



Influenza and Emerging Diseases

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November 7, 2017
BARDA Industry Day



Mission and Scope

PREPAREDNESS

H7N9

vaccine

Pneumonia

Monoclonal

Drug-Resistant

swine flu

Fear

ventilator

Avian flu

Quarantine

H5N1

Syringe

H1N1 pdm

1918

H3N2v

severe

Deaths

Diagnostics

PANDEMIC influenza

sustainable IRAT N95 mask

RESPONSE

Zika outbreak

LAIV Highly Pathogenic

Rapid Response

MERS

Fever

Antiviral

Transmission

Manufacturing

Regulatory

Hospitalization

Therapeutics

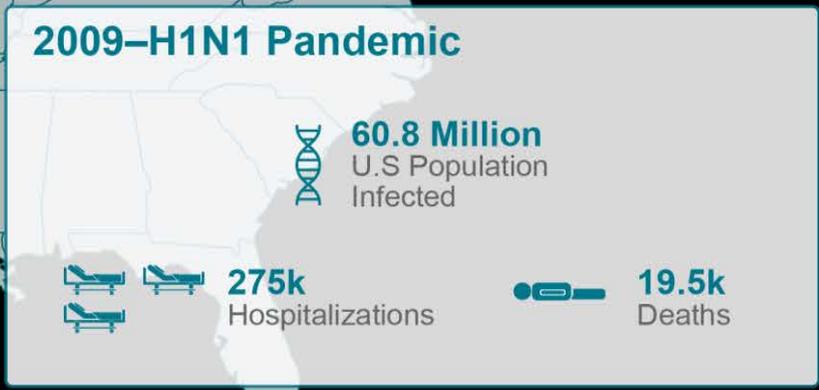
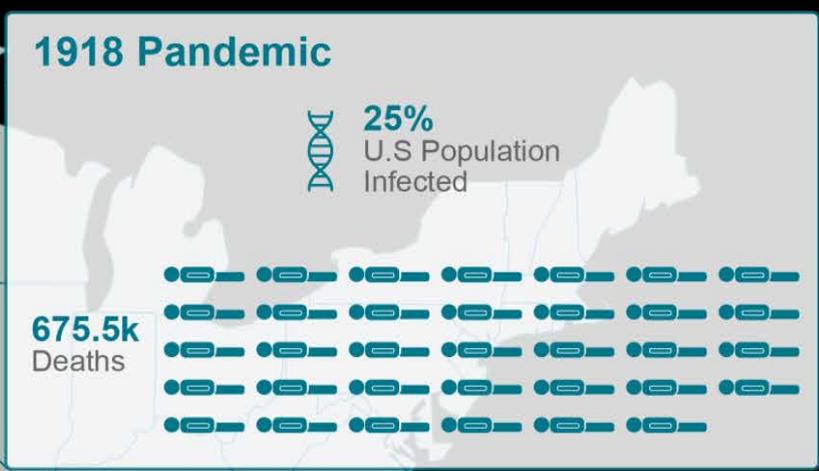
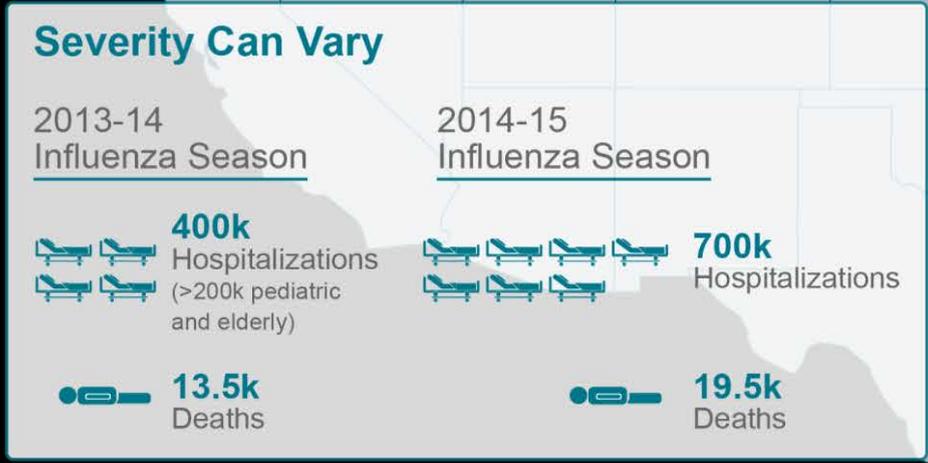
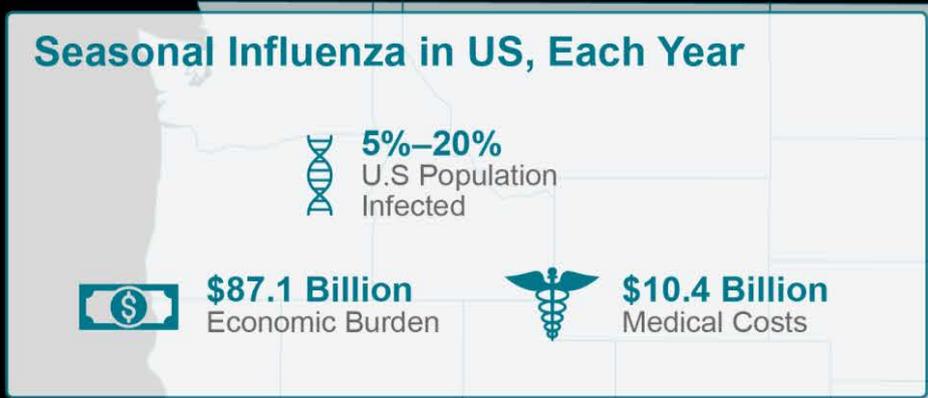
EMERGING infectious diseases

Emergency Use

adjuvant



Public Health Impact





1918-2018: H1N1 Centennial

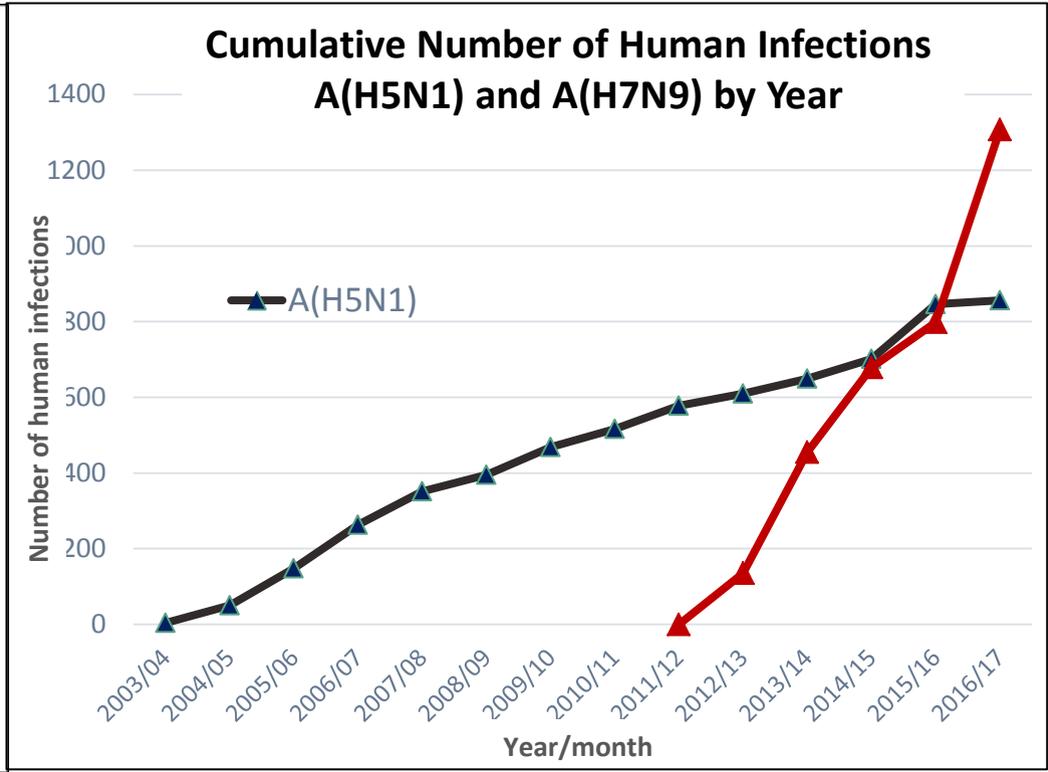
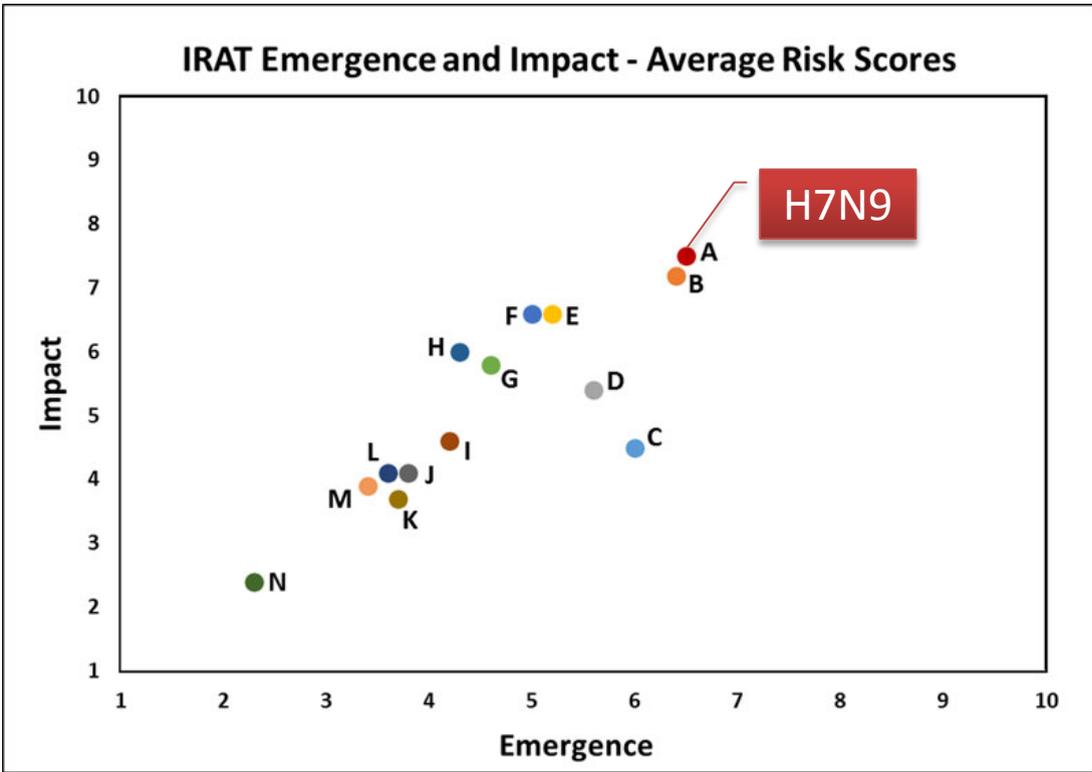
- One third of the world's population (≈ 500 M) infected
- Case fatality ratio $>2.5\%$ (vs. $<0.1\%$ in other pandemics)
- ≈ 50 M deaths: 5 – 20 times higher than expected.
- Half of influenza deaths in 20–40 years of age
- Even with today's healthcare, a 1918-like pandemic would likely kill >100 million people worldwide.





H7N9 Pandemic Risk: 2017

CDC IRAT ranks H7N9 as the greatest risk for pandemic emergence and impact

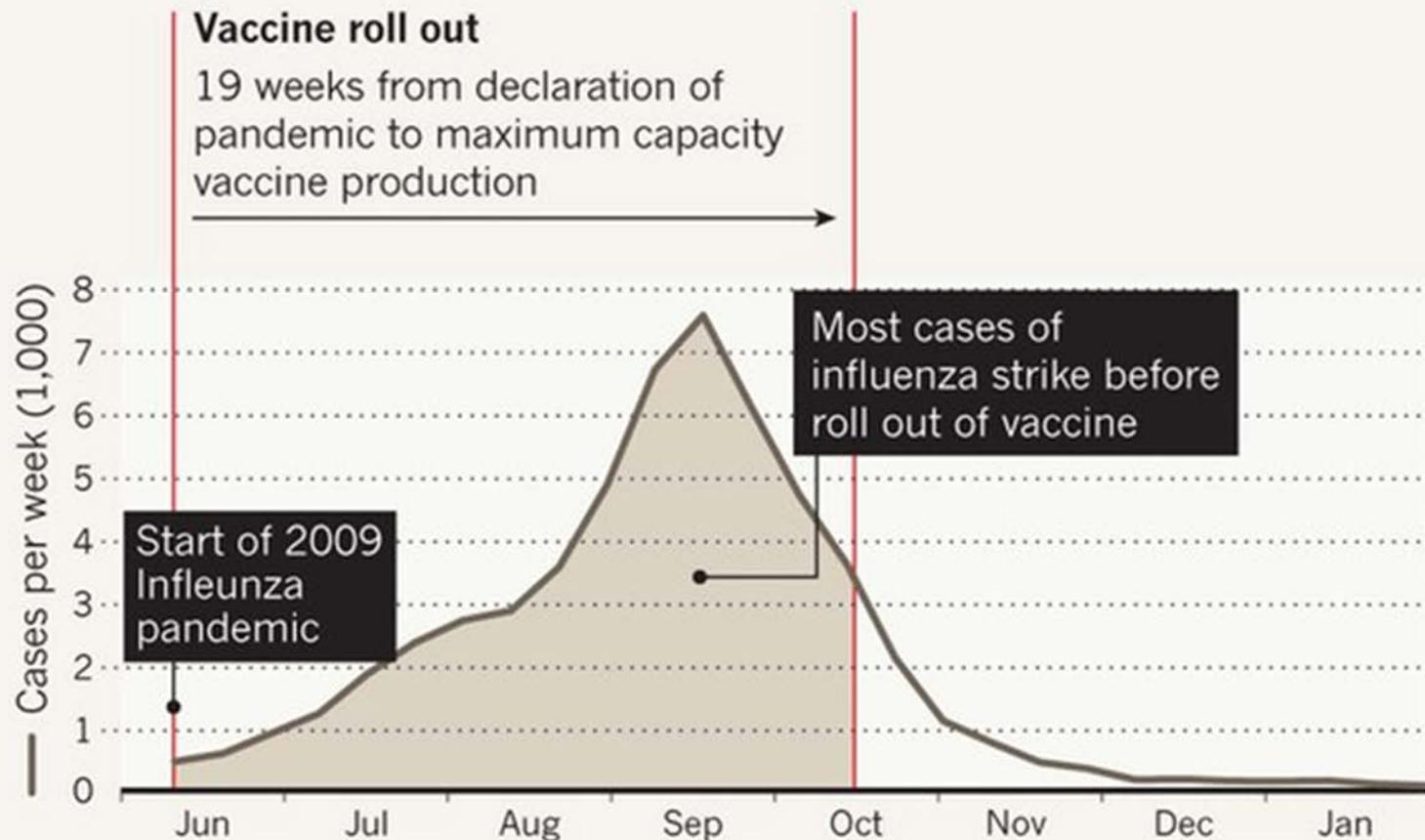




Are we ready to mitigate the impact of the next pandemic?

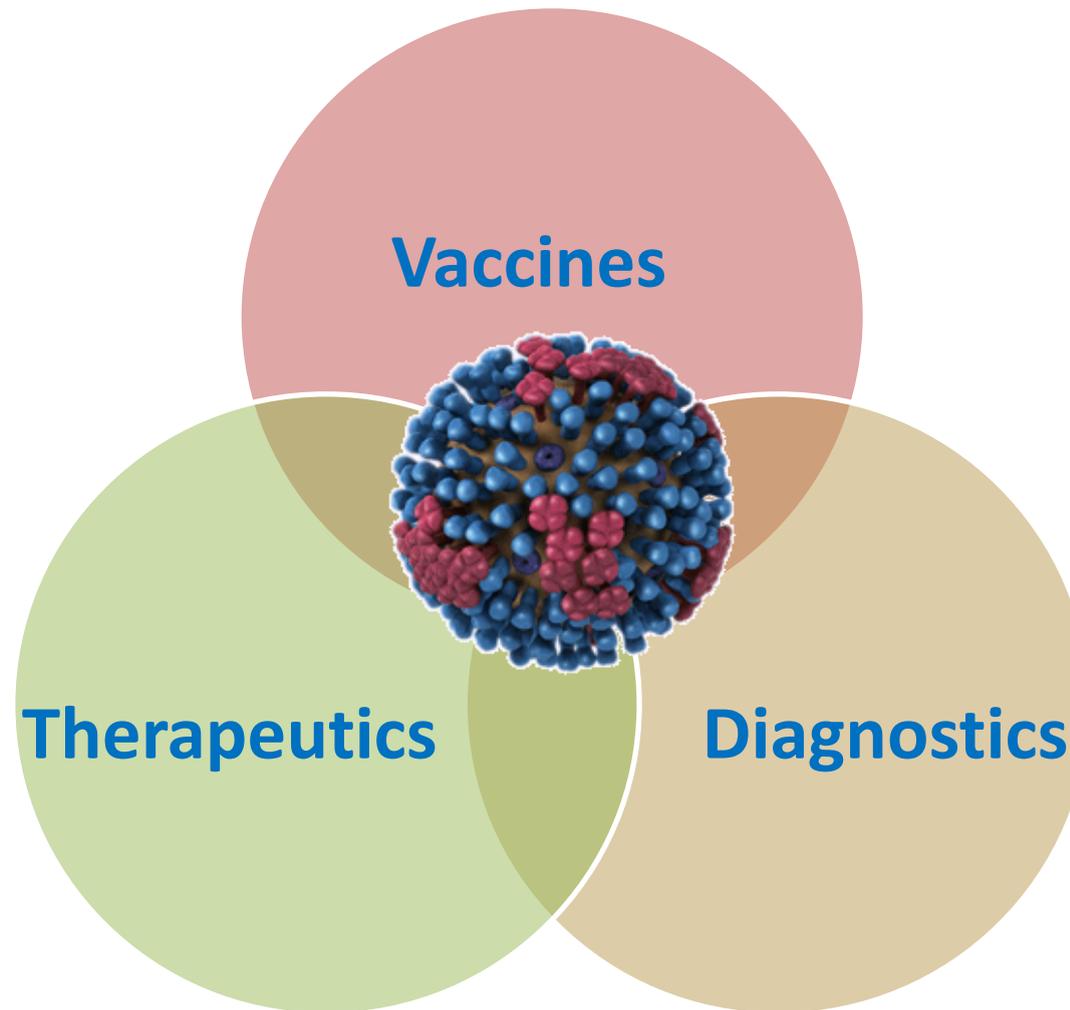
LATE TO THE PANDEMIC

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





Influenza and EID Strategy



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

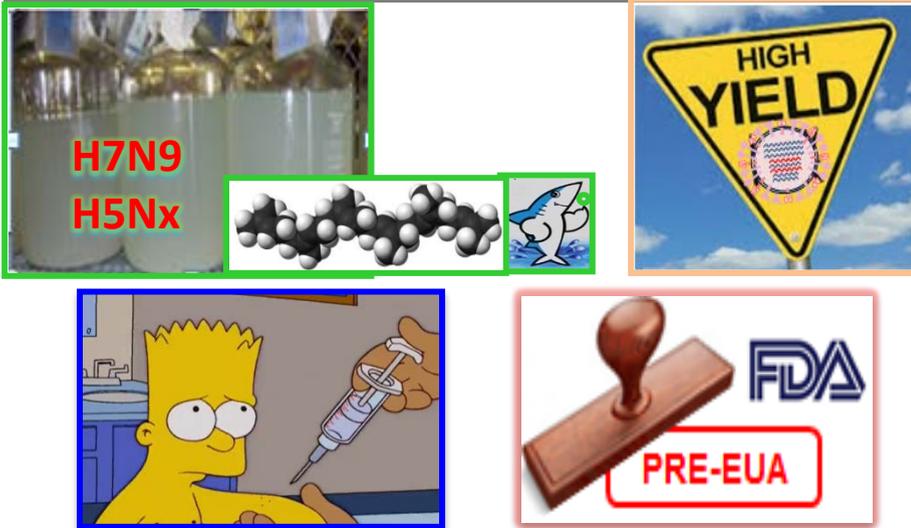


- Parenteral antiviral drug formulations
- Patients unable to take oral medications
 - Severely ill hospitalized patients.



Pandemic Influenza Stockpile and Infrastructure Strategy

Pandemic Vaccine Preparedness



- Risk-based vaccine preparedness; IRAT scoring, CVV, stockpile
- Clinical studies and analytical testing
 - Evidence-based decisions
 - Regulatory path

US-Based Manufacturing Facilities



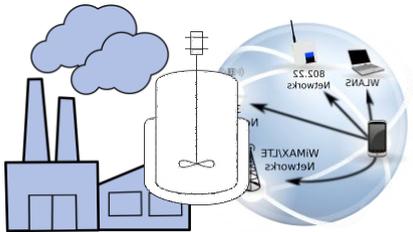
- Risk-mitigation:
 - Robust supply chains Resilience
 - New technology platforms
- Sustainability: Seasonal vaccine market sales support infrastructure capacity and readiness



Interagency Partnerships



Early detection & rapid virus seed production



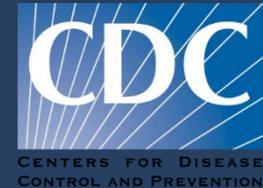
Manufacturing improvement



Potency reagent availability



Vaccine distribution and use



**Risk
Management**





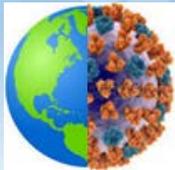
Pandemic Influenza Gaps

01

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

02



FDA
APPROVED



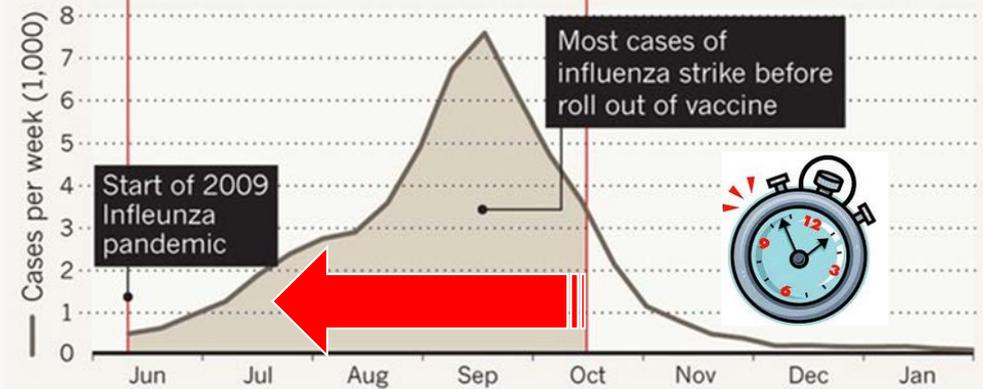
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04

Vaccine roll out

19 weeks from declaration of pandemic to maximum capacity vaccine production





End to End Strategy

Target Product Profile (TPP)

Manufacturing 1 Mfg 2 Mfg 3

Discovery R&D

Preclinical

P1 Clinical

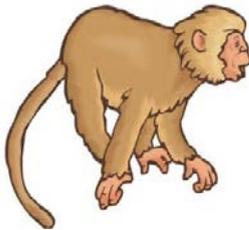
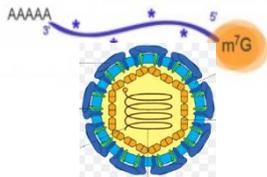
P2

P3

FDA Licensure

Recommendations

Stability Effectiveness

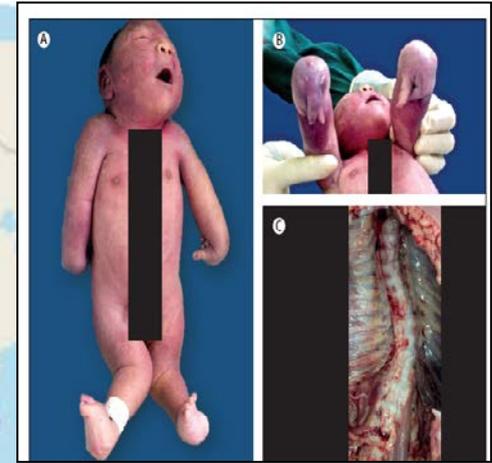
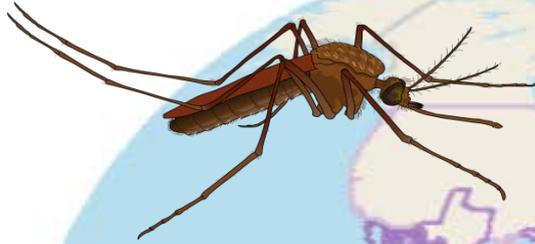


Alignment to Pandemic Influenza Gaps





Unpredictable New Threats: Zika



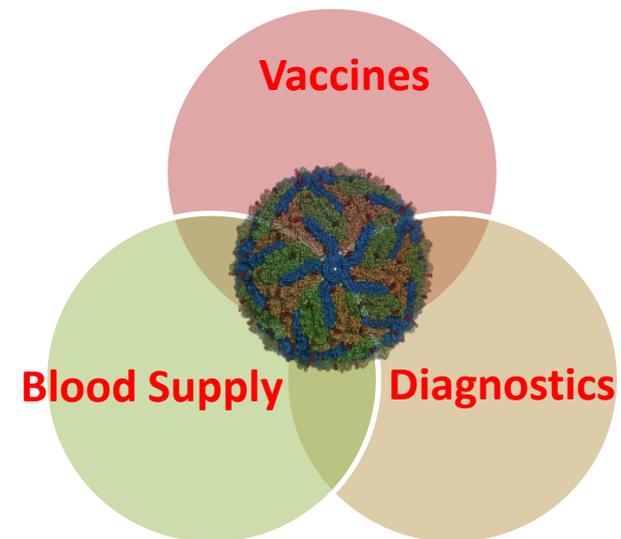
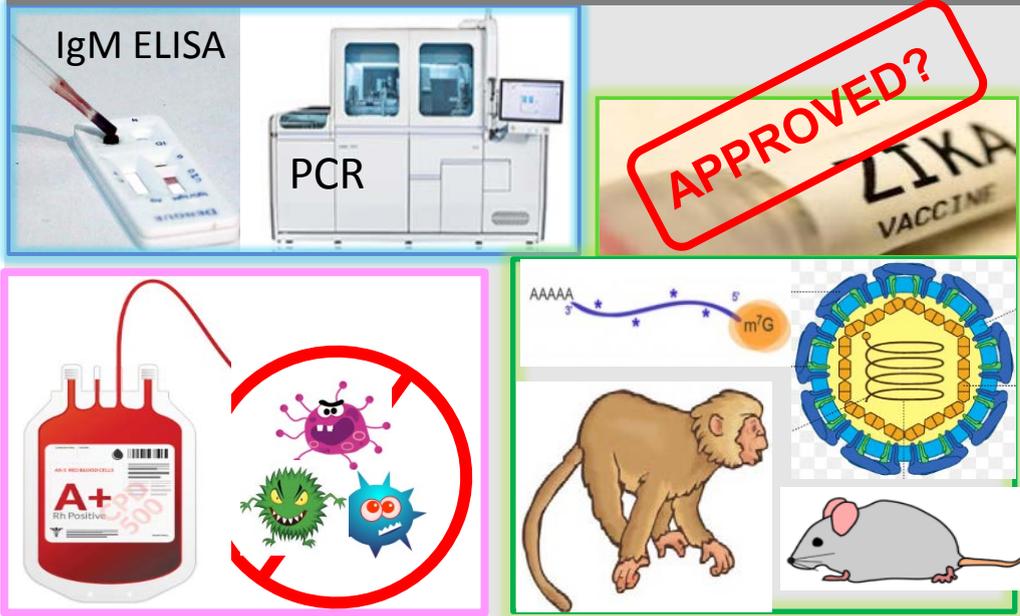
Until EIDs can be anticipated or avoided, future outbreaks will have to be managed with the classic approach to control — surveillance, rapid detection and rigorous efforts to **treat, control, and prevent infection.**

<https://wwwnc.cdc.gov/travel/page/world-map-areas-with-zika>



Zika Virus Response Investments

Zika Virus Response



Diagnostic tests

- Laboratory and POC: support medical interventions

Blood Supply

- Safe blood supply by screening and pathogen reduction

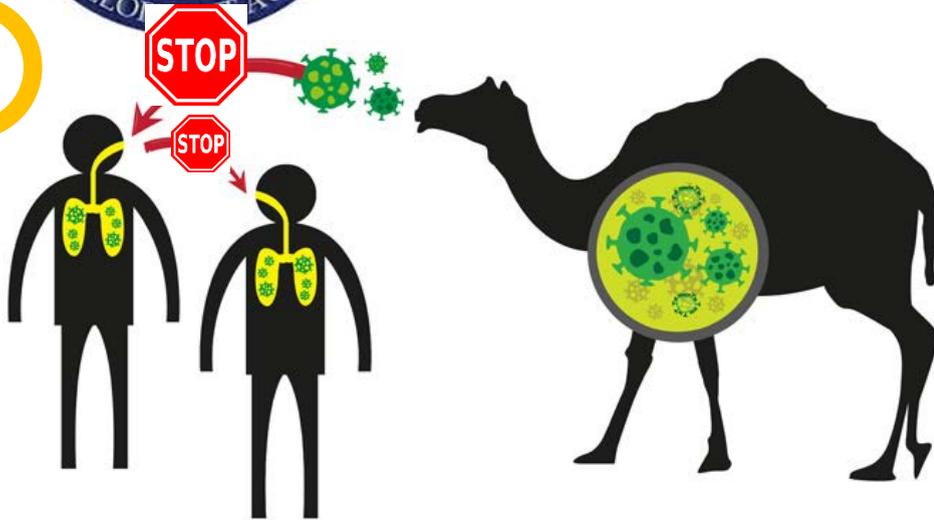
Vaccine Development

- Robust and diversified vaccine development pipeline

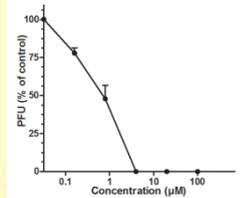
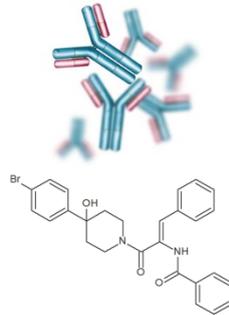
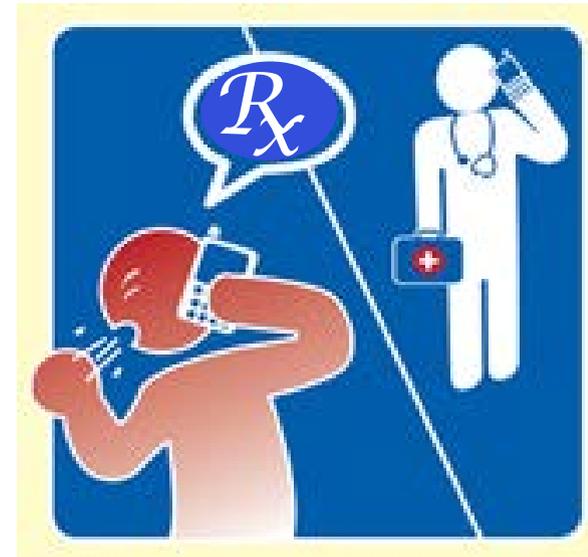


EID Preparedness Gaps: From Reactive to Proactive

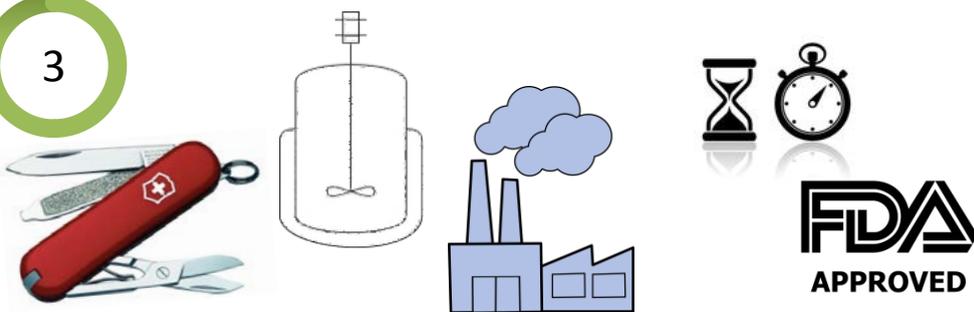
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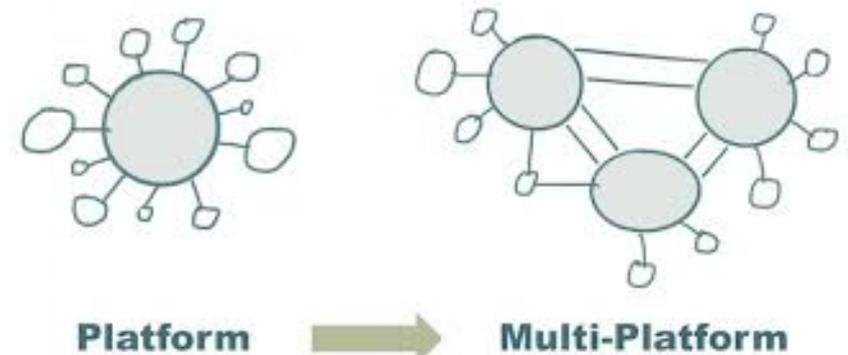
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Industry Partnerships





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!!

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