BARDA Industry Day

Lew Radonovich
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)
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
Lew Radonovich, MD
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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)
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)
Questions or Comments

Thank You