Influenza and Emerging Diseases

Dr. RUBEN DONIS,
Deputy Director,
Influenza and Emerging Diseases Division

November 7, 2017
BARDA Industry Day
Mission and Scope

PREPAREDNESS
- Drug-Resistant
- H5N1
- 1918
- Deaths
- Diagnostics
- sustainable
- LAIV
- Highly Pathogenic
- Rapid Response
- Manufacturing

PANDEMIC influenza
- H7N9
- Fear
- ventilator
- H3N2v
- Avian flu
- Quarantine
- severe
- Pneumonia
- Monoclonal
- IRAT
- N95 mask

RESPONSE
- Fever
- Antiviral
- Therapeutics
- Emergency Use
- Regulatory
- Hospitalization
- MERS

EMERGING infectious diseases
- Zika outbreak
- Swine flu
- H1N1pdm
- Drug-Resistant
- IRAT
- 1918
- N95 mask
- Syringe
- Sustainable
- LAIV
- Manufacturing
- Rapid Response
Public Health Impact

Seasonal Influenza in US, Each Year
- 5%–20% U.S. Population Infected
- $87.1 Billion Economic Burden
- $10.4 Billion Medical Costs

Severity Can Vary
- 2013-14 Influenza Season: 400k Hospitalizations (>200k pediatric and elderly), 13.5k Deaths
- 2014-15 Influenza Season: 700k Hospitalizations, 19.5k Deaths

1918 Pandemic
- 25% U.S. Population Infected
- 675.5k Deaths

2009–H1N1 Pandemic
- 60.8 Million U.S. Population Infected
- 275k Hospitalizations
- 19.5k Deaths
1918-2018: H1N1 Centennial

- One third of the world’s population (≈500 M) infected
- Case fatality ratio >2.5% (vs. <0.1% in other pandemics)
- ≈50M deaths: 5 – 20 times higher than expected.
- Half of influenza deaths in 20–40 years of age
- Even with today’s healthcare, a 1918-like pandemic would likely kill >100 million people worldwide.
CDC IRAT ranks H7N9 as the greatest risk for pandemic emergence and impact.
Are we ready to mitigate the impact of the next pandemic?

LATE TO THE PANDEMIC

Influenza vaccine doses became available in large quantity only after the 2009 pandemic had peaked.
Influenza and EID Strategy

Vaccines

Therapeutics

Diagnostics

Early Detection  ➔  Early Response  ➔  Saving Lives
Pandemic Influenza Strategy Implementation

**Diagnostics, Ventilators, Masks**
- Influenza diagnostics closer to the patient
- Improved antiviral drug use
- Detect emerging pandemic viruses

**Vaccine Development**
- New antigen-sparing adjuvant technology
- Egg-independent vaccine platforms
- Pandemic response and surge capacity

**Therapeutics**
- Parenteral antiviral drug formulations
- Patients unable to take oral medications
  - Severely ill hospitalized patients.
Pandemic Influenza Stockpile and Infrastructure Strategy

**Pandemic Vaccine Preparedness**

- H7N9
- H5Nx

**US-Based Manufacturing Facilities**

- Swiftwater, PA
- Holly Springs, NC
- CT & NY
- Marietta, PA

**Risk-based vaccine preparedness; IRAT scoring, CVV, stockpile**

**Clinical studies and analytical testing**
- Evidence-based decisions
- Regulatory path

**Risk-mitigation:**
- Robust supply chains Resilience
- New technology platforms

**Sustainability:** Seasonal vaccine market sales support infrastructure capacity and readiness
Interagency Partnerships

Early detection & rapid virus seed production

Manufacturing improvement

Potency reagent availability

Vaccine distribution and use

Risk Management
THE COMPELLING NEED FOR GAME-CHANGING INFLUENZA VACCINES

AN ANALYSIS OF THE INFLUENZA VACCINE ENTERPRISE AND RECOMMENDATIONS FOR THE FUTURE

OCTOBER 2012

CIDRAP
Center for Infectious Disease Research & Policy
University of Minnesota

Vaccine roll out
19 weeks from declaration of pandemic to maximum capacity vaccine production

Most cases of influenza strike before roll out of vaccine

Start of 2009 Influenza pandemic

Cases per week (1,000)
End to End Strategy

Target Product Profile (TPP)

Discovery R&D > Preclinical > P1 Clinical > P2 > P3 > FDA Licensure > Recommendations > Stability Effectiveness

Manufacturing 1 > Mfg 2 > Mfg 3

Alignment to Pandemic Influenza Gaps
Until EIDs can be anticipated or avoided, future outbreaks will have to be managed with the classic approach to control — surveillance, rapid detection and rigorous efforts to treat, control, and prevent infection.

Zika Virus Response Investments

Zika Virus Response

IgM ELISA
PCR

Blood Supply Diagnostics

Vaccines
Blood Supply
Diagnostics

Diagnostic tests
• Laboratory and POC: support medical interventions

Blood Supply
• Safe blood supply by screening and pathogen reduction

Vaccine Development
• Robust and diversified vaccine development pipeline
EID Preparedness Gaps: From Reactive to Proactive
Industry Partnerships
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
Thank You!!

Email: ruben.donis@hhs.gov