



# **Dr. Chris T. Pernell, MD, MPH, FACPM**

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# The Development of COVID-19 Vaccines: A “Pandemic Speed”

1199SEIU Training and Employment Funds

January 24, 2021

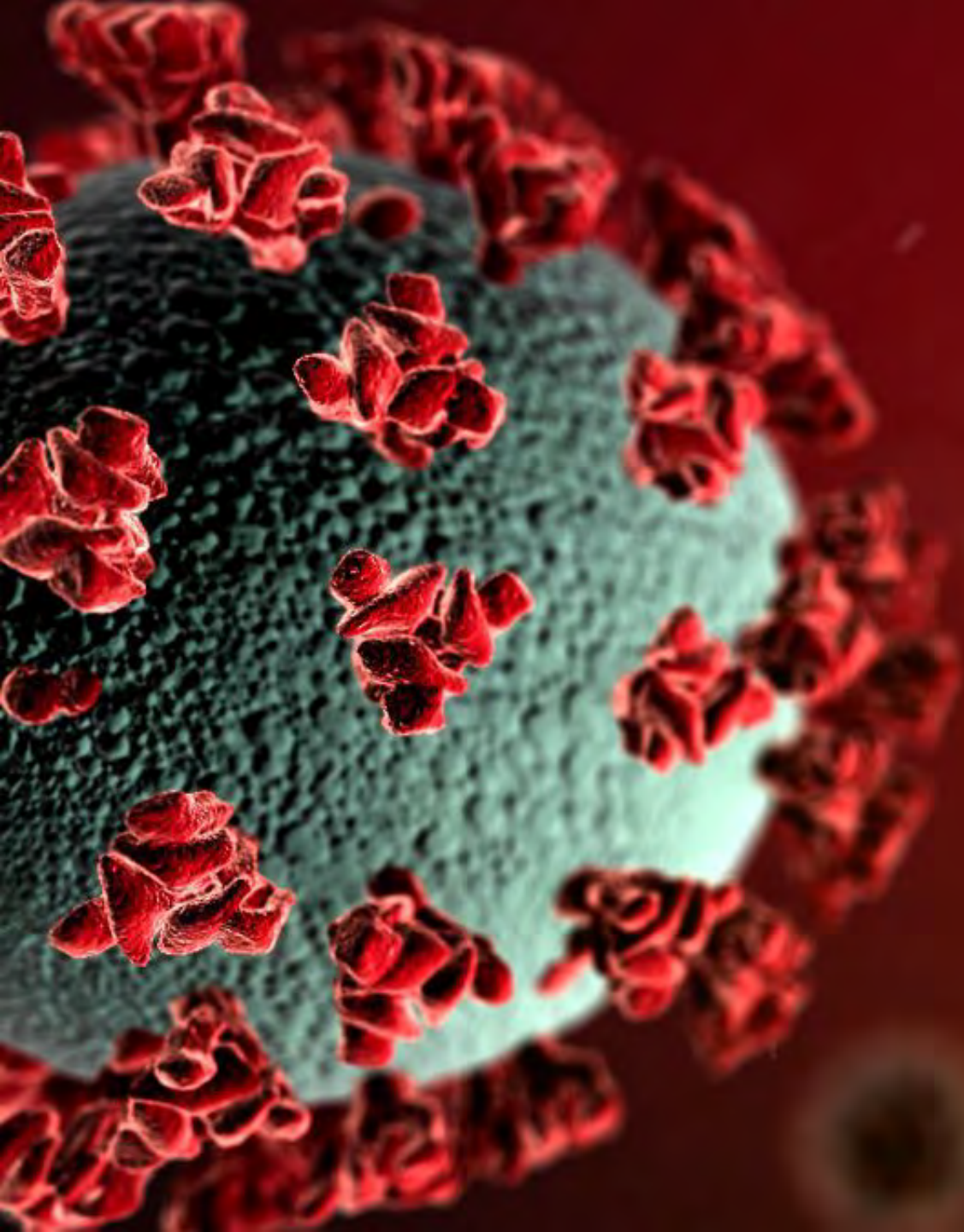
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- **First confirmed case in the US reported on January 20, 2020<sup>1</sup>**
- **Record number of cases confirmed in one day: 314K on January 8, 2021<sup>2</sup> and over 24.5M+ US cases to date<sup>3</sup>**
- **~116,000+ current hospitalizations in the US<sup>4</sup>**
- **410,000+ deaths in the US and rising<sup>3</sup>; tracking to be the 3<sup>rd</sup> leading cause of death in the US in 2020<sup>5</sup>**
- **CDC estimates there have been ~376,000+ cases among healthcare workers and ~1275 deaths<sup>6</sup>**

# Fast and Slow Pandemics: COVID-19 and Earthquakes of Devastation in Black and Brown Communities

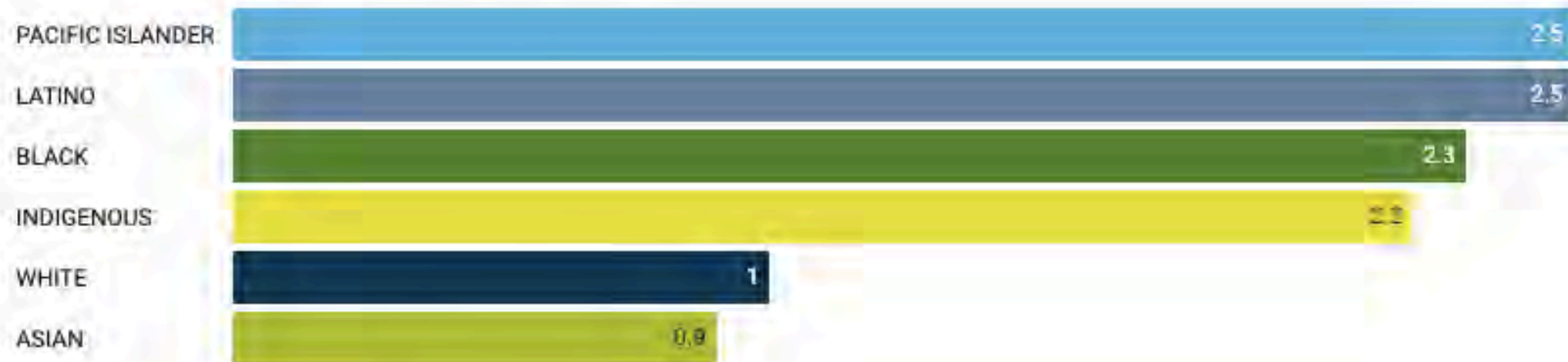
**According to the most recent data compiled by the Color of Coronavirus project:**

- ❖ 1 in 595 Indigenous Americans has died
- ❖ 1 in 735 Black Americans has died
- ❖ 1 in 895 Pacific Islander Americans has died
- ❖ 1 in 1,000 Latino Americans has died
- ❖ 1 in 1,030 White Americans has died
- ❖ 1 in 1,670 Asian Americans has died



# Adjusted for age, other racial groups are this many times more likely to have died of COVID-19 than White Americans

Reflects mortality rates calculated through Jan. 5, 2021.



Indirect age-adjustment has been used.

Source: APM Research Lab • Get the data • Created with Datawrapper



# COVID-19 Hospitalization and Death by Race/Ethnicity: Racism as a Pre-existing Condition

**“Race and ethnicity are risk markers for other underlying conditions that impact health including socioeconomic status, access to health care, and exposure to the virus related to occupation, e.g., frontline, essential, and critical infrastructure workers.” (CDC, November 30, 2020)**

Rate ratios compared to White, Non-Hispanic persons	American Indian or Alaska Native, Non-Hispanic persons	Asian, Non-Hispanic persons	Black or African American, Non-Hispanic persons	Hispanic or Latino persons
Cases <sup>1</sup>	1.8x	0.6x	1.4x	1.7x
Hospitalization <sup>2</sup>	4.0x	1.2x	3.7x	4.1x
Death <sup>3</sup>	2.6x	1.1x	2.8x	2.8x

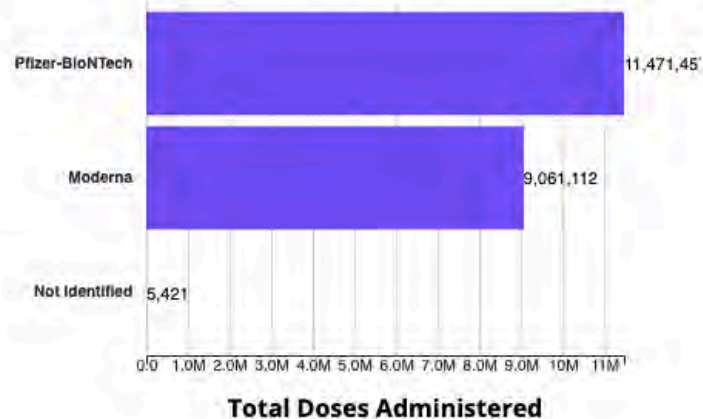
# How Did We Get Here: A Pandemic Speed

## COVID-19 Vaccinations in the United States

Overall US COVID-19 Vaccine Distribution and Administration



U.S. COVID-19 Vaccine Administration by Vaccine Type



**View:**

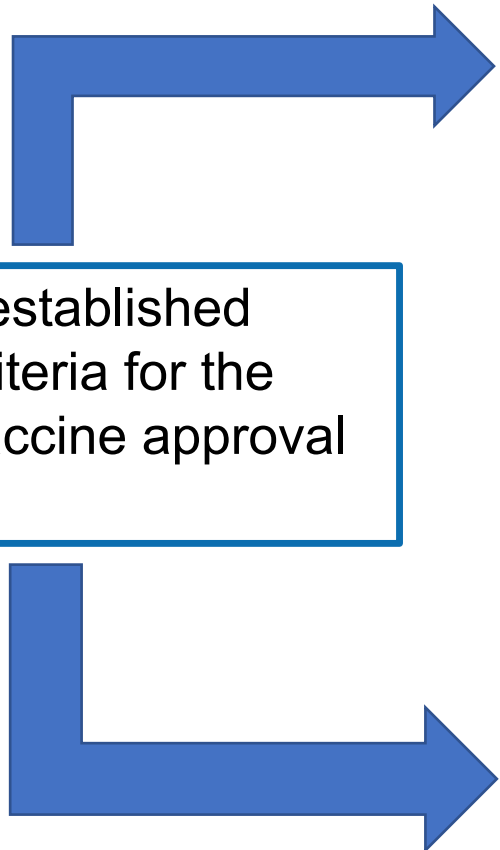
- Total Doses Administered
- People Receiving 1 or More Doses
- People Receiving 2 Doses
- Total Doses Distributed

**Metric:**

- Count
- Rate per 100,000

Total Doses Administered Reported to the CDC by State/Territory and for Selected Federal Entities per 100,000

# Key Steps Along the Pathway to Vaccine Emergency Use Authorization (EUA) and Phased Distribution: Health Equity Implications



FDA has established several criteria for the COVID vaccine approval process

- Vaccine trials must be large enough to demonstrate safety and efficacy (**i.e. many thousands**)<sup>1</sup>
- FDA expects the **vaccine would prevent disease or decrease its severity in at least 50%**<sup>1</sup> of people who are vaccinated
- **Must include diverse populations**<sup>2</sup> in all phases of clinical development, including populations most affected by COVID-19, specifically communities of color, **as well as adequate representation in late phase trials of elderly individuals and those with medical comorbidities**

**Steckelberg, A., Johnson, C.Y., Florit, G., Alcantara, C. (2020, November 23). These are the top coronavirus vaccines to watch. *Washington Post*. <https://www.washingtonpost.com>**

### How long it took to develop other notable vaccines



DATE	MILESTONE
December 1	Covid-19 illness documented (unpublicized Nov 17 <sup>th</sup> ) <sup>18</sup>
January 10	SARS-CoV-2 virus sequenced
January 15	NIH designs mRNA vaccine in collaboration with Moderna
March 16	Moderna Phase 1 2 trial begins
May 2	Pfizer/BioNTech Phase 1 2 trial begins
July 14	Moderna Phase 1 2 trial published in NEJM
July 27, 28	Moderna and Pfizer/BioNTech Phase 3 trials begin
August 12	Pfizer/BioNTech Phase 1 2 trial published in Nature
October 22, 27	Enrollment in both Phase 3 trials complete; >74,000
November 9	Pfizer/BioNTech reports interim analysis efficacy > 90%
November 16	Moderna announces interim analysis efficacy > 94.5%
November 18	Pfizer/BioNTech announces 95% efficacy as final result
November 20	1 <sup>st</sup> EUA submitted by Pfizer/BioNTech
<b>December 11; December 12</b>	FDA granted Emergency Use Authorization of Pfizer/BioNTech; CDC approved use in persons $\geq$ 16
<b>December 14</b>	Phase 1a Vaccination begins for health care workers
<b>December 18; December 19</b>	FDA granted EUA of Moderna; CDC approved use in persons $\geq$ 18

# How Is the Coronavirus Vaccine Development Different?

- ❖ Government has taken on the financial risk of COVID vaccine development
  - ✓ The US gov't invested \$9.5B+ to speed up development and jumpstart manufacturing before testing is finished
  - ✓ Removed the financial disincentives to manufacture vaccines before a drugmaker knows they will work
  - ✓ NIH entered into public-private-partnerships with drug companies where hundreds of millions of dollars in funding have allowed specific companies to expedite the process and raise large-scale nationwide trials (e.g., Moderna, J&J, AstraZeneca)

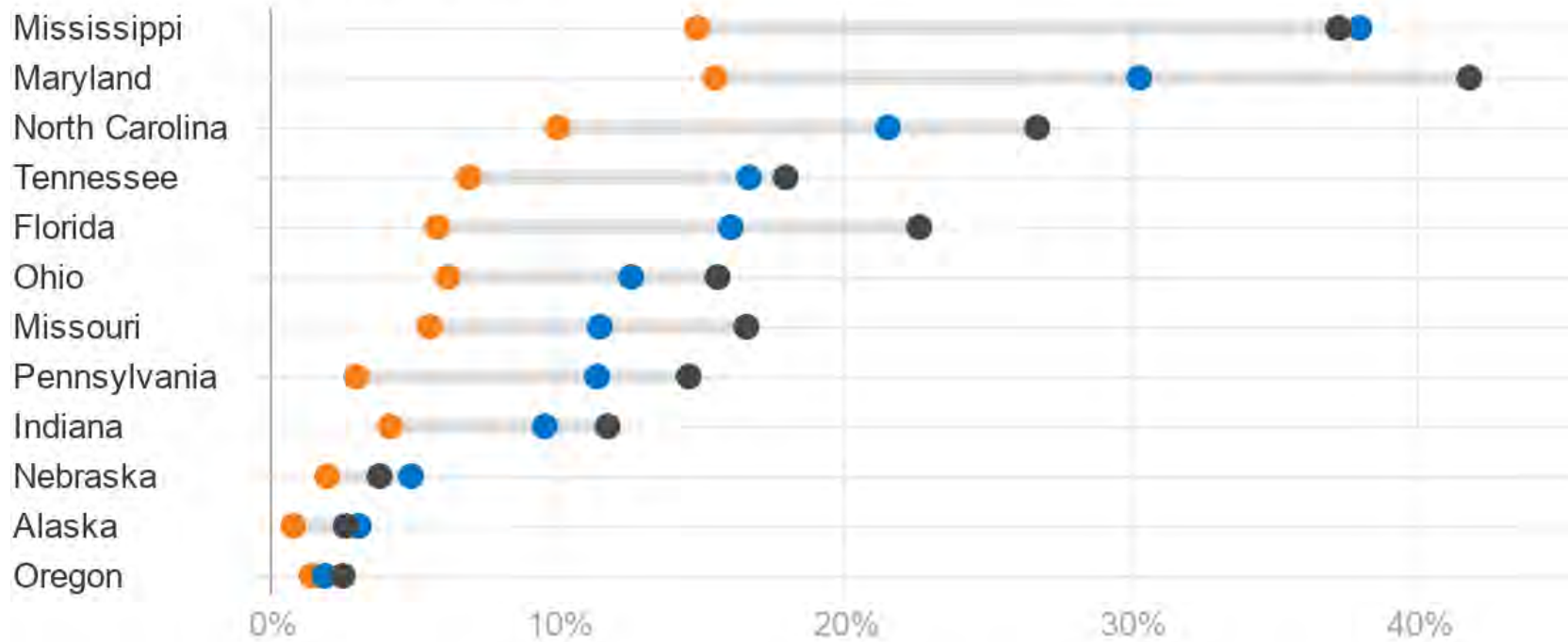
# How Is the Coronavirus Vaccine Development Different?

- ❖ New technologies have given researchers new tools
  - ✓ Synthetic genetic material can be delivered into the body's cells, making them into **factories to produce specific proteins**, which then trigger a robust immune response
  - ✓ Skipping otherwise time-consuming steps such as manufacturing viral proteins or growing the whole virus in chicken eggs
- ❖ **Pfizer and Moderna are the only two vaccine candidates that specifically use mRNA technologies**
  - ✓ Have the advantage of speed – can be designed and manufactured quickly
  - ✓ RNA vaccine research made significant advances over the last 10-15 years
  - ✓ In particular, research on past outbreaks (MERS and SARS) gave scientists key insights on the approach

# Black Americans Significantly Trail in Covid Vaccinations

The percentage of those vaccinated who are Black is far lower than their share of both the general population and the health care workforce. Most people who have been vaccinated are health workers.

- Share of vaccinated who are Black
- State residents who are Black
- Health workers who are Black



NOTE: The 12 states shown are those that report race separately from ethnicity; four other states with incomparable data were excluded. Covid vaccinations for which the race of the recipient is unknown were excluded.

CREDIT: Hannah Recht/KHN

SOURCE: Data from state health departments as of Jan. 14, 2021; American Community Survey 2019; Integrated Public Use Microdata Series





# Demonstrating Trustworthiness and Building Trust

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Editor's Note: This article was published on October 16, 2020, at NEJM.org.

## Perspective

### Trustworthiness before Trust — Covid-19 Vaccine Trials and the Black Community

Rueben C. Warren, D.D.S., Dr.P.H., M.Div., Lachlan Farrow, M.D., David Augustin Hodge, Sr., D.Min., Ph.D., and Robert D. Truog, M.D.

Article Metrics

November 26, 2020  
N Engl J Med 2020; 383:e121  
DOI: 10.1056/NEJMp2030033

5 References 2 Citing Articles

The only way out of today's misery is for people to become worthy of each other's trust.  
— Albert Schweitzer

AS THE RACE TO DEVELOP A VACCINE FOR COVID-19 HAS REACHED PHASE 3 CLINICAL trials, concerns are increasing about the low rates of trial participation in important subgroups, including Black communities. Recent data show that although Black people make up 13% of the U.S. population, they account for 21% of deaths from Covid-19 but only 3% of enrollees in

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