The American Recovery and Reinvestment Act of 2009 (ARRA)

NIAID Plans for ARRA Funds

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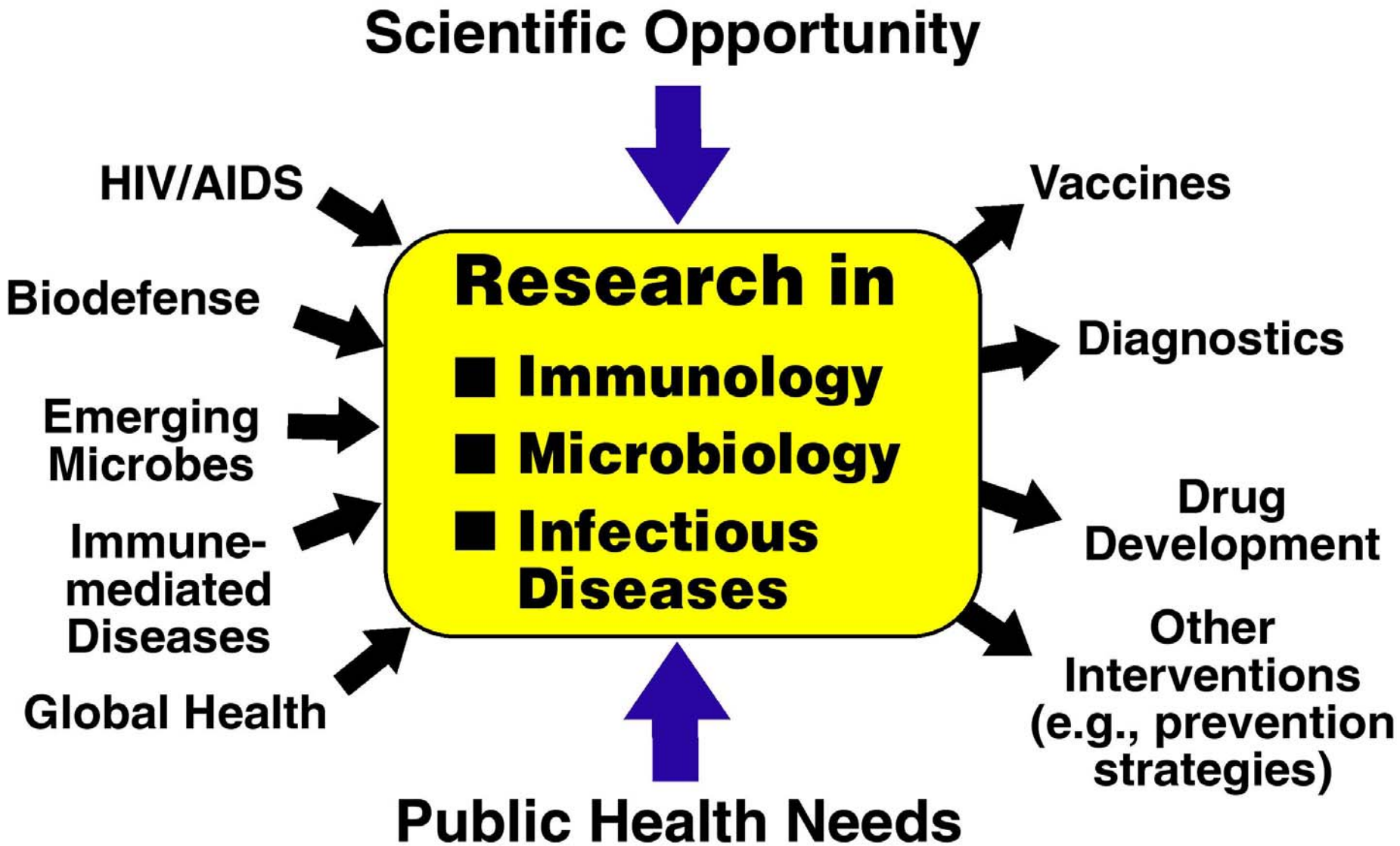
National Institutes of Health

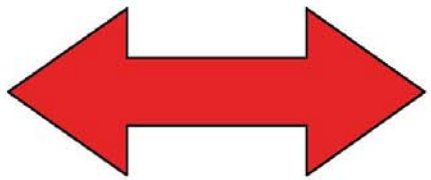
June 1, 2009

National Institute of Allergy and Infectious Diseases (NIAID)
National Institutes of Health (NIH)

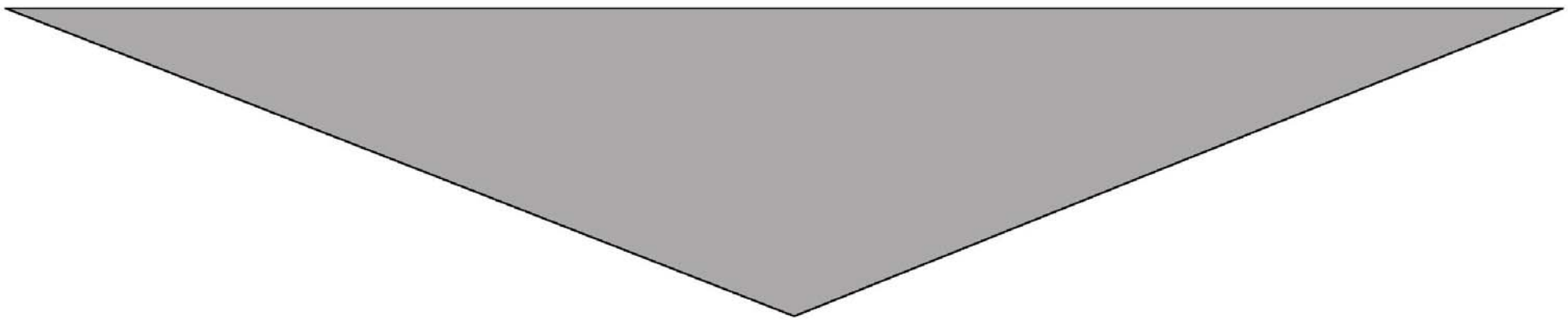


NIAID Research: A Dual Mandate

Maintain and "grow" a robust basic and applied research portfolio in microbiology, infectious diseases, immunology and immune-mediated diseases



Respond rapidly to new and emerging disease threats



New/Improved Interventions

American Recovery and Reinvestment Act of 2009 (ARRA): Funding Goals

- Stimulate the economy
- Create and preserve jobs
- Advance biomedical research

NIH Plans for ARRA Funds

- $10.4B to be spent over two years (FY 2009/FY 2010)
- NIH will distribute among 27 ICs/Offices
  - $7.4B - ICs for scientific research priorities
  - $800M - NIH Office of the Director (includes $200M for Challenge Grants)
  - $1.0B - NCRR for extramural construction, repairs, and alterations
  - $300M - NCRR for shared instrumentation and other capital equipment
  - $500M - NIH buildings and facilities
  - $400M - Comparative Effectiveness Research

NIAID Plans for ARRA Funds

- NIAID allocation of ARRA Funds: $1.11B
- Support unfunded RPGs from FYs 2008-2009
- 1-2 years of funding
- R01 or Bridge Award
  - 12th to 25th percentile
- R21/R03
  - 200 priority score
- Participation in NIH-wide ARRA programs
- NIAID Signature Projects

NIAID Participation in NIH-wide ARRA Programs

- Challenge Grants
  - Explore the earliest events in HIV infection
  - Develop diagnostics and drugs for MDR/XDR TB
  - Develop drugs for neglected tropical diseases
  - Explore novel methods in mucosal immunology
  - Characterize human immune response to infection/immunization
- Grand Opportunities ("GO" Grants)
  - Develop medical countermeasures for radiological/nuclear threats

NIAID Signature Projects

- Stopping the HIV Pandemic
- Protection of Human Health by Immunology and Vaccines
- Biodefense and Emerging Infectious Diseases:
  - Expanding Research Capacity through the Regional Centers of Excellence
  - Developing Partnerships to Translate Research into Products

NIAID Signature Projects

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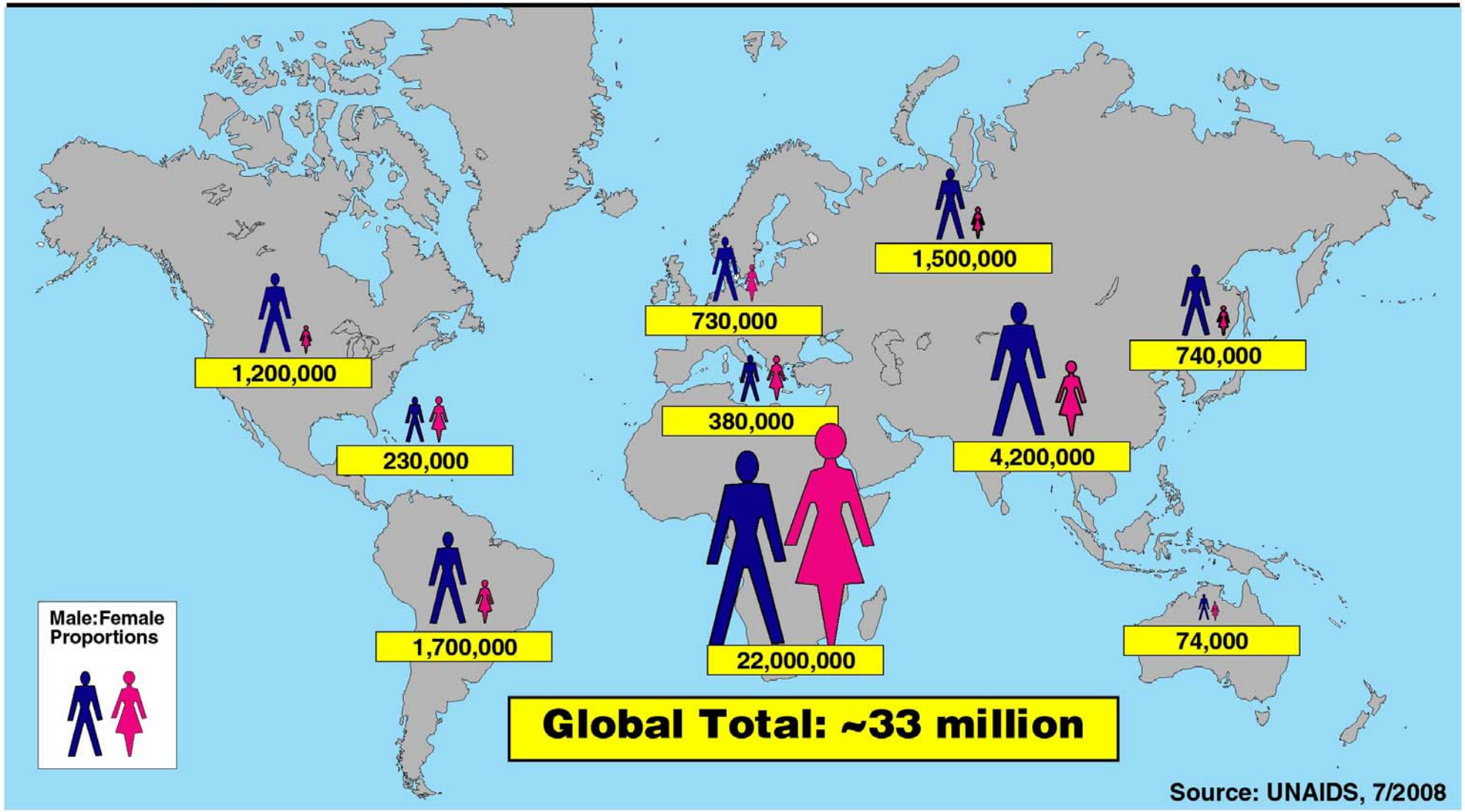
Adults and Children Estimated to be Living with HIV, 2007

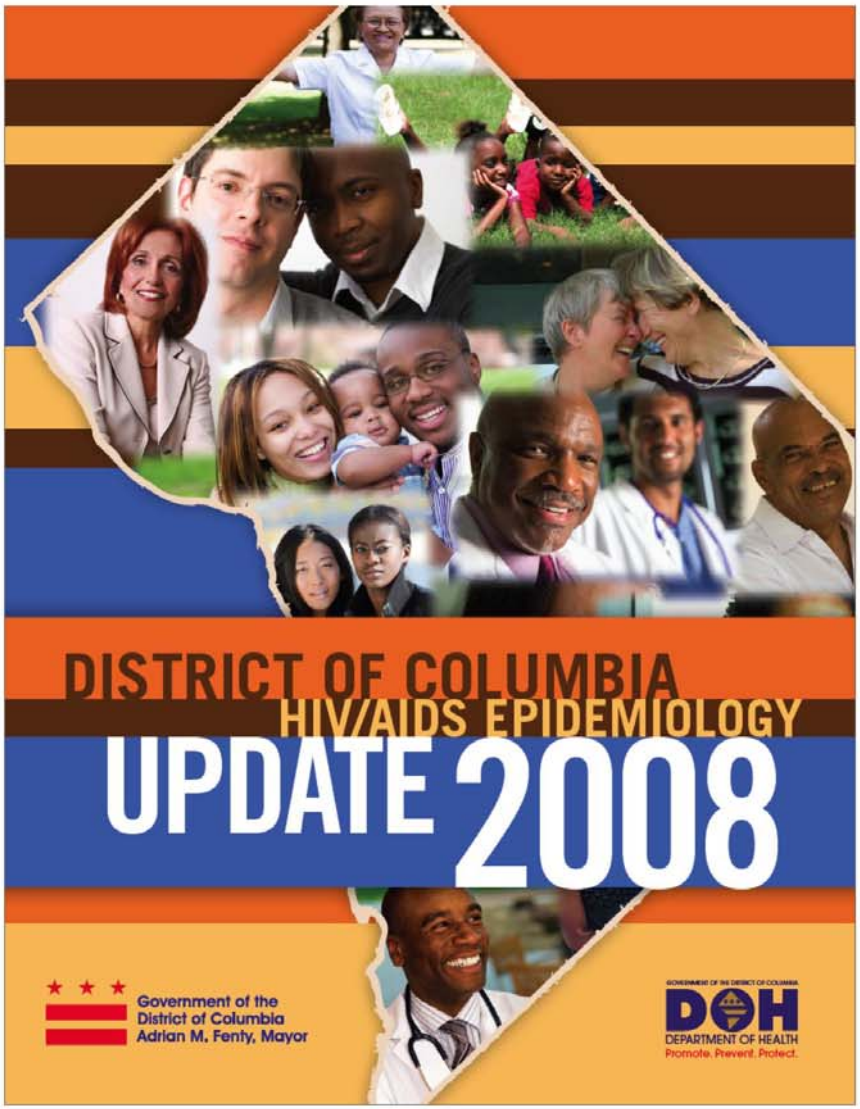


HIV/AIDS in the United States

- 562,793 cumulative deaths
- ~1.1 million living with HIV
  - 21% unaware of their infection
- ~56,300 new infections in 2006
  - 53% male-to-male sexual contact, 31% heterosexual contact
  - 45% blacks, 35% whites, 17% Hispanics
  - incidence rate among blacks 7 times higher than whites

Source: CDC, Includes 50 states and District of Columbia

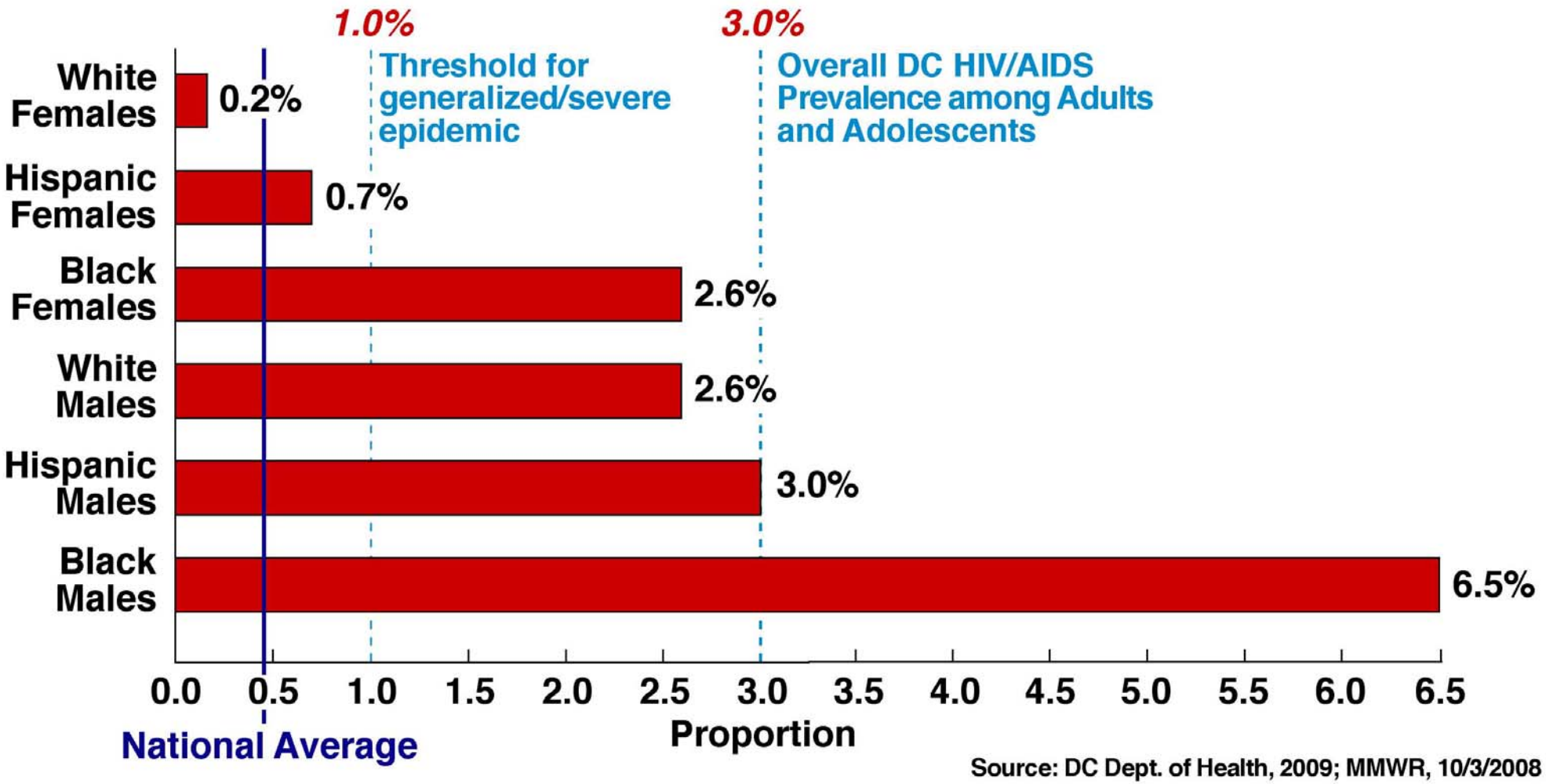
HIV/AIDS in Washington, DC



- ~3% of adults and adolescents in District living with HIV/AIDS, end-2007
- An underestimate, as between 1/3 and 1/2 of DC residents may be unaware of their HIV infection status

Report released 3/16/2009

Proportion of Washington, D.C. Adults and Adolescents Living with HIV/AIDS by Race and Sex, End-2007



Source: DC Dept. of Health, 2009; MMWR, 10/3/2008

The Washington Post

April 16, 2009

A Policy Cocktail for Fighting HIV

By Anthony S. Fauci

Three-pronged approach to curbing HIV/AIDS pandemic:

- Pre-exposure prophylaxis of high-risk individuals with antiretroviral therapy (PrEP)
- Universal, voluntary testing/immediate antiretroviral therapy ("test and treat" approach)
- Cure/functional cure research

The Promise of Pre-Exposure Prophylaxis (PrEP)

- Well-established tool for preventing other infectious diseases, e.g. malaria
- ARVs proven to prevent mother-to-child HIV transmission, and as post-exposure prophylaxis
- Generally positive NHP data with tenofovir +/- emtricitabine, drugs with long-half lives, good safety profiles, high genetic barrier to resistance (tenofovir)
- Promise of good acceptability -- PrEP inhibits HIV without requiring change in sexual habits

Voluntary "Test and Treat" Concept

THE LANCET

Available online November 27, 2008

Universal Voluntary HIV Testing with Immediate Antiretroviral Therapy as a Strategy for Elimination of HIV Transmission: a Mathematical Model

RM Granich et al.

- Model indicates that universal and annual voluntary HIV testing followed by immediate antiretroviral therapy treatment (irrespective of clinical stage or CD4 count) could reduce new HIV cases by 95% within 10 years
- Concerns: feasibility, protection of individual rights, drug resistance, toxicity, financing

The Main Obstacles to a Cure for HIV Disease

- HIV hides from the immune system
- HIV forms a latent reservoir protected from drug therapy

NIAID Signature Projects

- Stopping the HIV Pandemic
- Protection of Human Health by Immunology and Vaccines
- Biodefense and Emerging Infectious Diseases:
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Protection of Human Health by Immunology and Vaccines

- New collaborative consortium of Human Immunology Research Centers
- Research to characterize the protective immune response in humans using modern tools (e.g., genomics and proteomics) and other modern technologies, including systems biology approaches

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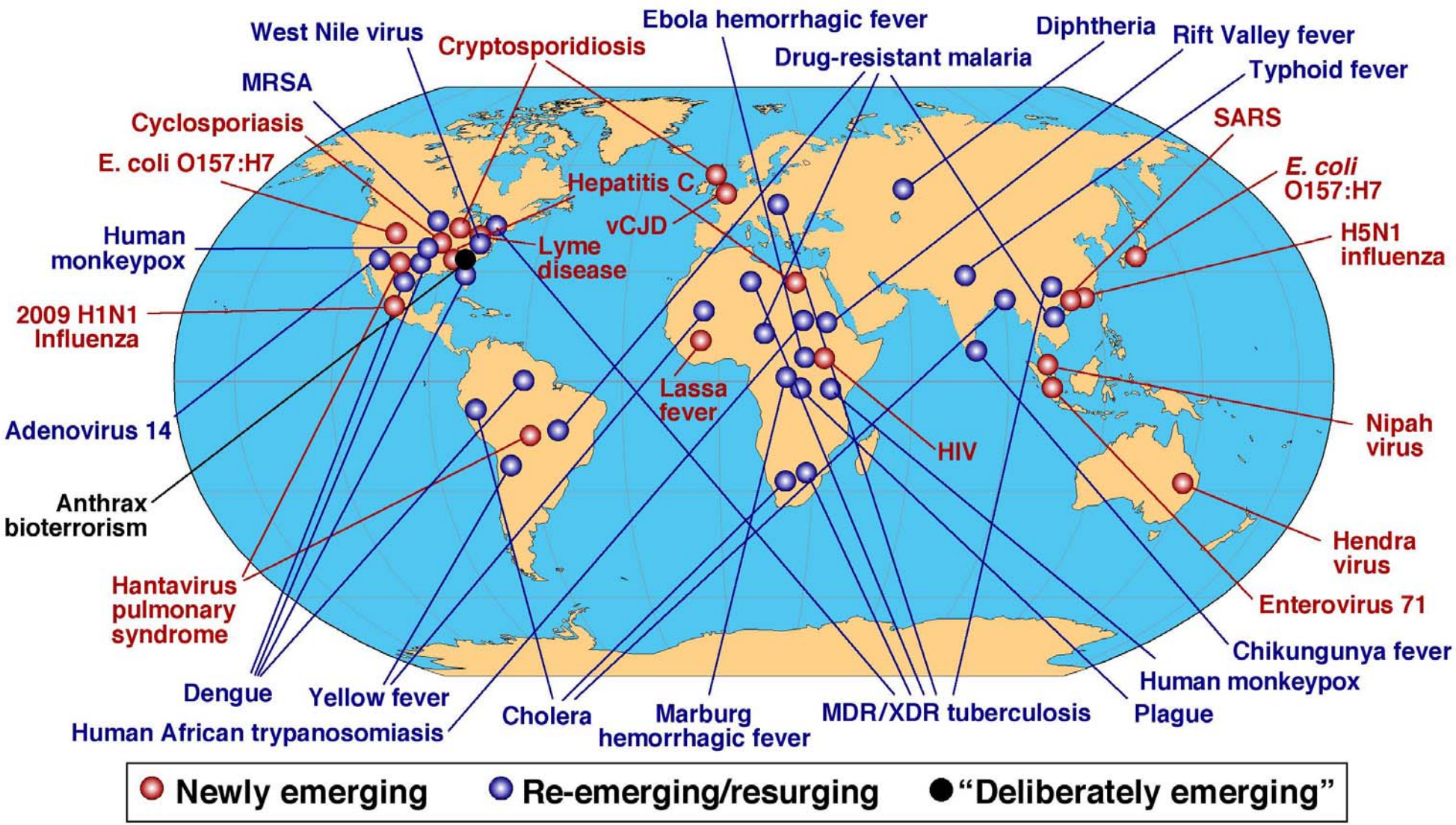
Global Examples of Emerging and Re-Emerging Infectious Diseases



Examples of Human Disease Outbreaks, 2006-2009

- H5N1 avian influenza
- Chikungunya fever
- Dengue
- *E. coli* O157:H7
- *Fusarium* keratitis
- Poliomyelitis
- Rift Valley fever
- XDR-TB
- Ebola hemorrhagic fever
- Marburg hemorrhagic fever
- Methicillin-resistant *Staphylococcus aureus* (MRSA)
- Adenovirus Serotype 14
- Yellow fever
- *Salmonella*
- 2009 H1N1 influenza

NIAID Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases

PI – Dr. Samuel Miller
University of Washington
Seattle, WA

PI – Dr. John Belisle
Colorado State University
Fort Collins, CO

PI – Dr. Olaf Schneewind
University of Chicago
Chicago, IL

PI – Dr. Dennis Kasper
Harvard Medical School
Boston, MA

PI – Dr. W. Ian Lipkin
Columbia University
New York, NY

PI – Dr. Jay A. Nelson
Oregon Health & Science
University
Portland, Oregon

PI – Dr. Myron Levine
University of Maryland
Baltimore, MD

PI – Dr. Alan G. Barbour
University of California
Irvine, CA

PI – Dr. David Walker
University of Texas Medical Branch
Galveston, TX

PI – Dr. Samuel Stanley
Washington University
St. Louis, MO

PI - Dr. Fred Sparling
University of North Carolina
Chapel Hill, NC

Biodefense and Emerging Infectious Diseases: Developing Partnerships to Translate Research into New Products

- Expansion of NIAID initiative to support collaborative projects with academia and industry to advance promising products, including vaccines, therapeutics, and medical diagnostics, e.g.:
  - new tools for influenza diagnosis, treatment and prevention
  - a vaccine that protects against multiple viral hemorrhagic fever viruses

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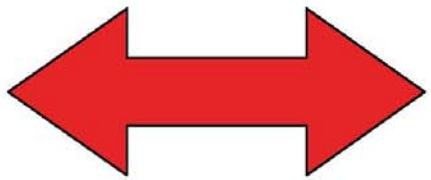

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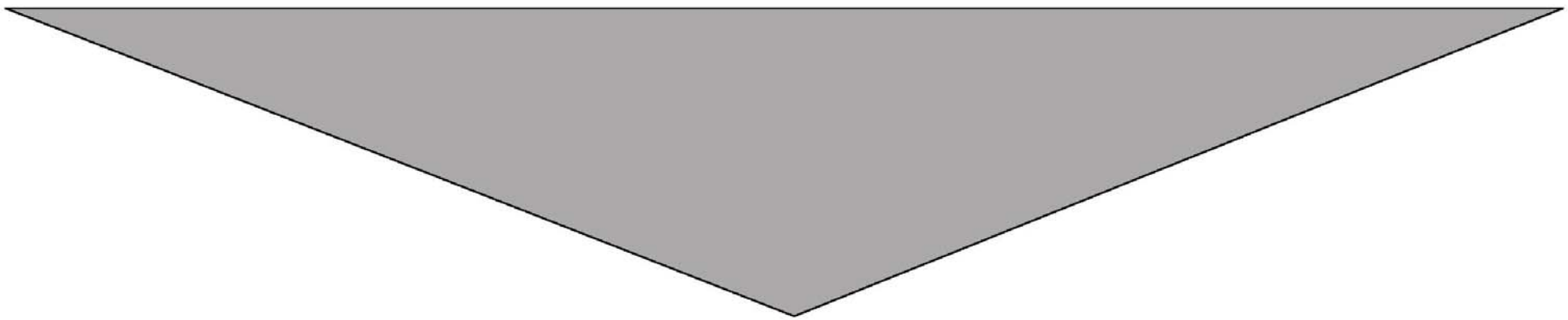


New/Improved Interventions

The New York Times

April 24, 2009

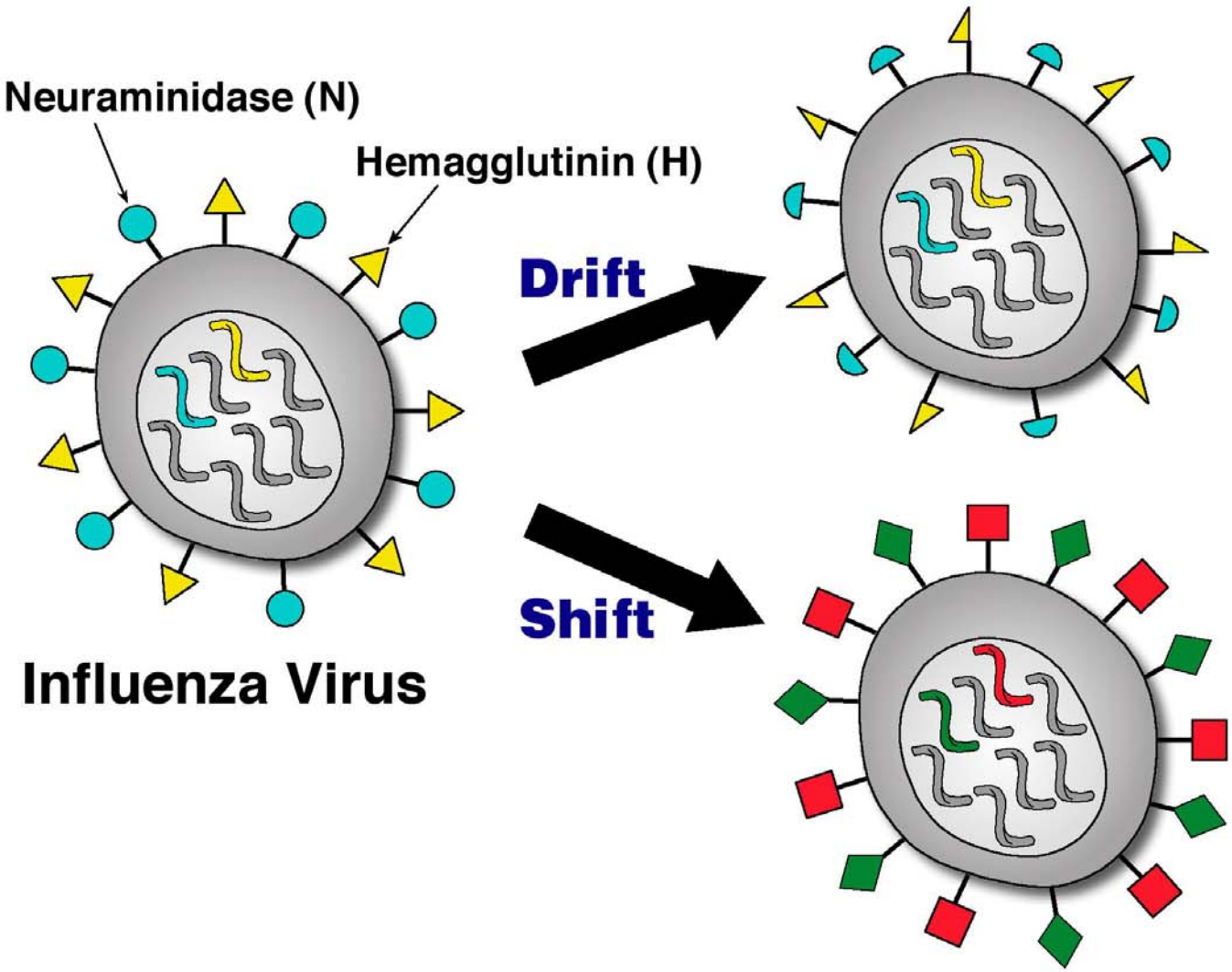
Unusual Strain of Swine Flu Is Found in People in 2 States

Associated Press

April 26, 2009

Swine Flu Empties Mexico City's Churches, Streets

Seasonal vs. Pandemic Influenza



Seasonal Influenza

- Predictable annual occurrence
- Residual immunity in population

Pandemic Influenza

- Unpredictable rare occurrence
- "Naïve" population

Influenza Pandemics in the 20th Century

1918	H1N1	"Spanish Flu"	>50 million deaths
1957	H2N2	"Asian Flu"	1-2 million deaths
1968	H3N2	"Hong Kong Flu"	700,000 deaths

Influenza A (H1N1): Confirmed Cases in the United States, as of May 29, 2009

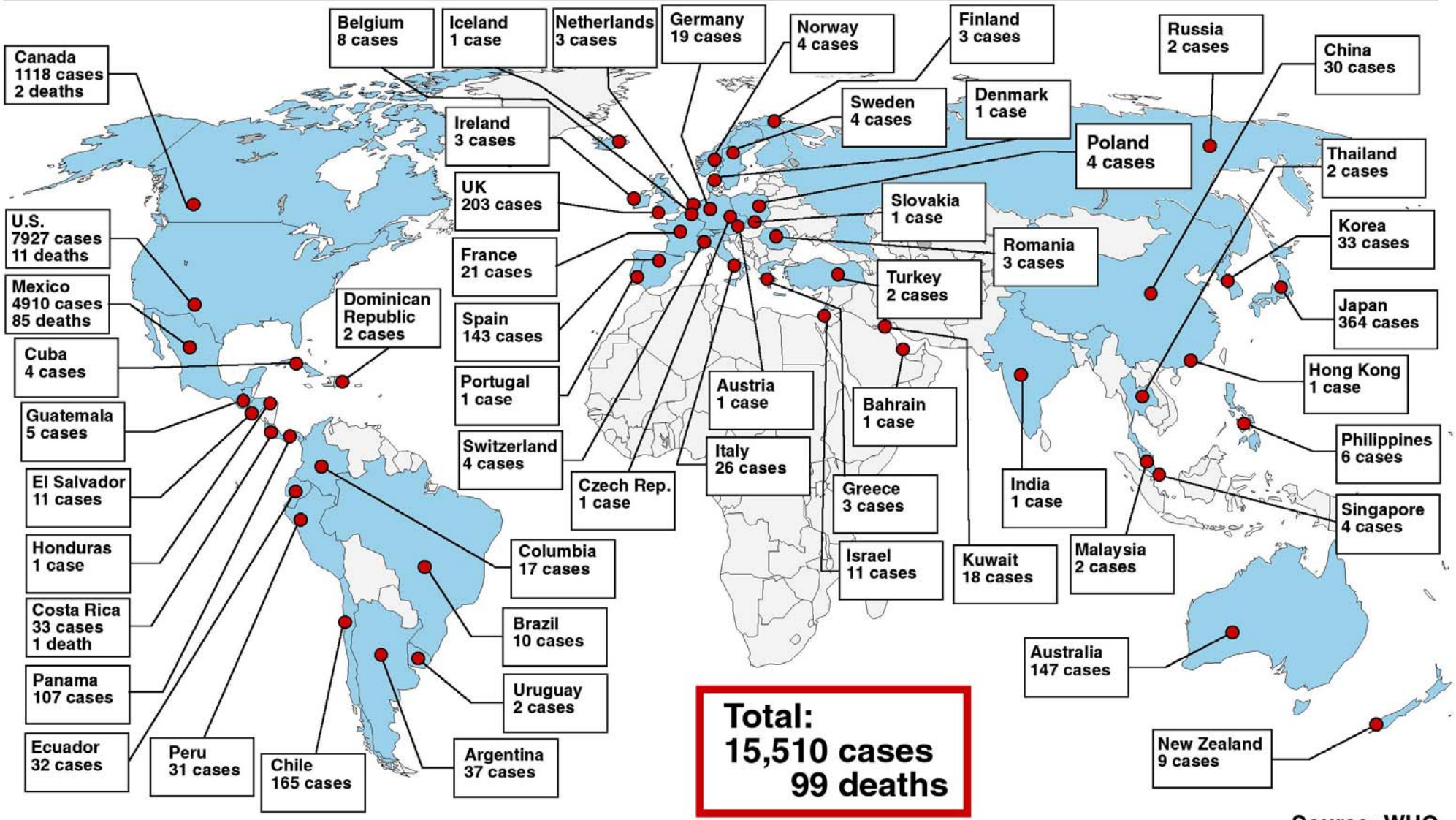
Total:

8,975 confirmed and probable cases in 49 states

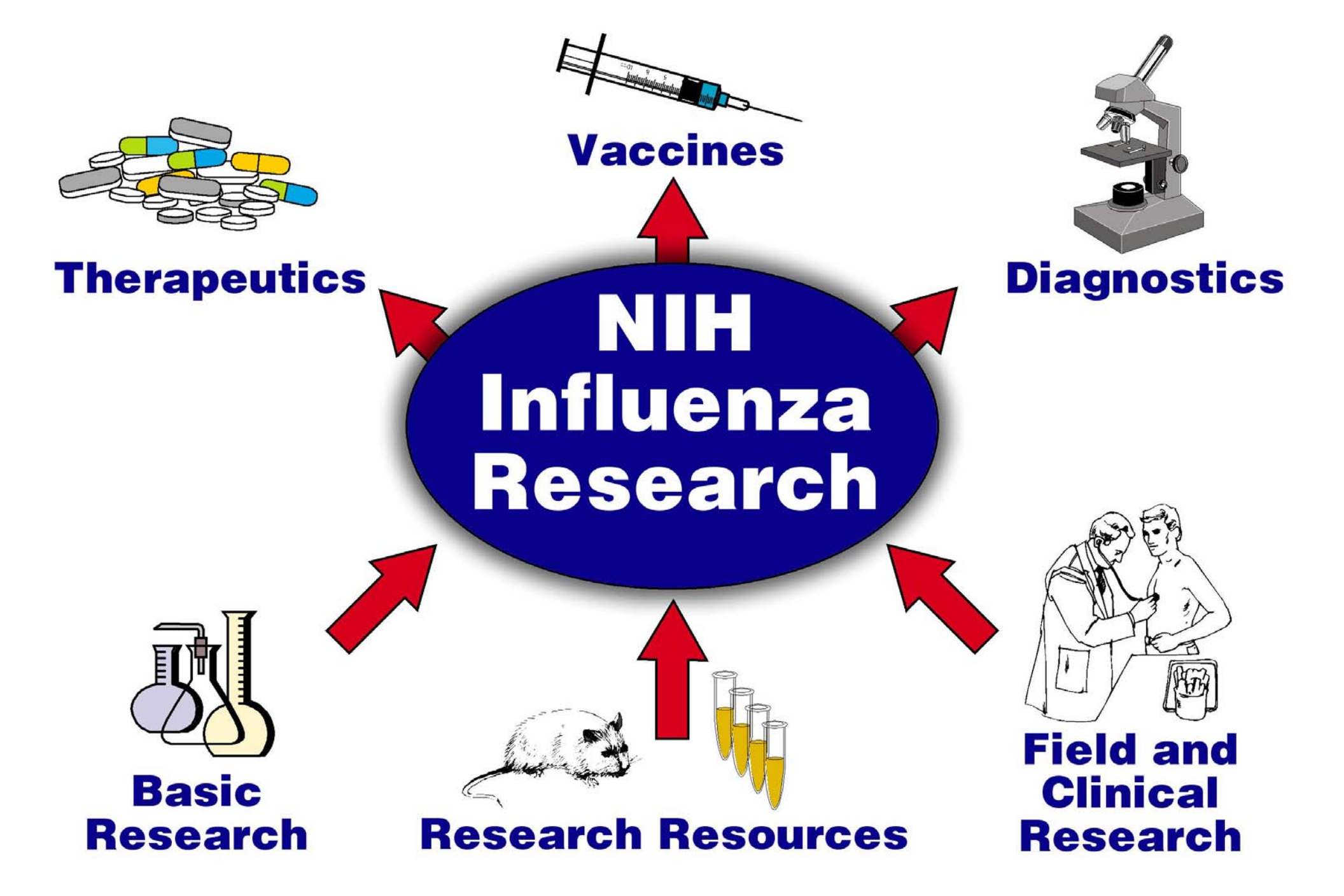
15 deaths in 7 states

Source: Centers for Disease Control and Prevention (CDC)

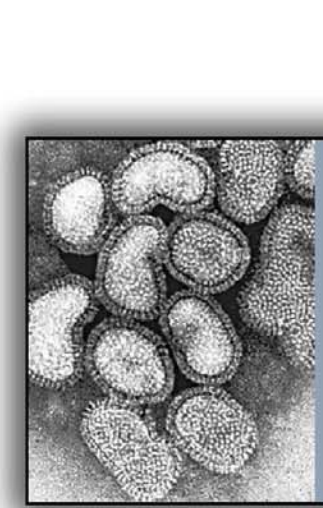
Global Influenza A (H1N1) Laboratory-Confirmed Cases and Deaths, as of May 29, 2009



Source: WHO


Vaccines
Therapeutics
Diagnostics
NIH Influenza Research
Basic Research
Research Resources
Field and Clinical Research

H1N1 Influenza Vaccine Development: A Collaborative Process



Isolation and Characterization

Seed Virus

Pilot Lots

Scale-up for Commercial Production

Clinical Evaluation (e.g. in VTEUs)

Commercial production

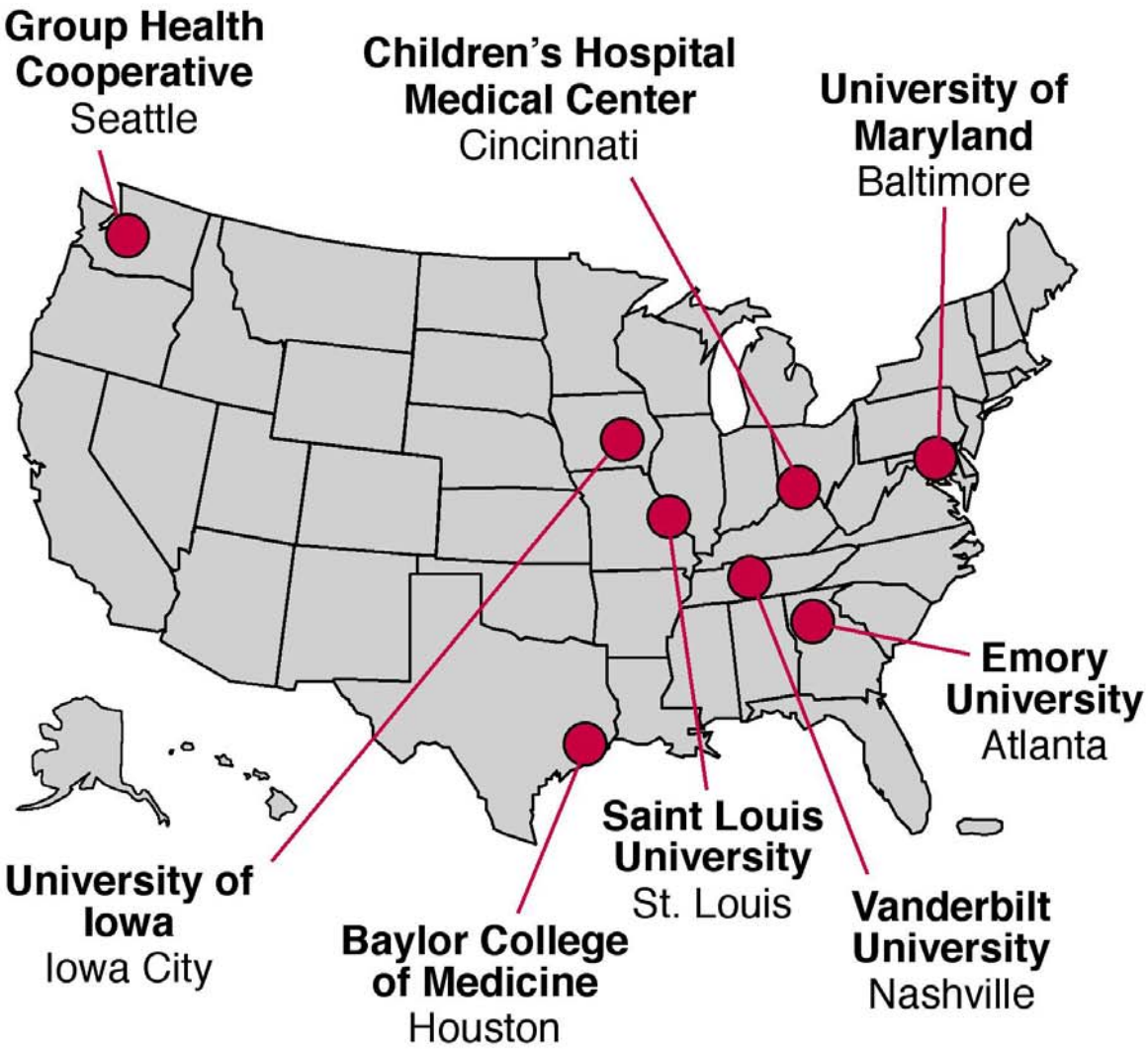
Formulation, Filling and Delivery

Influenza Virus

Where we are now

New Vaccine

NIAID's Network of Vaccine and Treatment Evaluation Units (VTEUs)



- Established in 1962
- >160 Phase I, II, and III clinical trials since 1995
- Trials of
  - Seasonal vaccines
  - Pre-pandemic vaccines
  - Antivirals

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