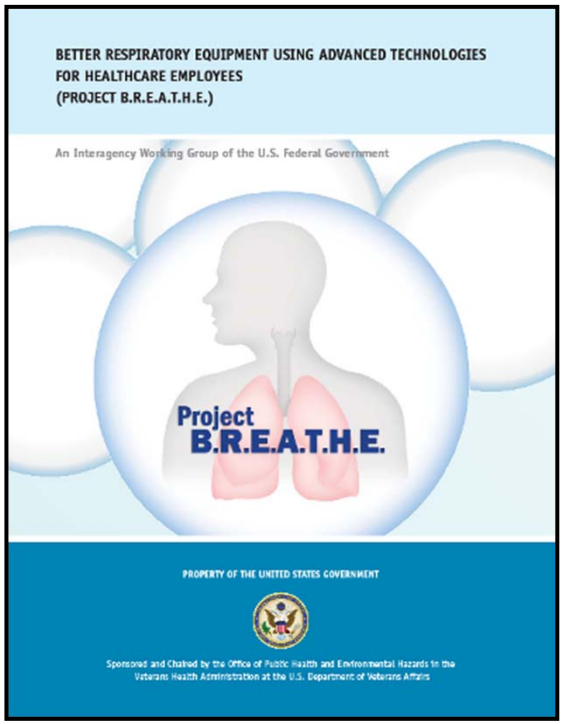
- **Ensembles Research**
  - Surgical/isolation gowns
- **Filtration Research**
  - Nanoparticles / Bioaerosols
- **Respirator Fit Research**
  - Facial anthropometrics
  - Frequency of fit testing
  - Respirator fit test research (user seal check, novel methods, multiple donnings)
- **Respirator Comfort Research**
  - Physiology studies
  - Project BREATHE
- **Commit to Worker Safety and Appropriate Use of PPE**
  - Demo and Sentinel Surveillance
  - REACH I/II
  - Best practices, outreach
- **Respirator Performance & Usability Research**
  - Performance against cough generated aerosols
  - PPE combinations
  - **Respirator clinical effectiveness**
- **Influenza Pandemic**
  - Risks of handling a contaminated respirator
  - Decontamination of filtering facepiece respirators (FFRs)
  - **Assessing modes of transmission**

Project BREATHE - Better Respirator Equipment using Advanced Technology for Healthcare Employees

- Objective: To improve HCW respirator compliance
- Approach: Develop (1) information products, (2) respirator performance requirements, and (3) advanced technologies for the next generation of HCW respirators that are more comfortable and tolerable
- Partnership: Veterans Health Administration (VHA)

Project BREATHE 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



http://www.publichealth.va.gov/docs/cohic/project-breathe-report-2009.pdf

Current Status

Develop clinically-validated "B95" test methods	"B95" prototype development	"B95" standards development
• Multiple research projects and collaborations initiated to study & quantify FFR comfort and measure impact of FFR design on comfort • > 20 manuscripts published to date • http://www.cdc.gov/niosh/topics/flu/respiratory.html	• Collaborations with Georgia Tech, 3M, and Scott Safety 	• In collaboration with the VHA, identified draft set of B95 requirements, criteria, and test methods

Respiratory Protection Effectiveness Clinical Trial (ResPECT)

- Funded by CDC and VHA
  - Principal Investigators: Trish Perl (Johns Hopkins University, JHU), Lew Radonovich (VHA)
  - CDC project officer: Ron Shaffer
- Primary question: How well do FFRs (2009 CDC nH1N1 Flu Guidance) protect HCWs in the outpatient setting against influenza and other respiratory illnesses, as compared to surgical masks (2007 CDC Seasonal Flu Guidance)?
- Approach: prospective, un-blinded, cluster randomized evaluation of N95 FFRs (arm #1) vs. surgical masks (arm #2)

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MEDICINE

Results to Date

	Pilot (2010-1)	Year 1 (2011-2)	Year 2 (2012-3)
# of Cities	1	3	5
# of Clusters	6	53	95
# Enrolled	148	663	1174
% Flu Vaccine	40%	81%	TBD
# Symptomatic Swabs	36	263	450**
% Positive*	TBD	22%	TBD
# Asymptomatic Swabs	1083	1198	2200***
% Positive*	TBD	4%	TBD

* PCR detected respiratory viruses: Adenovirus, Coronavirus, Metapneumovirus, Influenza, and RSV. Data current as of Oct 2012.
** 450 symptomatic swabs have been collected as of 13 Feb 2013.
*** Asymptomatic swabs estimated based on number of participants and Year 1's swabbing rates.

Current Status

- Estimate that after year 2:
  - ~35% completed for an “any PCR-confirmed symptomatic respiratory virus” outcome
  - ~18% completed for a “lab confirmed influenza” outcome
- Challenges:
  - Influenza endpoint is highly influenced by influenza incidence and vaccine match
  - Mandatory vaccination policies may depress influenza attack rate in future years
  - Project is only funded through FY13
- Study is collecting a rich dataset with many opportunities for collaborations

Why Hospital Staff Catch the Flu Study

- Aims: (1) measure influenza on surfaces and PPE (gloves and masks) and in the air during flu season and (2) determine the potential for direct-contact transmission from doffing of contaminated PPE
- Collaboration between NIOSH (NPPTL, HELD, DSHEFS) and JHU
- "Piggy-back" on ResPECT

Lab Study Hypotheses

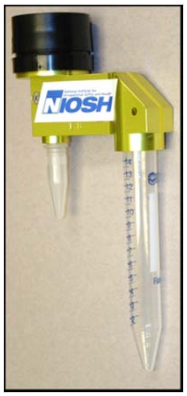
- FY12 – Influenza contamination levels recovered from PPE will correlate with controlled influenza exposure levels
- FY15 – Direct-spray PPE contamination will result in higher % of virus transferred to the hands than droplet nuclei

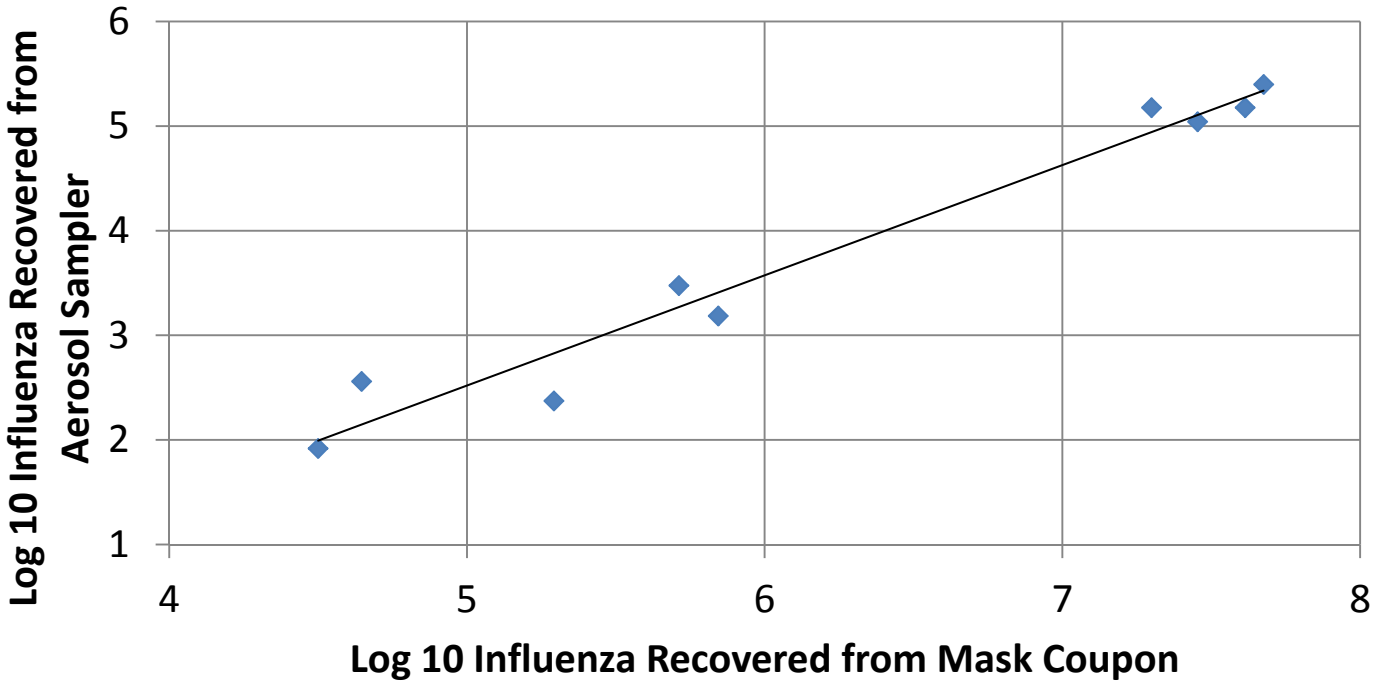
Field Study Hypotheses

- FY13 – PPE and environmental sampling from areas where suspected influenza patients are treated will contain higher influenza levels than control areas
- FY14 – PPE and environmental samples will contain higher levels of influenza prior to subjects becoming symptomatic than a control period

Lab Results

NIOSH sampler





Breathing mannequin

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Thank you

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