

COVID-19 Vaccines: Progress and Priorities

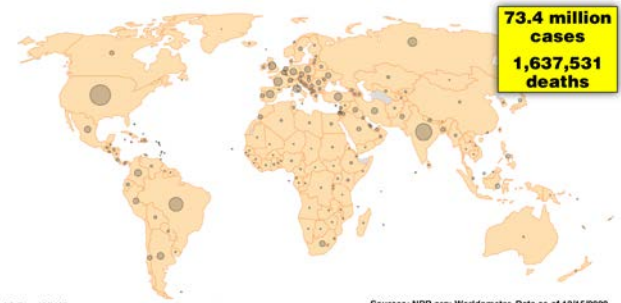


Anthony S. Fauci, M.D.
Director
National Institute of Allergy and
Infectious Diseases
National Institutes of Health
December 16, 2020



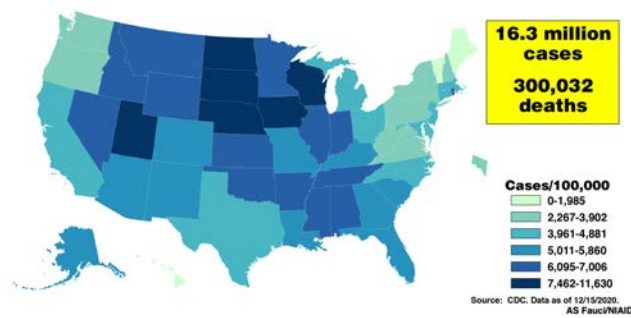
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COVID-19 Globally



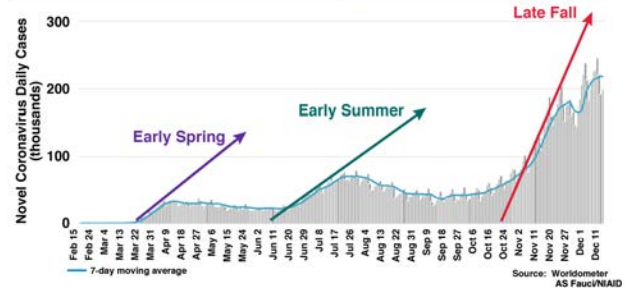
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COVID-19 in the United States



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Daily New COVID-19 Cases Reported in the United States - Slopes of 3 Surges



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JAMA
The Journal of the American Medical Association

May 11, 2020

Viewpoint COVID-19 and Racial/Ethnic Disparities

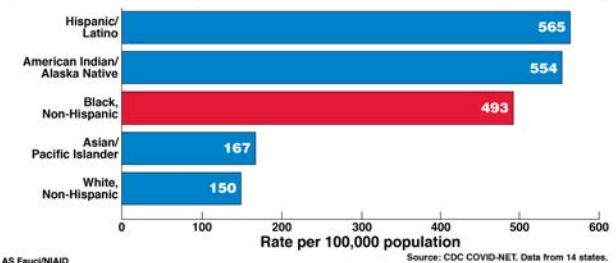
MW Hooper, AM Nápoles and EJ Pérez-Stable

"The most pervasive disparities are observed among African American and Latino individuals, and where data exist, American Indian, Alaska Native, and Pacific Islander populations."

AS Fauci/NIAD

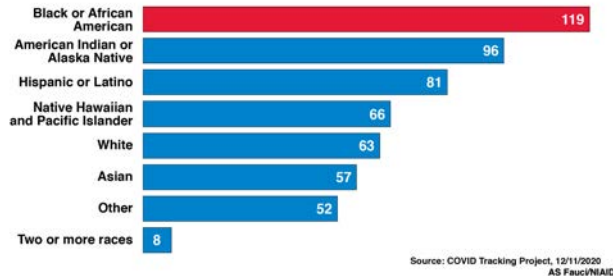
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Age-Adjusted COVID-19-Associated Hospitalization Rates by Race and Ethnicity, United States, March 1 - December 5, 2020



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COVID-19 Deaths per 100,000 People by Race or Ethnicity, United States



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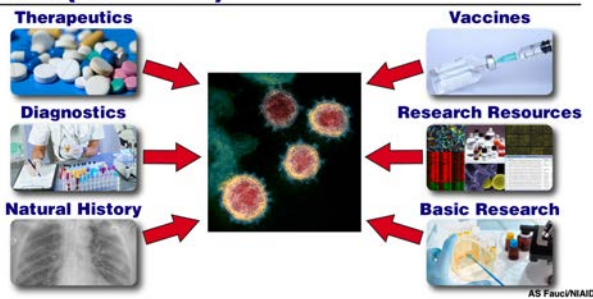
Longstanding Systematic Health and Social Inequities Drive COVID-19 Disparities

- **Discrimination**
- **Limited healthcare access and use**
- **Occupation** – disproportionately in essential work settings where remote work or physical distancing is impossible
- **Educational, income, and wealth gaps**
- **Housing** – some people living in crowded conditions; hard to follow prevention strategies

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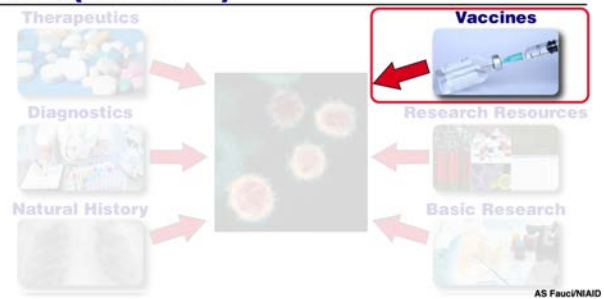
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NIH Research on Coronavirus Disease 2019 (COVID-19)



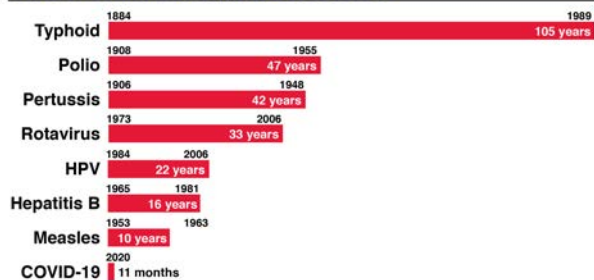
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NIH Research on Coronavirus Disease 2019 (COVID-19)



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Time to Develop a Vaccine



Duration between discovery of microbiologic cause of selected infectious diseases and development of a vaccine. Adapted from AVAC
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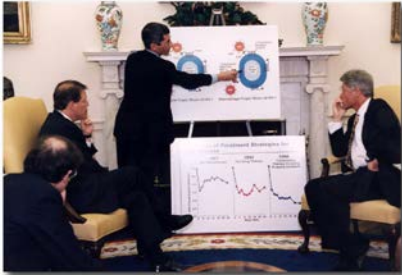
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History of the NIAID Vaccine Research Center

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Meeting at the White House to Discuss AIDS Research, Dec. 3, 1996



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Commencement Address by President Clinton at Morgan State University, Baltimore, May 18, 1997

"If America commits to find an AIDS vaccine and we enlist others in our cause, we will do it... **Today I'm pleased to announce the National Institutes of Health will establish a new AIDS vaccine research center dedicated to this crusade.**"



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NIAID Vaccine Research Center



VRC Senior Investigators

Basic Research → Clinical Trials

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VRC Research: From HIV to Zika



- HIV
- West Nile virus
- Chikungunya
- Ebola/Marburg
- Influenza
- Malaria
- **Coronaviruses**
- RSV
- Tuberculosis
- Venezuelan, Eastern, and Western equine encephalitis viruses
- Zika


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NIH RECORD
December 11, 2020 Vol. LXIX, No. 20

Fast, Reliable, Universal

Corbett Recounts Quest for COVID Vaccine



Dr. Kizzmekia Corbett is a central figure in COVID vaccine science.



Corbett and VRC deputy director Dr. Barney Graham attend a vaccine briefing for the president last March.

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Structure-based Design of MERS Vaccine

August 29, 2017
PNAS
Proceedings of the National Academy of Sciences of the United States of America

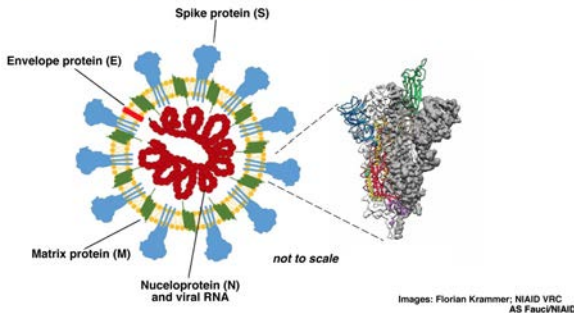
Immunogenicity and Structures of a Rationally Designed Prefusion MERS-CoV Spike Antigen

Jesper Pallesen, Nianshuang Wang, Kizzmekia S Corbett, Daniel Wrapp, Robert N Kirchdoerfer, Hannah L Turner, Christopher A Cottrell, Michelle M Becker, Lingshu Wang, Wei Shi, Wing-Pui Kong, Erica L Andres, Arminja N Kettenbach, Mark R Denison, James D Chappell, Barney S Graham, Andrew B Ward, Jason S McLellan.

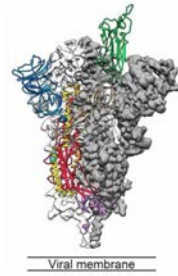
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SARS-CoV-2 and the Key Spike Protein



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Atomic-level structure of SARS-CoV-2 spike protein. Receptor binding domain is colored green.

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- 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.

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Operation Warp Speed



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Elements of OWS Harmonized Protocols

- Harmonized endpoints
- Collaborating clinical trials networks
- Shared immune assays
- Common Data and Safety Monitoring Board
- Shared statistical plan for immune correlates of protection

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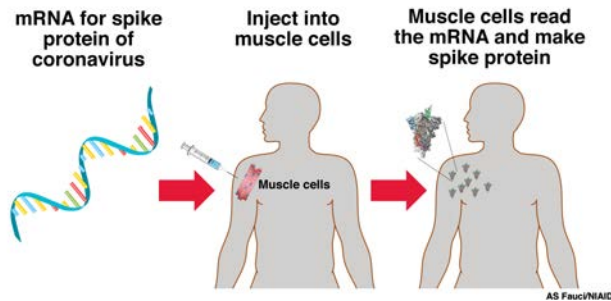
COVID-19 Vaccines in Operation Warp Speed Development

| | | | |
|-------------|--------------------------------|--|---|
| moderna | mRNA | | ■ mRNA: rapid manufacturing facilitating efficient move to clinic, highly immunogenic |
| BIONTECH | mRNA | | |
| AstraZeneca | Adenovirus vector | | ■ Adenovirus: rapid manufacturing facilitating efficient move to clinic, vaccine using this platform is approved in Europe |
| Janssen | Adenovirus vector | | |
| NOVAVAX | Recombinant protein + adjuvant | | ■ Adjuvanted recombinant protein: not as fast to manufacture but scalable, several approved vaccines use this approach |
| gsk SANOFI | Recombinant protein + adjuvant | | |

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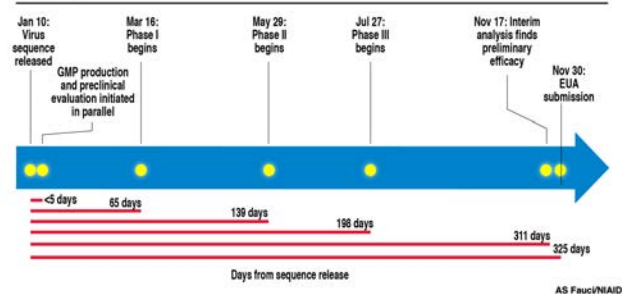
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mRNA Vaccine Approach



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SARS-CoV-2 Vaccine Development: mRNA-1273



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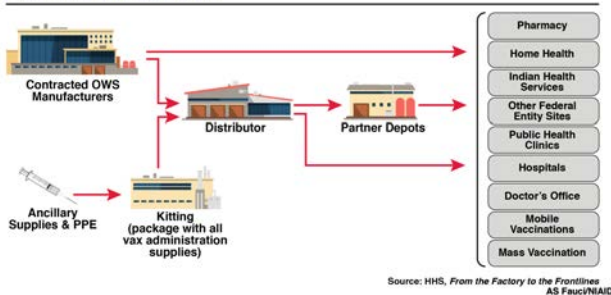


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OWS Overview of Distribution and Administration



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Vaccine Administration Sites



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moderna Press Release

November 30, 2020

Moderna Announces Primary Efficacy Analysis in Phase 3 COVE Study for Its COVID-19 Vaccine Candidate and Filing Today with U.S. FDA for Emergency Use Authorization

- Vaccine efficacy against COVID-19 was 94%; vaccine efficacy against severe COVID-19 was 100%

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U.S. Department of Health & Human Services
FDA U.S. Food and Drug Administration
Protecting and Promoting Your Health

Vaccines and Related Biological Products Advisory Committee December 17, 2020 Meeting Announcement

Date: December 17, 2020
Time: 9:00 AM - 6:00 PM ET

- The FDA Center for Biologics Evaluation and Research's (CBER), Vaccines and Related Biological Products Advisory Committee (VRBPAC) will meet in open session
- **Emergency Use Authorization (EUA) of the Moderna, Inc., COVID-19 Vaccine** for the prevention of COVID-19 in individuals 18 years and older will be discussed

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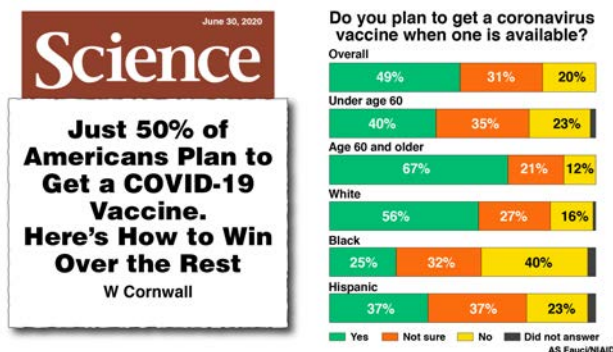
Efficacy

Versus

Effectiveness

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 **COVID-19**
Prevention Network

coronaviruspreventionnetwork.org

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