



BARDA Innovation: Reconceptualizing Diagnostics and Respiratory Protective Devices

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BARDA Innovation: Our Vision

*BARDA's vision for innovation is to **shrink the gap**--between patient and treatment, between disease emergence and response*

Products that are:

- **Readily available**
- **Integrated into daily life**

Enabling transformational technologies include:

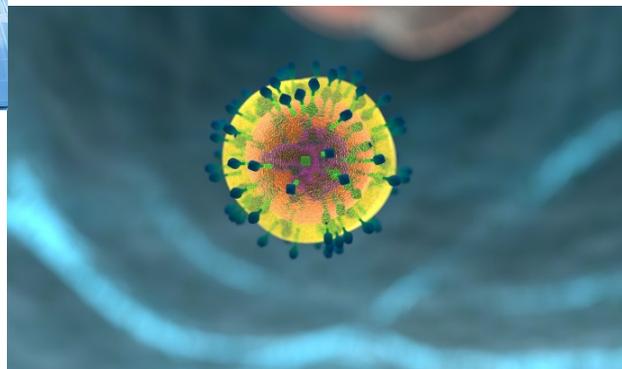
- Widely available Home/Wearable diagnostic devices
- Comfortable, universal fit respiratory protection
- Platform technologies to rapidly produce vaccines and therapeutics





BARDA Innovation Incubator

- Innovation is a high priority to BARDA
- BARDA will establish a dynamic portfolio of innovative technologies supported under private/public partnerships
 - Efforts will consist of short term investments to evaluate novel technologies
- Successful technologies will transition into BARDA advanced research and development program areas





21st Century Cures Act

Sec. 3084. Medical countermeasures innovation.

Section 3084 amends the PHS Act to direct BARDA to enter an agreement with an independent, nonprofit entity (a Medical Countermeasures Innovation Partner) to:

- Foster and accelerate development and innovation of medical countermeasures and technologies that may assist advanced research and development of qualified countermeasures, including using strategic venture capital practices;
- Promote the development of new and promising technologies that address urgent medical countermeasure needs as identified by HHS;
- Address unmet public health needs relating directly to medical countermeasure requirements; and
- Provide expert consultation and advice to foster viable medical countermeasure innovators.

Innovation

Under the agreement, BARDA must provide direction to the partner, including by communicating the medical countermeasure needs, requirements, and problems to be addressed. The section requires that BARDA provide Congress quarterly reports from the partner on the progress being made toward meeting the needs set out in the agreement. In addition, the section directs GAO within 4 years of the date of enactment of the Act to conduct an independent evaluation and report to Congress on the activities conducted under this section. This section sunsets after September 30, 2022.





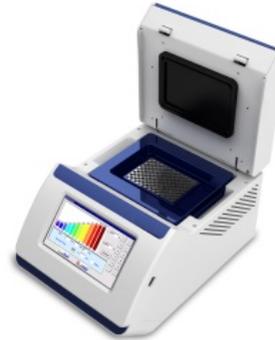
Challenges of Pandemic Response: Treatment



- Three FDA approved antiviral drugs for treatment of influenza
- Most effective within a narrow treatment window
- Not widely used, likely because patients present to healthcare workers outside of optimal treatment window



Challenges of Pandemic Response: Diagnosis



- Available diagnostics: Rapid Influenza Diagnostic Tests, Immunofluorescence, Molecular, Serologic Testing
- Non-networked capabilities
 - Limited capability in cloud based reporting
- Not easily accessible
 - Clinic & laboratory based testing



Solution: The Individual is the Pandemic First Responder

Vision: A personalized approach to a global problem. Empower patients to seek treatment and prevent transmission.

- Early identification and treatment is critical for pandemic mitigation
- In-home, or wearable devices allow for early, actionable information
- The faster a diagnosis can be made, the faster treatment can be administered to prevent further progression of illness and transmission within a community
- Increase and diversify data sources to provide situational awareness, and enable real-time forecasting for emerging and reemerging threats





RAPID, SPECIFIC, POINT OF CARE DIAGNOSTIC MEDICAL DEVICES

- 20 MINUTE SUBTYPING AND CHARACTERIZATION
- HIGH THROUGHPUT DEVICE
- DRUG RESISTANCE BIOMARKER SCREENING
- REAL TIME DATA COLLECTION
- GEO-SPATIAL + CLOUD BASED TEST RESULT INFORMATION

POINT OF NEED, IN-HOME RAPID DIAGNOSTIC

- IN-HOME DIAGNOSTIC CAPABILITIES
- 10 MINUTE IN HOME TESTING
- MULTIPLE DIAGNOSTIC TARGETS
- REAL TIME DATA COLLECTION
- GEOSPATIAL + CLOUD BASED TEST RESULT INFORMATION

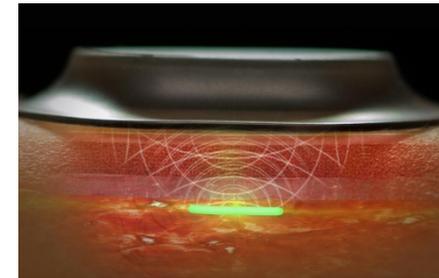
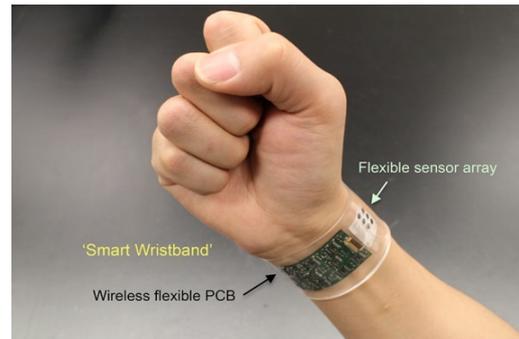
HOST-BASED BIOSENSING WEARABLE

- DETECTING PRE-SYMPTOMATIC ILLNESS
- MACHINE LEARNING AND TRACKING ALGORITHMS
- 24/7 MONITORING AND TRACKING
- PUBLIC HEALTH MONITORING AND DETECTION OF INFECTIOUS DISEASE OUTBREAKS



Creating an Ecosystem: Wearable Devices for Early Disease Identification

- Development of a next generation wearable device

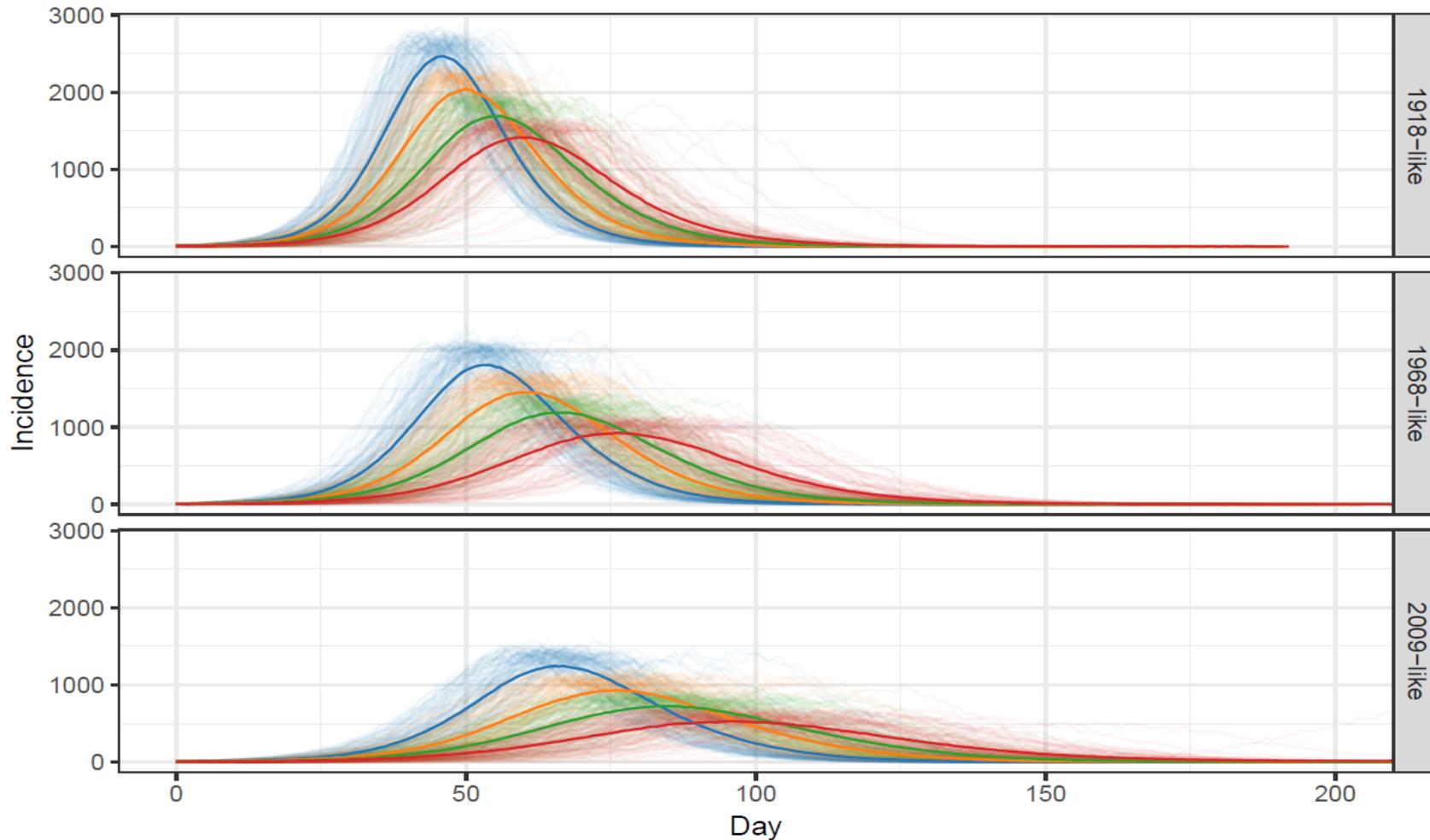


- Invasive and Non-Invasive Technology
 - Sweat Analytes
 - Interstitial Fluids
 - Biomarkers
 - Biophysical Activity Sensing
- Multi-purpose device that can be used to track and inform end user on health related variables
- **Ultimate goal: Pre-symptomatic detection of influenza and other emerging infectious diseases**



Impact of In-Home and Wearable Diagnostics

Impact of In-Home and Wearable Diagnostics across Pandemic Scenarios



— Unmitigated — 25% In-Home — +25% Wearable — +50% Wearable





Creating an Ecosystem: Areas of Interest

In-Home Diagnostic Devices

- FDA cleared
- Accurately diagnose influenza positive patients within 10 minutes
- Cloud-network based access
- Non-traditional sample collection technology
- Built in intervention post positive testing
- Affordable

Wearable diagnostic devices

- FDA cleared
- Accurately diagnose influenza
- Automatic data transmission to signal community outbreaks
- **Ultimately, predict pre-symptomatic illness**

Use of innovative technologies to improve clinical trial end points

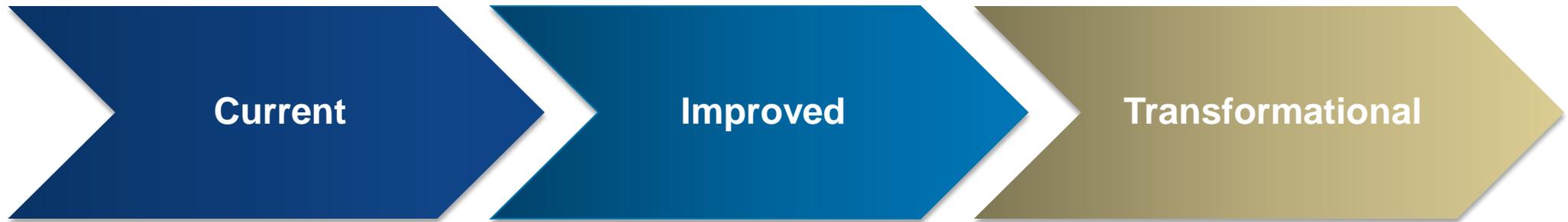
- Wearables
- Rapid, point-of-need diagnostic devices
- Continuous data collection





Reconceptualizing Respiratory Protective Devices

- Well defined problem, needing transformational solutions





Shrinking the Gap: Join Us

- **BARDA Innovation initiatives build on the successes of last 10 years**
- **If you have a way to do something better– we want to hear from you!**
 - Improvements for drug and vaccine dispensing/delivery
 - Tools to protect and empower the individual with actionable information
 - Technologies and approaches for predicting disease emergence and spread





Online Resources

<https://www.medicalcountermeasures.gov/home.aspx>

- Portal to BARDA: Register to request a **TechWatch** meeting

<https://www.fbo.gov/> ("FedBizOpps")

- Official announcements and info for all government contract solicitations

<https://www.usajobs.gov/>

- Join the team!

<https://www.phe.gov/about/BARDA/Pages/default.aspx>

- Program description, information, news, announcements

