



United States Department of

Health & Human Services

Office of the Assistant Secretary for Preparedness and Response



BARDA Industry Day 2012

Respiratory Devices for Medical Countermeasures

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Respiratory Devices Program



- i. Advanced development of **next generation transport ventilators** that can provide standard of care to respiratory compromised patients during pandemic influenza outbreak or any all-hazards events.

- ii. Advanced development and characterization of **respiratory protection devices** (RPD) to address performance, usability and domestic supply chain concerns during pandemic influenza outbreak or any all-hazards events.



Next Generation Transport Ventilators



Next Generation Transport Ventilators: Overview



- Ventilators address multiple threat agents to support patients with severe respiratory failure
- 2007 HHS pandemic influenza medical countermeasures gap analysis revealed a national need for a significant number of portable ventilators for emergencies
- Blue-ribbon panel of experts identified parameters, product requirements, and considerations for next generation portable ventilators
- Interagency project team consisting of PHEMCE partners formed for planning and implementation
- Invest in the development of innovative ventilator equipment with standardized interchangeable components that are lower cost, easier to use, and flexible for a variety of populations, conditions, and settings



Next Generation Transport Ventilators: Desired Characteristics



- Ease of use by untrained care providers
- Wide patient population (*i.e.*, neonate to adults)
- Portability and environmental considerations
- Standard of care
- Stockpiling and maintenance ease
- Low cost (< \$3000 per fully-kitted unit)
- Domestic surge production
- FDA clearance/approval



Next Generation Transport Ventilators: Current Activities



- One product in advanced development expected completion in FY 2013 to meet established requirements
- Mitigate risks by diversifying program and increasing potential for domestic surge production capacity
- More candidates for development activities pending under 2011 and 2012 Flu BAA
- Collaborative efforts: submission evaluation by experts within PHEMCE and other government and non-government agencies



Respiratory Protection Devices (RPD)



Respiratory Protection Devices: Known Concerns



- RPDs address multiple threat agents transmitted by aerosolized particles and large droplets
- Level of needed protection from infection (e.g., surgical face mask, N95 or other)
- Influenza transmission not well understood
- Minimal research available to verify safety and effectiveness in healthcare environment
- Evidence-based performance requirements to innovate and strengthen RPD material, design, testing and certification
- Sufficient data to support NIOSH certification and/or FDA clearance
- Availability / Ease of Stockpiling and Inventory Management

2007 IOM Report – Preparing for an Influenza Pandemic: PPE for Healthcare Workers

2010 IOM Report – Preventing Transmission of Pandemic Influenza and Other Viral Respiratory Diseases, PPE for Healthcare Personnel



Respiratory Protection Devices: BARDA Initiatives



- 2009 acquisition of N95 respirators and surgical face masks for HHS Critical Workforce as part of HHS continuity of operations strategy
- Desired Characteristics: Demonstration of advanced features for functionality, usability, comfort, decontamination & reuse, cost efficiency, and durability; Protection for pediatric population
- Applied research project with Air Force Research Laboratory and collaboration with NIOSH to:
 - Assess filtration efficiency of N95s to pathogenic organism
 - Develop a tool and method to characterize total inward leakage for fit evaluation and gain insight to possible advanced development options
- Pending activities under 2012 BAA to support advanced development and characterization of RPDs
- Collaborative efforts: submission evaluation by experts within PHEMCE and other government and non-government agencies



Respiratory Protection Devices: Ongoing Activities



Government-Academic-Private Collaboration:

- Presence of influenza virus in respiratory particles
- Clinical studies for influenza transmission, respiratory protection and engineering controls (e.g., ResPECT Clinical Trial)
- Understanding transmission of influenza from RPD
- Improved respiratory protection devices (e.g., Project BREATHE)



Broad Agency Announcement



Advanced Development of Medical Countermeasures for Pandemic Influenza

Solicitation Number:

BARDA-12-100-SOL-00018

Areas of Interest:

1. Personal Protective Equipment (Masks and Respirators) for Influenza Infection & All-Hazards
2. Full-Featured Continuous Ventilators for Influenza Infection & All-Hazards

Website:

https://www.fbo.gov/index?s=opportunity&mode=form&id=5d4847b944cd4992b68c6980d3f14d5d&tab=core&_cvview=1

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