Update on COVID-19 for NIAID HIV/AIDS Community Advisory Boards

Anthony S. Fauci, M.D.
Director
National Institute of Allergy and Infectious Diseases
National Institutes of Health
June 10, 2020

Science
January 3, 2020

Novel Human Virus? Pneumonia Cases Linked to Seafood Market in China Stir Concern

By Dennis Normile

The Washington Post
January 3, 2020

Washington Post: China Identifies New Strain of Coronavirus as Source of Pneumonia Outbreak
Health officials run thermal scans on passengers arriving from Wuhan, China, at Bangkok’s Suvarnabhumi Airport on Wednesday.

By Gerry Shih and Lena H. Sun

The Washington Post
January 21, 2020

Travelers at 3 U.S. Airports to Be Screened for New, Potentially Deadly Chinese Virus
U.S. Screenings for the Coronavirus Expanded to Airports in Atlanta and Chicago

First Travel-related Case of 2019 Novel Coronavirus Detected in United States

Centers for Disease Control and Prevention
Press Release
January 21, 2020

COVID-19 Globally: 7.1 Million Cases in 213 Countries and Territories

Reported COVID-19 Cases and Deaths in the United States

Sources: NY Times; Worldometer. Data as of 6/10/2020, 6:04 am

Reported cases: 2,007,531
Reported deaths: 112,471
NIH Strategic Plan for COVID-19 Research

April 13, 2020

- Improve fundamental knowledge of SARS-CoV-2 and COVID-19 disease
- Develop diagnostics and assays
- Characterize and test therapeutics
- Develop safe and effective vaccines

Basic Research, Pathogenesis, Animal Models, Epidemiology

- Basic research on viral biology, life cycle, pathogenesis, and transmission
- Large-scale natural history, serosurveillance and immunophenotyping studies
  - Identify predictors of disease progression
  - Characterize disease progression and antibody response
  - Characterize transmission, particularly the role of asymptomatic transmission and children
- Set up animal model testing for therapeutics and vaccines
- Source research reagents and make them available to the research community

NIH Mobilizes National Innovation Initiative for COVID-19 Diagnostics

- NIH Rapid Acceleration of Diagnostics (RADx) Initiative for COVID-19
- Award up to $500 million to support development of COVID-19 diagnostics

NIH Strategic Plan for COVID-19 Research

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### Investigational Therapeutics for COVID-19
- Remdesivir
- Other broad-spectrum antivirals
- Convalescent plasma/hyperimmune immunoglobulin
- Repurposed drugs, e.g. hydroxychloroquine, lopinavir/ritonavir
- Host modifiers/immune-based therapies
- Anti-SARS-CoV-2 monoclonal antibodies
- Others

### NIAID Adaptive Randomized, Controlled Treatment Trial for COVID-19

1.063 enrollees at trial close, 4/19/2020

### The New England Journal of Medicine

J.H. Beigel, H.C. Lane et al. for the ACTT-1 Study Group Members

- Patients who received remdesivir had a 32% faster time to recovery than those who received placebo (p<0.001)
- Results also suggested a survival benefit
- N=1,063 patients from 10 countries in U.S., Europe, Asia

### NIH News Release

**NIH Clinical Trial Testing Antiviral Remdesivir Plus Anti-Inflammatory Drug Baricitinib for COVID-19 Begins**

### NIH News Release

**Expert U.S. Panel Develops NIH Treatment Guidelines for COVID-19**

“Living document” expected to be updated often as new clinical data accrue
- Covid19treatmentguidelines.nih.gov

### NIAID Strategic Plan for COVID-19 Research

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Vaccine Platform Technologies

Genetic immunization (DNA and RNA vaccines)
- Inovio (DNA) – phase 1 ongoing
- Moderna (mRNA) – phase 1 ongoing
- Pfizer (mRNA) – phase 1 ongoing

Viral vector
- Janssen (Ad26) – phase 1 TBD
- Merck (VSV) – phase 1 TBD
- Univ Oxford (ChAdOx1) – phase 1/2 ongoing

Recombinant protein
- Sanofi – phase 1 TBD
- Novavax – phase 1 ongoing

BARDA-Supported COVID-19 Vaccine Candidates

mRNA
- Moderna
- AstraZeneca
- Janssen
- Sanofi
- Merck

Replication Incompetent Adenovirus (ChAdOx1)
Replication Incompetent Adenovirus (Ad26)
Adjuvanted protein subunit
Replication-competent Vesicular Stomatitis Vector (VSV)

BARDA-Supported COVID-19 Vaccine Candidates

mRNA Vaccine Approach

mRNA for spike protein of coronavirus
 Inject into muscle cells
 Muscle cells read the mRNA and make spike protein

NIH Vaccine Research Center: Vaccines for Emerging Diseases

NIH Clinical Trial of Investigational Vaccine for COVID-19 Begins
Study Enrolling Seattle-Based Healthy Adult Volunteers

- Trial of vaccine candidate mRNA-1273 will enroll 45 healthy adult volunteers ages 18 to 55 years over approximately 6 weeks

Sequence Selection to 1st Human Injection

- SARS
  - April 14, 2003
  - 8 months

- H5N1 Influenza
  - Feb. 11, 2006
  - 11 months

- H1N1 Influenza
  - April 27, 2009
  - 3 months

- Zika
  - April 24, 2016
  - 3.25 months

- Coronavirus
  - Jan. 13, 2020
  - 60 days
The New York Times
May 18, 2020

Moderna Coronavirus Vaccine Trial Shows Promising Early Results

Data from 8 healthy volunteers: vaccine safe and provoked a strong immune response. It is on an accelerated timetable to begin larger human trials soon.

Science
Published online May 11, 2020

A Strategic Approach to COVID-19 Vaccine R&D
L Corey, JR Mascola, AS Fauci & FS Collins

- Unprecedented collaboration and resources will be required to research and develop safe and effective vaccines for COVID-19 that can be manufactured and delivered in the scale of billions of doses to people globally.

Health and Human Services
Press Release
May 15, 2020

Trump Administration Announces Framework and Leadership for 'Operation Warp Speed'

- National program to accelerate development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics
- Public-private partnership between components of HHS (CDC, FDA, NIH, BARDA); Department of Defense; other federal agencies; and private firms
- Chief Scientific Advisor: Moncef Slaoui, Ph.D.
- Chief Operating Officer: General Gustave F. Perna

National Institutes of Health
Friday, April 17, 2020

NIH to Launch Public-Private Partnership to Speed COVID-19 Vaccine and Treatment Options

- The Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership will:
  - Standardize and share preclinical evaluation methods in an open forum
  - Prioritize and accelerate clinical evaluation of therapeutic candidates with near-term potential
  - Maximize clinical trial capacity and effectiveness
  - Advance vaccine development

The NIAID CoV Prevention Network (CoVPN)

- The CoVPN combines expertise from 3 networks supported by DAIDS and DMID and their global partners
  - HVTN, HPTN and Infectious Diseases Clinical Research Consortium (IDCRC)
  - Serve as focal point for USG-sponsored trials of COVID-19 vaccines and mAbs for preventing acquisition of SARS-CoV-2 and reduce medical and economic consequences of COVID-19
- Networks will continue priority projects in HIV prevention (HVTN and HPTN) and non-COVID vaccine work (IDCRC)

The NIAID CoV Prevention Network (CoVPN)

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<thead>
<tr>
<th>Candidate COVID-19 vaccines</th>
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<tr>
<td>Platform 1</td>
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<tr>
<td>Harmonized immunity assays</td>
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<tr>
<td>1) Defining COVID infection from vaccination</td>
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<tr>
<td>2) Quantitative immune responses to spike and spike epitopes</td>
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<td>3) T-cell responses</td>
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NIH/COVID Network-supported infrastructure

- Data and Safety Monitoring boards
- Between-trial statistical group for comparators of protection
COVID-19 and Persons with HIV (PWH)

- Unknown if PWH have an increased incidence of infection with SARS-CoV-2
- Large study testing PWH for SARS-CoV-2 found no difference in incidence related to CD4+ T cell count, viral load or antiretroviral drug regimen
- PWH with co-morbidities are more vulnerable to complications of COVID-19 similar to general population with co-morbidities
- Complications of COVID-19 occur at younger age in PWH compared to general population (HIV premature aging phenomenon)
- The same minority groups who have disproportionate incidence of HIV have a disproportionate incidence of severe COVID-19 disease

January 29: White House Coronavirus Task Force Announced

Chair: VP Mike Pence
Response Coordinator: Deborah Birx

- Jerome Adams
- Alex Azar
- Stephen Biegun
- Robert Blair
- Ben Carson
- Francis Collins
- Ken Cuccinelli
- Kelvin Droegemeier
- Thomas Engels
- Anthony Fauci
- Joe Grogan
- Derek Kan
- Larry Kudlow
- Chris Liddell
- Steven Mnuchin
- Robert O’Brien
- Sonny Perdue
- Matthew Pottsinger
- Robert Redfield
- Seema Verma
- Joel Szabo
- Robert Wilkie

Briefing President Trump on the COVID-19 (Coronavirus) Outbreak

Questions?