

# BARDA Industry Day

Lew Radonovich



# An Ideal Environment for Health Care Field Testing

## Project BREATHE and Other Medical Countermeasures

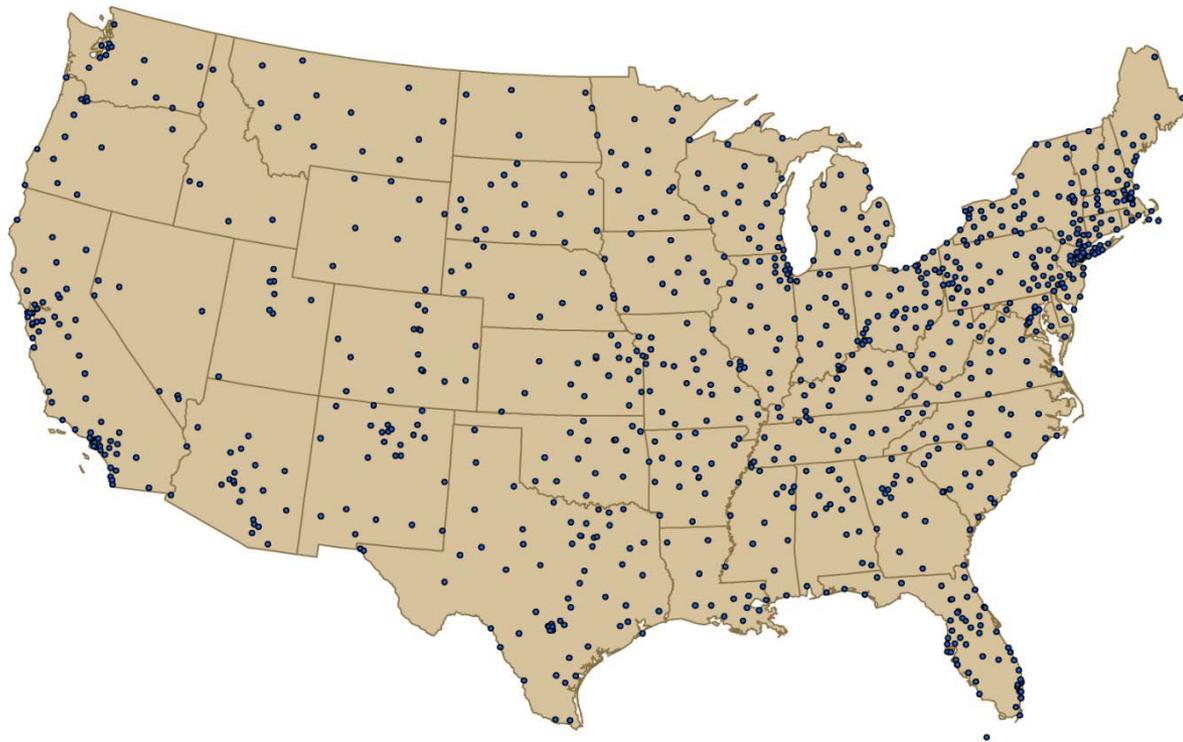
VA is one of the largest civilian employers in the federal government and one of the largest health care employers in the world.

- **269,000+** Total VHA Employees
- **83,000+** Veteran Employees
- **20,000+** Physicians
- **69,000+** Nurses\*

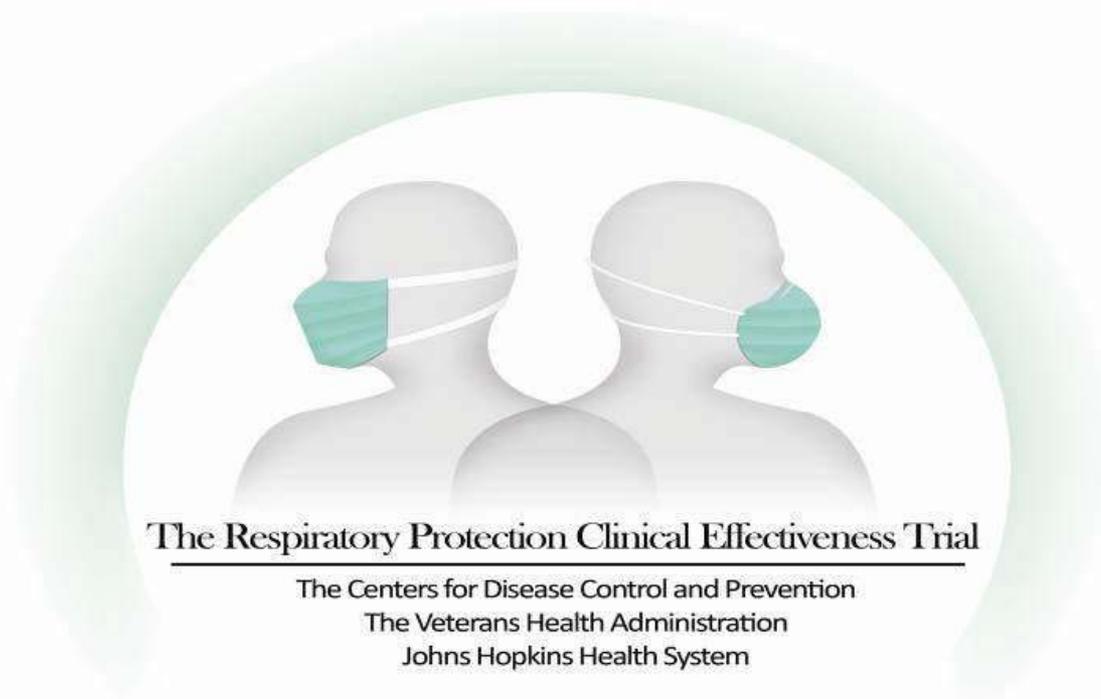
\*Includes registered nurses, licensed practical nurses and licensed vocational nurses.



# A Health System with Locations Nationwide



- **152** Medical Centers
- **981** Outpatient Clinics
  - 812** Community-Based
  - 152** Hospital-Based
  - 11** Mobile
  - 6** Independent
- **300** Vet Centers
- **50** Mobile Vet Centers
- **98** Domiciliary Residential Rehabilitation Programs
- **133** Community Living Centers



The Respiratory Protection Clinical Effectiveness Trial

The Centers for Disease Control and Prevention  
The Veterans Health Administration  
Johns Hopkins Health System

# Two Arms

2007 CDC Respiratory Protection Guidelines  
for Flu (Medical Masks)



2009 CDC Respiratory Protection Guidelines  
for Flu (N95 Respirators)



# Progress and Expectations

## Study Sites

- Johns Hopkins
- Denver Health
- Denver Childrens
- VA - NYC
- VA - Washington DC
- VA - Houston
- VA - Denver

## Goals

- ~ 600 subjects recruited as of March 2012
- Need ~ 2000 subjects
- Endpoints:
  - Influenza PCR + serology
  - All viral respiratory disease (PCR)

# Effective Size

## What represents a “clinically relevant reduction in infection”?

- We have designed the study to detect a **25%** reduction in influenza attack rate among those wearing respirators
- Informal survey of Infection Control and Occupational Medicine Communities (listservs)
- In comparison, Loeb study was only designed to detect relative reductions *greater than 37.5%*
- Effect size of interest has a strong impact on sample size

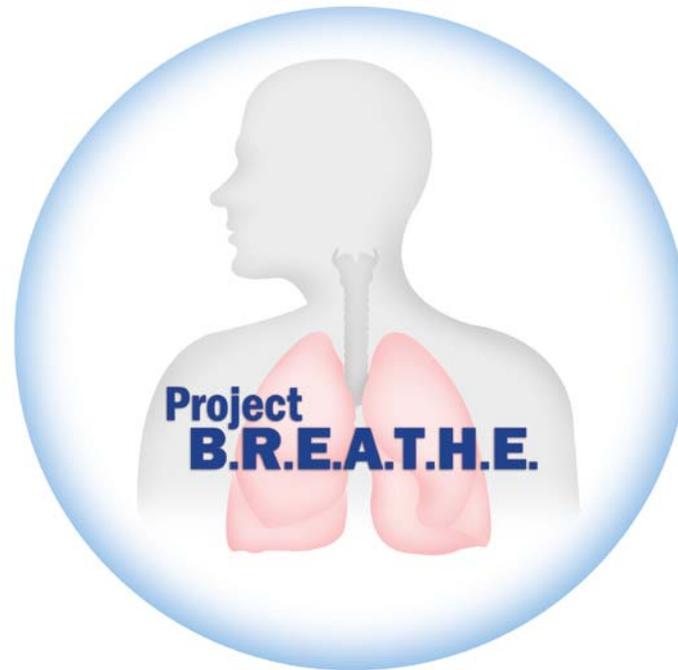
# Project B.R.E.A.T.H.E.

Developing New Respiratory Protective Devices to  
Safeguard Against Biological Hazards.

Veterans Health Administration

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**OSHA**<sup>®</sup>



**CDC**  
CENTERS FOR DISEASE CONTROL  
AND PREVENTION

**BETTER RESPIRATORY EQUIPMENT USING ADVANCED TECHNOLOGIES  
FOR HEALTHCARE EMPLOYEES  
(PROJECT B.R.E.A.T.H.E.)**

An Interagency Working Group of the U.S. Federal Government

**Project  
B.R.E.A.T.H.E.**

PROPERTY OF THE UNITED STATES GOVERNMENT

Sponsored and Chaired by the Office of Public Health and Environmental Hazards in the  
Veterans Health Administration at the U.S. Department of Veterans Affairs



**NIOSH**

**NIST**



# 28 Idealized Consensus Recommendations

## (4 Primary Categories)

### Respirators should:

- Perform their intended functions safely and effectively. (9)
- Support, not interfere with, occupational activities. (5)
- Be comfortable and tolerable for the duration of wear. (10)
- Comply with current standards and guidelines. (4)

CRADA Partners:



# Scott Safety

- High degree of interest and motivation
- Manufacturer of Self Contained Breathing Apparatus, commonly used for fire fighting, industrial use, and first responders
- Previous experience with simulated workplace protection factor studies for the military, interested in developing something similar for healthcare
- Have demonstrated ability to design products meeting user demands

(example shown)



**SCOTT**  
SAFETY



Questions or Comments

Thank You